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

FORM 10-K

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

For the fiscal year ended December 31, 2025

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

For the transition period from _____ to _____

Commission File Number 001-41265

JUPITER NEUROSCIENCES, INC.
(Exact name of registrant as specified in its charter)

Delaware	**47-4828381**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
1001 North US HWY 1, Suite 504 Jupiter, FL	**33477**
(Address of principal executive offices)	(Zip Code)

(561) 406-6154
(Registrant's telephone number, including area code)

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

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock	JUNS	The Nasdaq Capital Market

Securities registered pursuant to section 12(g) of the Act:

N/A
(Title of class)

N/A
(Title of class)

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

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 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 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. (Check one):

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

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

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

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

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

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

The aggregate market value of the Common Stock held by non-affiliates computed by reference to the price at which the Common Stock was last sold as of the last business day of the registrant's most recently completed second fiscal quarter was approximately $20.2 million.

As of March 31, 2026, there were 36,281,252 shares of common stock, par value $0.0001 per share, of the registrant issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Some of the statements contained in this Annual Report on Form 10-K may constitute "forward-looking statements" for purposes of the federal securities laws. Our forward-looking statements include, but are not limited to, statements regarding our or our management team's expectations, hopes, beliefs, intentions or strategies regarding the future. In addition, any statements that refer to projections, forecasts or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "might," "plan," "possible," "potential," "predict," "project," "should," "would" and similar expressions may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking.

The forward-looking statements contained in this Annual Report on Form 10-K are based on our current expectations and beliefs concerning future developments and their potential effects on us. There can be no assurance that future developments affecting us will be those that we have anticipated. These forward-looking statements involve a number of risks, uncertainties (some of which are beyond our control) or other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements. These risks and uncertainties include, but are not limited to, the following risks, uncertainties and other factors:

- Our substantial amount of indebtedness associated with the convertible promissory notes issued in connection with the Standby Equity Purchase Agreement may adversely affect our cash flow and our ability to operate our business, remain in compliance with debt covenants and make payments on our indebtedness.
- Low trading volume in our common stock may limit or prevent our ability to draw on the Standby Equity Purchase Agreement to pay down the convertible promissory notes.
- We have not generated meaningful revenue from product sales to date, have incurred significant net losses since our inception, and expect to continue to incur significant net losses for the foreseeable future;
- Our management has concluded that factors raise substantial doubt about our ability to continue as a going concern and our auditor has included an explanatory paragraph relating to our ability to continue as a going concern in its audit report for the fiscal years ended December 31, 2025 and 2024.
- We will require substantial additional capital to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our research and drug development programs or future commercialization efforts.
- Raising additional capital may cause substantial dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.
- Our business and future prospects with the Nugevia brand and our pharmaceutical products are significantly dependent on our exclusive, worldwide license agreement with Aquanova. Any adverse development related to this license agreement could materially and adversely affect our operations, financial condition, and results of operations.
- Clinical drug development involves a lengthy and expensive process with an uncertain outcome. The clinical trials of our product candidate may not demonstrate safety and efficacy to the satisfaction of the FDA, EMA or other comparable foreign regulatory authorities or otherwise produce positive results and the results of preclinical studies and early clinical trials may not be predictive of future results. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.
- We have limited resources and are currently focusing the majority of our efforts on developing JOTROL™ for particular indications. As a result, we may fail to capitalize on other indications or product candidates that may ultimately have proven to be more profitable.
- We face significant competition and if our competitors develop and market technologies or products more rapidly than we do or that are more effective, safer or less expensive than the products we develop, our commercial opportunities will be negatively impacted.

- We may not be successful in our efforts to develop our proprietary drug delivery platform, JOTROL™, to build a pipeline of indications.
- The FDA, EMA and other comparable foreign regulatory authorities may not accept data from trials conducted in locations outside of their jurisdiction.
- We may face difficulties from changes to current regulations and future legislation.
- Our success is highly dependent on our ability to attract and retain highly skilled executive officers and employees.
- The Company's failure to meet the continued listing requirements of The Nasdaq Capital Market could result in a delisting of its securities.
- The price of our common stock could be subject to rapid and substantial volatility. A "short squeeze" due to a sudden increase in demand for shares of our common stock could lead to extreme price volatility in shares of our common stock. As a relatively small-capitalization company with relatively small public float, we may experience greater stock price volatility, extreme price run-ups, lower trading volume and less liquidity than large-capitalization companies. In addition, if the trading volumes of our common stock are low, persons buying or selling in relatively small quantities may easily influence prices of our common stock. This low volume of trades could also cause the price of our common stock to fluctuate greatly, with large percentage changes in price occurring in any trading day session. Holders of our common stock may also not be able to readily liquidate their investment or may be forced to sell at depressed prices due to low volume trading; and
- Other risks and uncertainties, including those listed under the captions "*Description of Business*," "*Risk Factors*," and "*Management's Discussion and Analysis of Financial Condition and Results of Operations.*

Should one or more of these risks or uncertainties materialize, or should any of our assumptions prove incorrect, actual results may vary in material respects from those projected in these forward-looking statements. We undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws.

These and other risks are described under the heading "Risk Factors" in this Annual Report on Form 10-K. Those factors and the other risk factors described therein are not necessarily all of the important factors that could cause actual results or developments to differ materially from those expressed in any of our forward-looking statements. Other unknown or unpredictable factors also could harm our results. Consequently, there can be no assurance that actual results or developments anticipated by us will be realized or, even if substantially realized, that they will have the expected consequences to, or effects on, us. Given these uncertainties, prospective investors are cautioned not to place undue reliance on such forward-looking statements.

PART I

ITEM 1. BUSINESS

This Business section, along with other sections of this Annual Report on Form 10-K, includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While we believe that these industry publications and third-party research, surveys and studies are reliable, we have not independently verified such data and we do not make any representation as to the accuracy of the information. Unless the context otherwise requires, "JNS," "we," "us," "our," or the "Company" refers to Jupiter Neurosciences, Inc., a Delaware corporation.

Overview

Jupiter Neurosciences, Inc. (the "Company," "we" or "us") is a clinical stage research and development company focused on developing treatments for neuroinflammation through our unique resveratrol platform. Our platform product, JOTROL™, is an enhanced oral formulation of resveratrol, which has many potential indications. In the larger disease areas, we are primarily targeting Parkinson's Disease. We are presently in the process of conducting a Phase IIa clinical trial in Parkinson's Disease.

In March 2025, the Company unveiled a new strategic initiative to introduce Nugevia — a consumer-oriented product line dedicated to longevity and wellness. This initiative aims to meet the rising demand for wellness solutions by developing nutritional products that support both consumer health and wellness. The Company completed the formulations and initial sales through direct-to-consumer ("DTC") social media began in the second half of the year.

In December 2024, we received gross proceeds of $11 million in a registered public offering (the "Public Offering") of 2,750,000 shares of our common stock, par value $0.0001 per share ("common stock") at a price of $4.00 per share for gross proceeds of $11 million before deducting underwriting discounts and other related expenses. In connection with the Public Offering, the Company's common stock was registered under Section 12(b) of the Exchange Act and began trading on The Nasdaq Capital Market under the symbol "JUNS."

The Company was incorporated in January 2016 under Delaware law under the name of Jupiter Orphan Therapeutics, Inc. On August 30, 2021, the Company filed a Certificate of Amendment with the State of Delaware to change its name to Jupiter Neurosciences, Inc.

Business Overview

Jupiter Neurosciences, Inc. is a clinical stage research and development pharmaceutical company located in Jupiter, Florida. The Company is advancing a therapeutic pipeline targeting central nervous system ("CNS") disorders and rare diseases, while also expanding into the consumer market with its Nugevia™ product line. Both efforts are powered by JOTROL™, Jupiter's proprietary, enhanced resveratrol formulation that has demonstrated potential for significantly improved bioavailability in an FDA regulated Phase I study. The Company's therapeutic development pipeline is focused broadly on CNS disorders, presently with a Phase IIa clinical study in Parkinson's disease. The Company's Nugevia product line brings cutting edge science to the supplement space, supporting mental clarity, skin health, and mitochondrial function.

The Company completed preclinical studies at the University of Miami for Parkinson's Disease in 2021. These studies used a validated mouse model to mimic human disease characteristics. JOTROL™ demonstrated consistent improvements in motor coordination, endurance, and strength across multiple endpoints in a validated Parkinson's disease model, with statistically significant benefits versus untreated disease controls. The promising results have led the Company to initiate a Phase IIa clinical trial for Parkinson's Disease, which received final IND approval by the FDA in November of 2025 and is expected to start in the second quarter of 2026, with results anticipated 12 months later. The Company also aims to investigate other CNS indications, such as Mild Cognitive Impairment ("MCI") and Alzheimer's disease, following the Parkinson's study.

The Company believes, based on pre-clinical and clinical studies, that high doses of resveratrol are necessary for potential therapeutic effects. Currently available resveratrol products cannot reach these levels without causing severe gastrointestinal side effects. Human studies evaluating resveratrol in Alzheimer's patients (Turner et al 2015) and Friedreich's Ataxia patients (Yu et al 2015) indicate the concentration of resveratrol at its peak (CMax) measured in blood plasma should be 300 ng/ml or higher for a potential therapeutic effect. A Phase 1 study with 500mg of resveratrol as a maximum dose in the JOTROL™ formulation showed levels of resveratrol exceeding 800 ng/ml without generating any severe adverse events (AAPS Open 2022). Resveratrol was shown in the Turner Alzheimer's study to cross the blood-brain barrier, possibly indicating a potential for positive effects on oxidative stress and inflammation. Subsequent analysis published in Molecular Science 2025 (Mousa et al) further indicates that resveratrol may have an impact on neurodegeneration and neuroinflammation in Alzheimer's patients.

Over the past two years, JOTROL™ has garnered significant interest from Asian organizations. This interest is partly due to resveratrol's use in Asian herbal medicines, recent patent approvals in Hong Kong and China, and China's list of rare disease indications where JOTROL™ could be applicable. Additionally, recent publications in the Journal of Alzheimer's Disease and AAPS Open, along with the projected growth of the Traditional Chinese Medicine market, have contributed to this interest.

The Company has entered service agreements with firms in Hong Kong to accelerate product development in Southeast Asia. These agreements aim to leverage local expertise and networks to facilitate market entry and potential out-licensing deals. The Company entered into an agreement with Dominant Treasure Health to expand its business development in China, Malaysia, and Singapore, aiming to penetrate the large and challenging Asian market.

In March 2025, the Company unveiled a new strategic initiative to introduce Nugevia—a consumer-oriented product line dedicated to longevity and wellness. This initiative aims to meet the rising demand for scientifically backed wellness solutions by developing nutritional products that support both longevity and health span. Positioned within a rapidly growing global industry expected to reach $8 trillion by 2030, Nugevia products will leverage Jupiter's proprietary JOTROL™ technology, a resveratrol-based platform that is designed to deliver an increase in the bioavailability profile of resveratrol.

The first products under the Nugevia brand, focusing on supporting longevity and health span are available for sale and shipments began in the fourth quarter of 2025 through a DTC model. The products are:

- Nugevia GLO ("GLO"), which helps promote and support cellular functions and skin vitality;
- Nugevia MND ("MND"), which supports cognitive resilience; and
- Nugevia PWR ("PWR"), which helps support mitochondrial function, which is a key for sustained growth and performance.

The three debut formulations—GLO, MND, and PWR—are designed to support wellness and longevity through intelligent stacking of synergistic ingredients, all enhanced for optimal absorption via the JOTROL™ system.

The Company plans to market these products in the U.S. and internationally.

Nugevia's launch is a pivotal move to monetize Jupiter's proprietary science, support ongoing clinical trials, and capture a share of the booming longevity market.

The Company operates through two segments: (i) the sale of premium nutritional supplements under the Nugevia brand, and (ii) pharmaceutical operations centered on the development of drug candidates.

Resveratrol

Resveratrol, a natural antioxidant compound found in foods like red grapes and berries, has been studied for over 50 years by academic institutions as well as by small and large pharmaceutical companies. The multi-functional mechanisms of resveratrol are well documented in over 20,000 scientific publications. Several of these publications, including a summary paper by AY Berman et al, published in Precision Oncology 2017, point to the issue of the poor bioavailability that has stopped medical utilization of regular resveratrol and never received regulatory approval for any indication. We believe the Phase I study we have conducted indicates that we have resolved the poor bioavailability issue with JOTROL™.

Based upon available scientific literature, it appears that resveratrol is an activator of SIRT1, one of the mammalian forms of the sirtuin family of proteins. SIRT1 deacetylates histones and nonhistone proteins including transcription factors. The SIRT1-regulated pathway is believed to affect metabolism, stress resistance, cell survival, cellular senescence, inflammation/immune function, endothelial functions, and circadian rhythms. Resveratrol has been documented in scientific literature to activate SIRT1, NrF2, NLRP3 inflammasomes and have an epigenetic mechanism, and therefore, is predicted to benefit diseases affected by abnormal metabolic control, inflammation, and cell cycle defects. Nonetheless, the administration of currently available resveratrol poses a major challenge for the pharmaceutical industry, due to its poor solubility and bioavailability, as well as severe gastro-intestinal side effects when taken at effective dose levels (over 2,000 mg daily).

JOTROL™

JOTROL™ was developed together with our technology partner Aquanova, headquartered in Darmstadt, Germany. JOTROL™ is formulated with a unique patented micellar technology that is projected to increase the bioavailability profile of resveratrol. Manufacturing technology transfers were completed in 2017, and manufacturing procedures and clinical trial supply manufacturing have been completed at Catalent Pharmaceutical Services, Inc. ("Catalent"), St Petersburg, Florida. Catalent has also completed the manufacturing of the clinical trial supplies for our Phase IIa trial in Parkinson's Disease.

JOTROL™ is a micellar non-aqueous solution of resveratrol delivered in a softgel capsule. Each capsule includes 100mg of resveratrol. Pre-clinical trials in mice and rats were conducted comparing JOTROL™ to micronized resveratrol, labeled to have the highest bioavailability in the nutritional market, to demonstrate that we could achieve a significantly higher bioavailability. A Phase I dose finding pharmacokinetic ("PK") study in healthy volunteers was completed during the first half of 2021. The study results met our targeted goals.

The Phase I study demonstrated JOTROL™'s potential for higher bioavailability compared to resveratrol used in earlier clinical trials (e.g., Turner, MCI/Early Alzheimer's Disease trial and Yui et al., Friedreich's ataxia trial). The results of this Phase 1 study were published in the Journal of Alzheimer's diseases and AAPS Open in February 2022. Subject to additional discussions with and approval from FDA, we hope to use the results of this study as a cross-reference for other indications to allow JOTROL™ to be tested in Phase II and Phase III clinical trials. FDA accepted this cross-reference in the approval of the IND application for the Parkinson's Phase IIa trial. The Company has not discussed the use of cross-referencing in this manner with the FDA or other comparable regulatory authorities for any other indications, and FDA (or any comparable regulatory authorities) may preclude us from the use of cross-referencing with respect to the results of this study. As a result, we are presently unable to rely on potential cross-referencing other than the already cleared Phase II a Parkinson's study.

JOTROL™ Intellectual Property and License Agreement

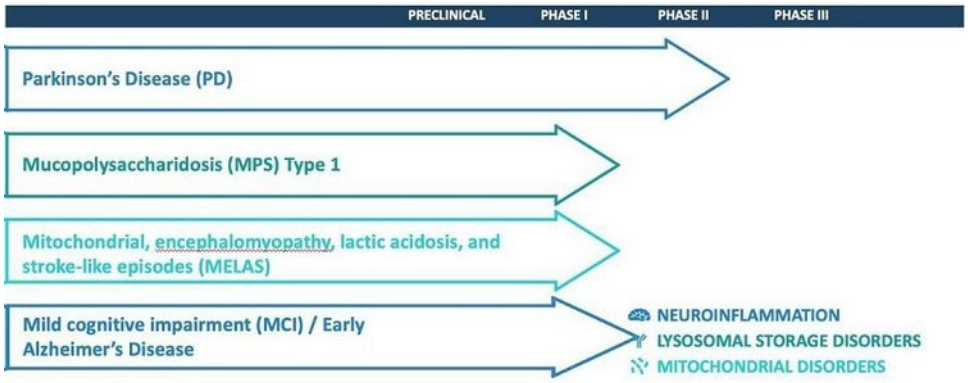
We hold an exclusive global license dated from Aquanova for micellar technologies to develop, manufacture, and sell JOTROL on the terms set forth in the license agreement. Our Chief Scientific Officer ("CSO"), Marshall Hayward, and Aquanova's founder, former CEO, and lead scientist, Darius Benham, invented JOTROL™. The patent is co-owned by Aquanova and us, with the application assigned to Aquanova. Filed in Germany on January 29, 2017, the patent (PCT/EP2017/O51659) expires in 2036 and is granted in the USA, Japan, China, Hong Kong, and specific European countries. The patent covers a solubilization product with resveratrol, polysorbate 80 and 20, MCT, and tocopherols for pharmaceutical use. It includes claims on formulation specifics, micelle size, turbidity, and treatment applications for diseases like Alzheimer's and diabetes. The product is available in various capsule forms and is administered orally.

Our license agreement with Aquanova is vital, as JOTROL™ is our primary product. Losing this agreement would delay our plans and force us to seek similar licenses, if available, adversely affecting our business. The agreement grants us worldwide exclusivity to utilize granted and pending patents. Effective from September 15, 2016, it lasts until patent expiration or ten years after the first commercial sale. We paid an upfront fee of $20,000 and an annual license fee of $75,000 until the first product approval. Milestone payments of $200,000 are due per territory upon regulatory approval, with royalties set at 5% of net sales. Each party has the option, within 180 days of a US Marketing approval, to demand that the Company pay a one-time payment of $3 million for reduced royalties of 1.25%. Termination can occur due to material breach or insolvency, with specific provisions for retaining licenses. Recent amendments include a Debt Forgiveness and Exchange Agreement on December 1, 2021, where $225,000 of debt was forgiven in exchange for $125,000 cash, a $100,000 promissory note, and stock options.

The Company relies on trade secret protection and contractual confidentiality obligations to safeguard certain proprietary know-how related to JOTROL™. The Company also asserts common law trademark rights in the JOTROL™ name. In January 2025, the Company filed an intent-to-use trademark application with the U.S. Patent and Trademark Office

Product Pipeline

The Company's pharmaceutical product pipeline is built around its proprietary platform product, JOTROL™ an enhanced oral formulation of resveratrol. Resveratrol, a natural compound is optimized in JOTROL™, which is being evaluated to better understand its therapeutic benefits and its potential relevance to biological pathways of interest, including those involving oxidative stress, inflammation and mitochondrial issues linked to neurological conditions. The Company has designated the different indications with project numbers, JNS101 - JNS115. The same JOTROL™ product is planned to be used in all indications although the number of capsules might vary and be indication specific and may be impacted by regulatory requirements and other factors not known to us at this time.



The pipeline chart above shows the indications that we presently are prioritizing and is subject to the availability of financing as further discussed in the "Risk Factors" section.

The validity of our product pipeline represented above relies on the assumptions drawing upon previous preclinical and clinical data conducted by third parties. This data is available either via public domain or under agreements with our key partners. The Company has not discussed with the FDA its ability to rely on and reference data from previous third-party trials, such as the Phase II trial in MCI/early Alzheimer's disease, conducted by Georgetown University.

Our top priorities are advancing our clinical studies for JNS115 for Parkinson's Disease followed by JNS108 for MCI/early Alzheimer's Disease. We executed all CMC, regulatory, and preparations with investigators including IND approval by FDA for our JNS115 Phase IIa trial and estimate that first dosing of patients will occur in the second quarter of 2026. We are also exploring clinical trials of JOTROL for other indications, including rare diseases. Based on the FDA's approval to use our Phase I study in support of the IND for our Phase IIa Parkinson's study, we believe there may be potential to cross-reference the Phase I data for additional indications in the future. However, we have not discussed this cross-referencing for any other indication with FDA, and we may be precluded from relying on cross-referencing other than in the Phase IIa Parkinson's study.

JNS115 Parkinson's Disease

We will be utilizing JOTROL™ for investigating a treatment for Parkinson's Disease (PD).

People are usually more familiar with the motor symptoms of Parkinson's disease (PD), which are noticeable and used by doctors for diagnosis. The three cardinal motor symptoms are stiffness (rigidity), slowness (bradykinesia), and resting tremors. Stiffness involves muscle rigidity detected during examination, while slowness refers to decreased spontaneous and voluntary movement, such as slower walking or reduced facial expression. Resting tremor is an involuntary shaking that occurs when a limb is relaxed and disappears during movement.

Non-motor symptoms, often called the "invisible" symptoms, can affect almost every body system and vary in severity. These symptoms can significantly impact quality of life and include autonomic dysfunctions like constipation, low blood pressure, sexual problems, sweating issues, and urinary problems. While available therapies can treat some symptoms, there is an urgent need for better treatments to improve quality of life and slow disease progression. Approved medications for motor symptoms include dopamine replacement therapy (levodopa/carbidopa), adenosine receptor antagonists, amantadine, anticholinergic medications, COMT inhibitors, decarboxylase inhibitors, dopamine agonists, and MAO-B inhibitors. Researchers are increasingly recognizing the debilitating nature of non-motor symptoms and are working on new therapies, while doctors manage these symptoms with current treatments.

Upcoming Phase IIa study in Parkinson's Disease patients

The Company has engaged Zina Biopharmaceuticals to assist with study design, FDA communications, including submission, of an Investigational New Drug (IND) application and to manage the execution of the trial. Catalent has been engaged to manufacture the JOTROL™ clinical trial supplies pursuant to the Manufacturing Agreement between Company and Catalent dated September 16, 2020, under which Catalent is to provide the Company with clinical batches of JOTROL™ using a softgel formulation, which will be for active and placebo batches for the Parkinson's disease study. The study design is described below and has received final IND approval by the FDA. The Company expects to start the clinical trial in the second quarter of 2026 and have the first study results available twelve months thereafter.

The multicenter, randomized, double-blind, placebo-controlled study involves approximately 30 participants across three centers in the US. Participants are randomly assigned to one of three groups to receive either a placebo or JOTROL™ at doses of 200 mg or 400 mg daily for three months. The study aims to explore JOTROL™'s potential to improve energy metabolism in Parkinson's Disease. An optional biomarker sub-study will assess cerebrospinal fluid, requiring additional patient consent. Each patient will be involved in the study for approximately four to five months, while the overall study including all subsequent analyses will span approximately two years, with initial results expected within twelve months of first dosing.

JNS108 Mild Cognitive Impairment/early Alzheimer's Disease

The Company had previously conducted studies which used JOTROL™ in our applications for investigating treatment of various segments of Alzheimer's disease of which MCI/early AD is the initial target.

The National Institute on Aging ("NIA") financed the Company's Phase I study with $1.76 million through grant 1R44AG067907-01A1. Because there were unanticipated higher costs, mostly due to COVID-19 related additional procedures during the Phase I trial, a supplemental grant of $233,281 was submitted to the NIA in December of 2021. We were awarded the supplemental grant on April 7, 2022.

In April 2021, we submitted our first grant application to the NIA for full funding of a Phase II trial in MCI and early Alzheimer's disease. The Phase II trial was designed to focus on 3 areas: (1) safety and tolerability; (2) pharmacokinetics and pharmacodynamics, measuring of responses from 2 different doses versus a placebo; and (3) measuring of effect on multiple biomarkers related to the disease. The application was not accepted, but we were encouraged by the NIA to refine our application and submit again. We have since submitted 3 grant applications, with budgets of $20 million or higher, to the NIA for full funding of such Phase II trial but none of those applications were successful. We are planning to submit the next grant application after we have the results from our Phase IIa study in Parkinson's patients as several biomarkers from that trial may apply to Alzheimer's patients as well. However, there can be no assurance that the results of this Phase IIa study will be positive or that NIA will approve any future grant application.

Early-stage Alzheimer's (mild)

Later stages of Alzheimer's are very difficult to reverse and therefore it is important to start treatment of Alzheimer's in the earliest possible stage so the individuals can continue living normal lives and maintain their independence.

In the early stage of Alzheimer's, a person may function independently. He or she may still drive, work, and participate in social activities. Despite this, the person may feel as if he or she is having memory lapses, such as forgetting familiar words or the location of everyday objects.

Symptoms may not be widely apparent at this stage, but family and close friends may take notice and a doctor would be able to identify symptoms using certain diagnostic tools. Common difficulties include finding the right word or name, remembering names when meeting new people, and performing tasks in social or work settings. People may also forget material they just read, lose or misplace valuable objects, and experience increased trouble with planning or organizing.

This is the Alzheimer's disease patient category that we plan to include in our grant application for a proposed Phase II clinical trial with the final objective of showing that JOTROL™ has the potential of slowing and/or possibly stopping the progression of this disease, subject to FDA's review of the clinical trial and the protocol. The effect of JOTROL™ treatment, in the potential Phase II trial, will primarily be measured through several biomarkers.

Economic burden of Alzheimer's disease on society in USA is generating a very large opportunity

According to Alzheimer's Association's 2020 annual report Alzheimer's disease has impacted 5.7 million Americans and that it costs the US $277 billion each year, excluding the cost of "unpaid time and effort of the people, mostly women, who are caring for spouses, parents, siblings, and friends with dementia." The Association explained, "In 2017, 16 million Americans provided an estimated 18.4 billion hours of unpaid care in the form of physical, emotional and financial support - a contribution to the nation valued at $232.1 billion." Any product that delays the onset of severe Alzheimer's disease should represent significant savings to society.

Proposed JNS108 Phase II Clinical Trial for MCI/early Alzheimer's Disease

Subject to FDA's review and approval, the Phase II trial will be built on utilizing published information from the earlier Turner et al Phase II trial, completed in 2015 with 119 patients with early Alzheimer's disease who were treated with 4 different doses of resveratrol. The study was conducted by Professor Raymond Turner, MD, Ph.D. at Georgetown University, a member of our Scientific Advisory Board, as the Principal Investigator. Dr. Turner is the Principal Investigator of our proposed Phase II trial. The study tried 500mg, 1000mg, 1500mg and 2000mg daily doses with each dose taken by the patients over 13 weeks. Only the highest dose of 2000mg (2 X 1g per day) showed positive results on biomarkers which lead to the conclusion that this study was most likely underdosed for achieving the best therapeutic effect. Pharmacokinetic analysis showed that the average C-Max of resveratrol in the blood on the highest dose was 181 ng/ml, which is far from the target of 300ng/ml that we believe is needed for reaching therapeutic effect.

Our team of scientists in the Alzheimer's field, Professors Raymond Turner, MD, Ph.D. and Charbel Moussa, Ph.D. from Georgetown University and Li-Huei Tsai, Ph.D. from MIT have assisted in designing our Phase II a study to address and explore biomarkers. We believe these trial results can guide us to a follow-on studies that might generate meaningful outcomes for MCI/early Alzheimer's disease patients. The Company has not discussed its ability to rely on and reference the Phase II trial conducted by Georgetown with the FDA nor has it discussed the design of the planned study in MCI patients with the FDA.

Proposed JOTROL™ MCI Phase II Study

In the future, the Company hopes to pursue a phase II, randomized, double-blind, placebo-controlled study to assess the safety and efficacy of JOTROL™ (micellar resveratrol solubilization formulation) in early Alzheimer's disease ("AD") patients. If the study and protocol is approved by FDA, approximately 105 patients would be enrolled at study centers across the United States. Patients would be randomized into one of two active treatment arms to receive JOTROL™ 200 mg BID or JOTROL™ 500 mg BID or to a placebo group. We hypothesize that this proposed study would support JOTROL™ safety and tolerability in individuals with MCI/early AD.

Objectives

Primary Objective:

- To determine the safety and efficacy of JOTROL™ (200 mg resveratrol BID and 500 mg resveratrol BID) for neuroinflammation and biomarkers of MCI/early AD.
- To assess safety and tolerability of JOTROL™ in AD-MCI patients by monitoring adverse events (AEs) and serious adverse events ("SAEs") and assessing their relationship to the study drug. Tolerability will be measured by subjects' ability to remain on treatment. Overall tolerability of the drug will be defined as fewer than 25% discontinuations due to drug-related AEs and SAEs
- A first efficacy indicator will be stabilization of Abeta 40/42.

Secondary Objectives:

- To assess population pharmacokinetics ("Population PK") in the ITT population
- To measure the effect of JOTROL™ on biochemical markers for AD, neurodegeneration, vascular damage, metabolic effects, and neuroinflammation
- To determine the effects of JOTROL™ on whole-brain and regional brain atrophy
- To measure the effects of JOTROL™ on functional MRI measures
- To assess cognitive effects of JOTROL™
- To examine the influence of Apolipoprotein E genotyping on both biomarker and cognitive endpoints

Endpoints

Primary Endpoint:

- Assessment of safety/tolerability by monitoring AEs and SAEs, assessing their potential relationship to the study drug and Abeta 40/42

Secondary Endpoints:

- Levels of AD relevant biomarkers
- Volumetric MRI and Cortical Disarray Measurement
- Additional experimental biomarkers as stated in protocol, such as those for neuroinflammation

Study Population: Approximately 105 male or female subjects between 55 and 85 years of age with a diagnosis of MCI/early AD will be enrolled. MCI/early AD patients should be amyloid positive with an AD/MCI clinical diagnosis.

Phase: Phase II Description of Sites/Facilities Enrolling Participants: Approximately 8 study centers in the USA. Study sites will be determined by competitive selection of interested and eligible ADCS sites - with experienced study coordinators, raters, and site PIs.

Description of Study Intervention: Subjects will be randomized 1:1:1 to receive 500 mg bid (1g/day) resveratrol as JOTROL™; or 200 mg bid (400mg/day) resveratrol as JOTROL™; or placebo.

Participant Duration: Treatment phase will be 6 months with a one month follow up safety visit and safety monitoring over a 6-month period to ensure that patients have no long-lasting treatment related effects.

Rare Orphan Diseases

Proposed JNS102 Phase II trial for Mucopolysaccharidosis Type 1 ("MPS Type I" or "MPS-I")

JNS102 is investigating JOTROL™ for the potential treatment of Lysosomal Storage disease areas whereas MPS Type I is the first target.

MPS-I is divided into three subtypes based on severity of symptoms. All three types result from an absence or insufficient levels of the enzyme alpha-L-iduronidase. Children who have parents with MPS-I will carry the defective gene.

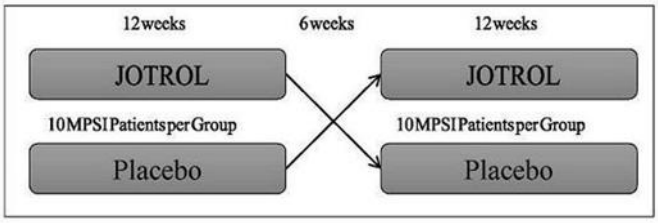
MPS-I patients are presently treated with an Enzyme Replacement Therapy ("ERT") named Aldurazyme. This requires a weekly infusion of 4 hours per event and costs over $500,000 per year per patient. The ERT is effective in significantly prolonging life. However, since the ERT does not penetrate the blood brain barrier, ears, eyes, or joints, it leaves the patients with a gradually worsening quality of life including loss of hearing, blindness and severe arthritis.

JNS102 is targeting the specific areas that ERT cannot treat, with JOTROL™.

Proposed JNS102 Phase II Clinical Trial

1. Preclinical studies conducted at University of Miami in MPS-I mice results showed that a high dose of resveratrol increased the alpha-L-iduronidase which is the critical enzyme that is too low in these patients.
2. IND application for Phase I study was approved by the FDA.
3. Final study details and start to be determined by consultation with the FDA and supportive additional financing.
4. Primary endpoint:

    - Safety, tolerability and PK/PD values



5. Secondary endpoints to include (subject to FDA acceptance)

    i. Improvement in 6-minute walk distance
    ii. Forced vital capacity
    iii. Biomarkers, such as alpha-L-iduronidase levels
    iv. MPS-I validated pain survey

JNS107 clinical trial for MELAS Syndrome

JNS107 is investigating JOTROL™ as a product candidate to treat MELAS Syndrome.

MELAS (Mitochondrial Encephalopathy, Lactic Acidosis, and Stroke-like episodes) syndrome is a rare disorder that begins in childhood, usually between two and fifteen years of age, and mostly affects the nervous system and muscles. The most common early symptoms are seizures, recurrent headaches, loss of appetite, and recurrent vomiting. Stroke-like episodes with temporary muscle weakness on one side of the body (hemiparesis) may also occur and this can lead to altered consciousness, vision and hearing loss, loss of motor skills, and intellectual disability. MELAS is caused by mutations in mitochondrial DNA. Pre-clinical trials performed with mice at University of Miami showed that JOTROL™ increased mitochondrial biogenesis in the liver with 70% and in the brain with 30%.

While symptoms of MELAS syndrome usually begin between the ages of two and fifteen years, delayed onset cases have also been reported in people aged fifteen to forty years and older. In approximately 75% of cases, onset of the disorder occurs before the age of 20 years. Symptoms and physical findings associated with MELAS syndrome vary greatly among affected individuals. The distinguishing feature in MELAS syndrome is the recurrence of stroke-like episodes. It is currently thought that the deficiency of a compound called nitric oxide in the small blood vessels of the brain may be responsible for the stroke-like episodes. Short stature and hearing loss may be present and fatigue and difficulty tolerating exercise may be early symptoms.

MELAS syndrome is a rare disorder that affects males and females in equal numbers. Although rare, MELAS syndrome is probably the most common type of mitochondrial myopathy caused by mutations in mtDNA. Some researchers believe that mitochondrial myopathies may go unrecognized and underdiagnosed in the general population, making it difficult to determine the true frequency of disorders like MELAS syndrome.

Opportunity for JNS107

The potential market for JOTROL™ in the USA includes approximately 80,000 patients[1]. With a projected treatment cost for MELAS syndrome of $75,000 per patient annually, treating 50,000 patients could generate around $3.75 billion per year. Furthermore, successful clinical trial results may extend JOTROL™'s applicability to other mitochondrial diseases, potentially expanding its market impact. There is no assurance that JOTROL™ will obtain regulatory approval to treat MELAS syndrome or any other mitochondrial diseases.

Competition

The following is an overview of JNS's competitors in the pharmaceutical industry. Many companies, including the largest pharma companies in the world, are competitors in some of the disease areas for which we are developing treatments for through our various projects. We will compete with both small and large companies in each indication we are pursuing.

There are a multiple of companies, both smaller biotech's as well as large pharmaceutical companies, that are working on solutions for the same indications that we are pursuing. There is no assurance that we will be able to compete with these companies even if our product is approved in an indication.

Parkinson's Disease

Despite the availability of FDA-approved treatments for Parkinson's disease, no breakthrough therapies have emerged recently to halt disease progression. The most commonly prescribed treatment is levodopa/carbidopa, which has been used since the late 1960s. Levodopa is absorbed in the intestine and converted to dopamine in the brain, addressing the dopamine deficiency in Parkinson's patients. Carbidopa prevents premature conversion of levodopa to dopamine outside the brain, reducing side effects like nausea. This combination is available in various forms, including pills, dissolvable tablets, and a gel infused directly into the intestine.

Levodopa/carbidopa significantly improves motor symptoms in most patients, especially those with mild symptoms, and remains effective over time. However, as Parkinson's progresses, dosage adjustments may be necessary. Initial side effects can include nausea and vomiting, which can be mitigated by taking the medication with a small snack or adding extra carbidopa. Other side effects may include drowsiness, low blood pressure, and hallucinations. Despite these challenges, levodopa/carbidopa remains a cornerstone in managing Parkinson's symptoms.

Alzheimer's Disease

Several companies are actively developing treatments for Alzheimer's disease, each with unique approaches and challenges. Biogen's Aduhelm, an IV infusion targeting amyloid-beta plaques, has faced reimbursement issues despite FDA approval, leading to low market penetration and market withdrawal. Eli Lilly's donanemab, targeting a modified form of beta amyloid, recently received FDA approval and is priced at $32,000 annually. It has shown promise in early Alzheimer's patients and is undergoing further trials. Cognition Therapeutics is developing CT1812, an orally dosed molecule in Phase II, supported by significant NIA grants.

Anavex Life Sciences is advancing Anavex 2-73, a Phase III candidate from their SIGMACEPTOR™ platform, targeting CNS conditions with genomic precision. Eisai and Biogen's Leqembi has received traditional FDA approval, potentially expanding Medicare coverage. Priced at $26,000 per year, Leqembi has shown benefits for early-stage Alzheimer's patients. Despite these advancements, the competitive landscape remains dynamic, with the possibility of other companies emerging with successful treatment

Rare Diseases

There are several companies that are targeting the same rare diseases as us. Below is a description of a selection of those companies that we see as our closest competitors. However, it is possible that another company, that is not listed below, could have a successful product approved before us and have a more effective treatment.

In the MPS-I space, several companies offer competitive products to Jupiter. Sanofi Genzyme's Aldurazyme has been the standard enzyme replacement therapy for nearly 20 years. RegenexBio is developing RGX-111, a gene therapy designed to deliver a functional copy of the IDUA gene to the central nervous system. Sigilon Therapeutics, Inc. is working on SIG-005, which uses a genetically modified human cell line to express the IDUA enzyme, with an Investigation New Drug ("IND") application for Phase I submitted to the FDA. Additionally, Sangamo Therapeutics, Inc. is exploring gene editing products, although no positive results have been published yet. These developments represent significant competition in the treatment of MPS-I.

[1] https://pmc.ncbi.nlm.nih.gov/articles/PMC8993002/

In the treatment of MELAS, several products present competition to Jupiter's offerings. Cyclerion Therapeutics is advancing CY643, currently in Phase 1B, which evaluates safety and its impact on mitochondrial dysfunction and cognition. Abliva AB is developing KL1333, which has been granted orphan drug designation in both the United States and Europe. This product has been tested in healthy volunteers and patients, with a registrational Phase II/III study initiated in December 2022. These developments underscore the competitive landscape in the search for effective MELAS treatments.

Competitive Advantages

We believe that we are positioned to outperform competitors in the pharmaceutical industry for the following reasons:

- We believe that the focus on a new product based on resveratrol with potentially higher bioavailability, JOTROL™, will enable us to explore its use for several research pathways and indications, subject to FDA's review and approval. Whether such path is viable would depend on regulatory submissions and data generated in pre-clinical and clinical trials. We believe that this enables us to have several opportunities to obtain regulatory approval in case we are able to show efficacy and safety acceptable to regulatory agencies for one or more of our targeted indications.

- JOTROL™ is an oral product based on a natural compound. Oral delivery of medications is a physician and patient preferred treatment compared with injections and infusions and we expect that our product will have an attractive and affordable price point for reimbursors and patients.

- We are building a close relationship with key opinion leaders ("KOLs") and patient organizations to facilitate a better understanding of patient needs and thereby design trials targeting solutions to those needs as long as these targets are acceptable to the FDA.

- The natural product resveratrol is well studied with over 20,000 scientific publications to date. Published scientific papers, such as AY Berman et al, indicate that a highly bioavailable product generating less GI side effects may have application in a number of indications.

- Based upon available scientific literature, it appears that resveratrol is an activator of SIRT1, one of the mammalian forms of the sirtuin family of proteins. SIRT1 deacetylates histones and nonhistone proteins including transcription factors. The SIRT1-regulated pathway affects metabolism, stress resistance, cell survival, cellular senescence, inflammation/immune function, endothelial functions, and circadian rhythms. Resveratrol has been documented in scientific literature to activate SIRT1, NrF2, NLR3P inflammasomes and have an epigenetic mechanism and therefore is predicted to benefit diseases affected by abnormal metabolic control, inflammation, and cell cycle defects. Nonetheless, resveratrol application is a major challenge, due to its poor solubility and bioavailability, as well as severe gastro-intestinal side effects when taken at high dose levels (over 2,000 mg daily). In this context, studies have proposed that structural changes in the resveratrol molecule, including glycosylation, alkylation, halogenation, hydroxylation, methylation, and prenylation could lead to the development of derivatives with enhanced bioavailability and pharmacological activity. Resveratrol has never been developed with all the necessary steps to achieve an approval as a pharmaceutical product because of severe gastro-intestinal side effects. This means that we need to take JOTROL™ through the full regulatory NDA requirement to obtain marketing approval. We were able to receive, through a confidential agreement from a major pharmaceutical company, chronic toxicology studies performed with resveratrol, in two different species, that was referenced in our approved Phase I IND application submitted to the FDA. The study was conducted by Charles River Laboratories.

- Possible out-licensing for Asian markets is being considered as it may reduce risk and cost of product development in those markets that requires confirming trials in an Asian population, while generating income through milestones and royalty agreements, see "—Asian Business Development Activities" regarding further developments and strategy in the Asian market.

Marketing and Commercialization Plan for Therapeutic Drug Candidates

The Company may consider out-licensing JOTROL™ for pharmaceutical uses to one or more companies that have such commercialization capability in place. We may consider at any time a complete exit through any proposed acquisition of our company. In case no acceptable M&A offer is presented, and in the event we were able to obtain FDA regulatory approval for JOTROL™ we might consider marketing and distributing JOTROL™ in the USA for the rare disease market only and have companies with large sales organizations distribute our product for larger indications. All international distributions would most likely be out-licensed.

The marketing and sales of orphan drugs can be relatively fast and effective. We believe, based on discussions with organizations such as the EveryLife Foundation an approval of a drug for a rare disease is efficiently communicated through social media to KOLs, patient advocacy groups and directly to patients, which may reduce marketing costs.

We have been approached by several large and mid-size pharmaceutical companies discussing interest in future collaborations once we have more clinical data available for JOTROL™. We will try to utilize this interest for out-licensing primarily in the Asian territories while waiting to conduct out-licensing in the USA and Europe until after Phase II results are obtained.

We have participated in several industry trade shows, such as Biotech Showcase, BIO USA, LSX World, World Orphan Congress, World Symposium for LSD, BIO Hong Kong 2023 and many others. We plan to continue to participate in those conferences as well as conferences targeting presentations by publicly traded companies.

Operation and Organization

We are, and plan to stay, primarily a virtual organization utilizing partnership arrangements for certain functions including but not limited to our R&D, clinical trial work, regulatory affairs and product manufacturing. A core organization is in place and will be expanded handling Strategy, Project Management, Clinical Trial Management, Regulatory Affairs, Finance and Business Development. We believe that our core management team structure has proven experience in utilizing outside resources which allows us to efficiently execute several programs simultaneously in what we believe to be a very cost-effective way.

Government Regulation

Regulatory Approval of our Drug Product Candidates

The FDA and comparable regulatory authorities in state and local jurisdictions impose substantial and burdensome requirements upon companies involved in the clinical development, manufacture, marketing, and distribution of drug products. These regulatory authorities and other federal, state, and local entities regulate the research and development, testing, manufacture, quality control, safety, effectiveness, labeling, storage, documentation and record keeping, approval, advertising and promotion, distribution, post-approval monitoring and reporting, and export and import of our drug candidates.

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act (the "FDCA"), and its implementing regulations. The process of obtaining regulatory approvals and compliance with applicable federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to a variety of administrative or judicial sanctions, such as the FDA's refusal to approve pending New Drug Applications ("NDAs"), withdrawal of an approval, imposition of a clinical hold, issuance of warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. The process required by the FDA before a drug may be marketed in the United States generally involves the following, among other things:

- completion of pre-clinical laboratory tests, animal studies and formulation studies in compliance with the FDA's good laboratory practice ("GLP") regulations;
- submission to the FDA of an IND application, which must become effective before human clinical trials may begin;
- independent Institutional Review Board ("IRB") approval;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practices ("GCPs") requirements to establish the safety and efficacy of the proposed drug product for each indication;
- demonstration that the API and finished drug product are manufactured under current good manufacturing conditions and meet all applicable standards of identity, strength, quality, and purity;
- submission to the FDA of an NDA;
- satisfactory completion of an FDA advisory committee review, if applicable;
- FDA review and approval of the NDA, including consideration of the views of any FDA advisory committee, prior to commercial marketing, promotion or sale of the drug in the United States; and
- compliance with any post-approval requirements, including the potential requirement to implement a Risk Evaluation and Mitigation Strategy (REMS) or to conduct a post-approval study.

Pre-clinical studies

Before testing any drug product candidate in humans, the product candidate must undergo rigorous pre-clinical testing. The pre-clinical developmental stage generally involves laboratory evaluations of drug chemistry, formulation, and stability, and studies to evaluate toxicity in animals, to assess the potential for adverse events (AEs) and, sometimes, to establish a rationale for therapeutic use. The conduct of pre-clinical studies is subject to federal regulations and requirements. An IND sponsor must submit the results of the pre-clinical studies, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND.

An IND is a request for authorization from the FDA to ship an investigational product and then administer it to humans for clinical research and must be allowed to proceed by the FDA before human clinical trials may begin. An IND typically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions before that time related to one or more proposed clinical trials and places the trial on clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Thus, submission of an IND does not guarantee that FDA will allow human clinical trials to commence.

Clinical trials

The clinical-trials stage of development involves the administration of the investigational product to healthy volunteers or patients under the supervision of qualified clinical trial investigators, generally experienced physicians, in accordance with GCPs, which includes the requirement that all research patients provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures and regimens, subject inclusion and exclusion criteria and the parameters to be used to monitor subject safety and assess efficacy of the investigational product. Each protocol, and any subsequent amendments to the protocol, typically must be submitted to the FDA as part of the IND. Moreover, each clinical trial must be reviewed and approved by an IRB for each institution where the clinical trial will be conducted. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. Human clinical trials are typically conducted in three sequential phases, which are summarized below at a high level:

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

FDA Marketing Approval

Assuming successful completion of required clinical testing, the results of the pre-clinical studies and clinical trials, together with detailed information relating to the product's chemistry, manufacture, quality controls, and proposed labeling, are submitted to FDA as part of an NDA requesting approval to market the product for one or more indications. In most cases, the submission of an NDA is subject to a substantial application user fee.

The length of the review process may vary but typically takes around twelve months from the date the NDA is submitted to FDA. FDA conducts a preliminary review of all NDAs to determine whether they are sufficiently complete to permit substantive review by FDA before accepting them for "filing." FDA may request additional information from the NDA applicant rather than accept an NDA for filing. If this occurs, the NDA will typically need to be resubmitted with the additional information requested by FDA. The resubmitted application is also subject to review before FDA accepts it for filing. Once an NDA submission is accepted for filing, the FDA begins a detailed substantive review. FDA reviews an NDA to determine, among other things, whether the drug is safe and effective and whether the facility in which it is manufactured, processed, packaged, or held meets standards designed to assure the product's continued safety, quality and purity. Under the current guidelines in effect in the Prescription Drug User Fee Act (PDUFA), the FDA has a goal to review and act on the submission within ten months from the completion of the preliminary review of a standard NDA for a new molecular entity.

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

Regulatory Approval of Rare Diseases

Our management, Scientific Board of Advisors and business advisors have extensive experience in regulatory affairs and clinical development of product candidates for the treatment of rare diseases, Parkinson's disease and Alzheimer's disease. The overall regulatory approval process for product candidates for the treatment of rare diseases are generally conducted with a smaller number of patients in clinical trials and over a shorter amount of time than more prevalent diseases. There is a documented pathway to obtain accelerated FDA approval for a rare disease indication if there is no existing treatment for the indication, if a product shows efficacy and has a good safety profile. There is also a possibility of receiving a Priority Review Voucher ("PRV") from the FDA upon an approval in pediatric population in a rare disease. One or more of our programs, such as MPS I, will be targeting pediatric patients. The voucher entitles the bearer to receive FDA's review of drug or biological product applications in six months rather than the standard ten months. The FDA awards a voucher following approval of a treatment for a neglected disease, rare pediatric disease, or medical countermeasure, upon the treatment meeting the statutory thresholds for such award. The voucher is transferable, and a subsequent holder may use it to obtain priority review for its own qualifying application.

There are four specific expedited development pathways that may be applicable to a rare disease indication. We will be evaluating and most likely applying for one or more of these when we get closer in the FDA approval process. These include the following pathways for the indications that it is targeting: (1) Priority Review (2) Fast Track (3) Accelerated Approval Pathway and (4) Breakthrough therapy.

Priority Review

Priority Review was authorized in 1992 by PDUFA which created the two-tiered FDA drug review system (standard versus priority). A product candidate is eligible for priority review if it treats a serious or life-threatening condition and, if approved, would provide a significant improvement in safety and effectiveness compared to available therapies. A Priority Review designation means that the goal for the FDA to review an application is six months, rather than the standard review of 10 months under the PDUFA goals. The FDA determines if a drug receives a standard or priority review, although sponsors may request a priority review.

Fast Track

Product candidates intended to treat a serious or life-threatening condition and show the potential to an unmet medical need may receive a Fast track designation. The purpose of this designation is to help make important new drugs available to patients earlier. Any drug being developed to treat or prevent a condition with no current therapy is directed at an unmet need. If there are available therapies, the new drug must demonstrate advantages, such as:

1. Show superior effectiveness, effect on serious outcomes or improved effect on serious outcomes;
2. Avoid serious side effects of the available therapy;
3. Decrease clinically significant toxicity of an available therapy that is common and causes discontinuation of treatment; and
4. Address an emerging or anticipated public health need

Fast Track designation should typically be requested at the time of the IND or after, and no later than the pre-BLA or pre-NDA meeting. Once in the Fast Track pathway, there are typically more frequent meetings with the FDA to discuss the development plan and appropriate data needed to support drug approval. The fast track designation may be withdrawn by FDA if it believes that the designation is no longer supported by data that emerges during the clinical trial process. Drugs in the Fast Track pathway are also eligible for accelerated approval and priority review if relevant criteria are met.

Accelerated Approval Pathway

Authorized in 1992 and updated in 2012, this pathway is available for a drug for a serious or life-threatening illness that provides meaningful therapeutic benefit to patients over existing treatments based upon a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant accelerated approval for such a condition when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, or IMM, and that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. If approved based on the accelerated approval pathway, the FDA may require the sponsor to conduct post-marketing confirmatory clinical trials to ensure that the drug provides the anticipated clinical benefits. If this requirement is not met, the FDA can withdraw its approval. In addition, promotional materials for product candidates approved under the accelerated approval pathway are subject to prior review by FDA.

Breakthrough Therapy

To qualify for the breakthrough therapy program, product candidates must be intended to treat a serious or life-threatening condition and preliminary clinical evidence must indicate that such product candidates may demonstrate substantial improvement on one or more clinically significant endpoints over existing therapies.

However, there is no guarantee that any designation for an accelerated pathway will lead to an accelerated FDA review or that a pediatric approval leads to grant of a PRV. Additionally, there can be no guarantee that the Company can be successful in its plans under any FDA review pathway.

Disclosure of Clinical Trial Information

Sponsors of clinical trials of FDA-regulated products, including drugs, are required to register and disclose certain clinical trial information. Information related to the product, patient population, phase of investigation, study sites and investigators, and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to discuss the results of their clinical trials after completion. Disclosure of the results of any such clinical trials can be delayed in certain circumstances for an extended period of time after the date of completion of the trial. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs.

Post-Approval Requirements

Even if an NDA is approved, a product will be subject to certain post-approval requirements. For example, the FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the internet. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved labeling.

Failure to comply with the applicable FDA post-marketing requirements may subject manufacturers and distributors to administrative or judicial sanctions. These sanctions could include, among other things, warning letters, product seizures, total or partial suspension of production or distribution, injunctions, civil money penalties, fines, restitution, disgorgement, or civil or criminal penalties. Further, the FDA has authority to issue mandatory recalls for medical devices and biologics, and we may need to undertake a voluntary recall for any of our products that may receive regulatory approval.

Regulation Outside the United States

In order to market any product outside of the U.S., we must also comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of drug products. Whether or not a product obtains FDA approval for a product, we would still need to obtain the necessary approvals by the comparable foreign regulatory authorities before we could commence clinical trials or marketing of any product in those countries or jurisdictions. The approval process ultimately varies between countries and jurisdictions and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

Government Regulation of Dietary Supplements

The Dietary Supplement Health and Education Act of 1994 (DSHEA), amended the FDCA to establish a new framework governing the composition, safety, labeling, manufacturing and marketing of dietary supplements. Generally, under DSHEA, dietary ingredients (e.g., vitamins; minerals; amino acids; or dietary substances for use by humans to supplement diet by increasing total dietary intake; or any concentrate, metabolite, constituent, extract or combination of any of the above) that were marketed in the United States prior to October 15, 1994 as a dietary supplement may be used in dietary supplements without notifying the FDA. “New” dietary ingredients (i.e., dietary ingredients that were “not marketed in the United States before October 15, 1994”) must be the subject of a new dietary ingredient notification submitted to the FDA unless the ingredient has been present in the food supply as an article used for food without being chemically altered. A new dietary ingredient notification must provide the FDA evidence of a “history of use or other evidence of safety” establishing that use of the dietary ingredient “will reasonably be expected to be safe.” A new dietary ingredient notification must be submitted to the FDA at least 75 days before introducing the product into interstate commerce. The FDA may determine that a new dietary ingredient notification does not provide an adequate basis to conclude that a dietary ingredient is reasonably expected to be safe. In addition, manufacturers of dietary supplements must ensure that ingredients in their products that are not defined as dietary ingredients comply with all the requirements applicable to conventional foods. For example, fillers and other constituents of the product must be approved as food additives or must be deemed generally recognized as safe for the conditions of use in order to be sold.

The FDA generally prohibits the marketing of a dietary supplement with a “disease claim,” including claims that the product is intended to treat, cure, mitigate or prevent disease or other health-related conditions, unless the claim constitutes a permissible “health claim” under FDA regulations and guidance. Statements of “nutritional support,” including so-called “structure/function claims,” may be permitted on labeling for dietary supplements, subject to certain requirements being met. Such statements may describe how a particular dietary ingredient affects the structure, function or general well-being of the body, or the mechanism of action by which a dietary ingredient may affect the structure, function or well-being of the body, but they may not state that a dietary supplement will reduce the risk or incidence of a disease unless such claim has been reviewed and approved by the FDA. A company that uses a statement of nutritional support in labeling must possess scientific evidence substantiating the statement as truthful and not misleading. FDA must be notified of any such statements no later than thirty days after first marketing the product with the certification that the company possesses the necessary evidence to substantiate any such statements and must be accompanied by an FDA mandated label disclaimer that “This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure or prevent any disease.”

In addition, the FDA has published detailed current Good Manufacturing Practice (cGMP), regulations that govern the manufacturing, packaging, and labeling of dietary supplements. The cGMP regulations, among other things, impose recordkeeping requirements on manufacturers and require dietary supplements to be of appropriate potency, purity and identity. The cGMP requirements are in effect for all dietary supplement manufacturers, and the FDA conducts inspections of dietary supplement manufacturers pursuant to these requirements. The FDA has broad authority to enforce the provisions of federal law applicable to dietary supplements, including, among other things, the authority to issue a public warning or notice of violation letter to a company, publicize information about illegal products, detain or seize products intended for import, require the reporting of serious adverse events, require a recall of illegal or unsafe products from the market, and request the Department of Justice initiate a seizure action, an injunction action or a criminal prosecution in the United States courts for violative conduct.

Nugevia Brand

The Company launched Nugevia, a premium line of longevity and performance supplements to support mental clarity and skin vitality. The Nugevia brand targets the growing consumer demand for wellness solutions, leveraging Jupiter's proprietary JOTROL™ technology—a resveratrol-based platform that is designed to provide higher bioavailability of resveratrol.

Nugevia's initial product line features three core formulations, each targeting a major aspect of health and longevity:

Product Name	Focus Area	Target Consumer Benefit
GLO	Skin beauty	Support skin beauty and healthy appearance
MND	Cognitive performance	Support mental clarity, cognitive resilience
PWR	Mitochondrial and physical health	Maintain energy, endurance, muscle recovery

Nugevia's formulations are built on Jupiter's patented JOTROL™ micellar delivery platform, which has shown potential for significantly enhanced bioavailability and serves as the foundation for the company's clinical-stage CNS investigational therapies. The debut products—GLO, MND, and PWR—are formulated to support cellular resilience through synergistic ingredient combinations, all optimized for absorption via the JOTROL™ system.

Market Positioning and Opportunities

The Nugevia brand will enter the nutraceutical market as a premium longevity and performance supplement line, capitalizing on a global industry projected to reach $8 trillion by 2030. Powered by JOTROL™, a patented resveratrol-based platform that is designed to provide greater bioavailability than standard resveratrol, Nugevia targets health-conscious consumers seeking science-backed solutions for mitochondrial and physical health, mental clarity, and skin vitality. Products like PWR and GLO address key market segments—dietary supplements and functional foods—driven by rising health awareness, an aging population, and a shift toward preventive healthcare. The DTC model positions Nugevia to capture high-margin revenue in a competitive but growing market, leveraging clinical-grade credibility to stand out in a competitive market.

Challenges and Competitive Landscape

The supplement market is fueled by increasing lifestyle-related disorders and demand for natural ingredients. However, Nugevia faces challenges including regulatory hurdles, complex product approvals, and competition from established players offering similar products. Consumer skepticism about resveratrol's historical bioavailability issues and the need for robust scientific validation could impact adoption. Nugevia's use of JOTROL™ alongside ingredients like NovaSOL® Astaxanthin and CoQ10 aims to address these concerns, while strategic partnerships with Aquanova and endorsements from figures like Annika Sörenstam and Chris Webber enhance brand trust. Success will hinge on overcoming market saturation and proving efficacy to stand out in a crowded field.

Marketing

The Company will employ a digital-first marketing strategy, leveraging a DTC e-commerce platform to reach health-conscious consumers seeking clinically validated wellness solutions. The Company has appointed Annika Sörenstam, a Hall of Fame golfer with over 95 tournament victories, as Nugevia's first brand ambassador, enhancing brand credibility and aligning with the product's focus on performance, focus, and longevity. In addition, the Company has partnered with Chris Webber, five-time NBA All-Star and Hall of Fame inductee, as the Company's second official brand ambassador for Nugevia. Marketing efforts also include tailored campaigns for international markets, with service partners in Hong Kong developing a specific program for Southeast Asia to address regional consumer preferences.

The initial launch in the USA utilized a DTC model, with the Nugevia website serving as the primary sales platform. Following this, the Company aims to expand distribution to Europe, the Middle East, and Southeast Asia through regional partnerships, capitalizing on the global demand for longevity solutions. By combining cutting-edge science, strategic marketing, and a robust manufacturing process, Nugevia is poised to capture a significant share of the longevity market while supporting Jupiter's long-term mission to advance treatments for CNS disorders.

Competitors

The longevity and wellness market, driven by increasing demand for health span extension, is highly competitive, with Nugevia facing established players like ChromaDex (offering NAD+ precursors like Tru-Niagen), Novos (targeting aging hallmarks with products like NOVOS Core), Timeline's urolithin A supplements and Tally Health (providing personalized longevity supplements and biological age testing). Larger competitors, including Nestle Health Science (with multiple brands and products), Amway (through Nutrilite's Healthy Aging Solution), and L'Oreal (via its Longevity Integrative Science initiative), are also expanding into this space, intensifying competition. Nugevia's differentiation lies in its proprietary JOTROL™ technology, which supports higher plasma concentrations (approximately 300 ng/ml) and effective CNS delivery, positioning it as a premium offering.

Brands like NOVOS, Blueprint, and Perpetua.Life offer formulas that combine resveratrol with other scientifically backed longevity compounds (e.g., NMN, quercetin, CoQ10, fisetin) for synergistic effects. In addition, advanced delivery systems such as Liposomal and micellar technologies are widely used by many companies to enhance the absorption of key actives, similar to Nugevia's approach, purity and clinical validation. Furthermore, companies such as ProHealth, Renue By Science, and Decode Age, who offer similar longevity supplements and sell their products online directly to consumers, emphasize ingredient purity, bioavailability, multi-ingredient formulations and evidence-based dosing, which is appealing to the target health-conscious consumers seeking credible, science-backed longevity solutions.

Manufacturing

Nugevia products will be manufactured by Aquanova in Germany. The manufacturing process has several steps, which are: (a) ingredient combinations are manufactured as a liquid solution by Aquanova in Germany, (b) the liquid solutions are shipped to GMP-certified facility in California for encapsulation into softgels and (c) finished products are sent in bulk to a final packing and fulfillment center, which ships directly to customers. While all steps except the initial solution preparation can be handled by U.S. suppliers, changing the first step would require a separate agreement with Aquanova.

The FDA requires that dietary supplement manufacturers comply with Current Good Manufacturing Practices ("cGMP") under 21 CFR Part 111, ensuring product safety, quality, and accurate labeling. Jupiter must verify that its manufacturing partners, including those involved in producing JOTROL™ or sourcing ingredients like CoQ10, meet these standards. Non-compliance, such as contamination or inconsistent ingredient potency, could lead to product recalls, enforcement actions, fines, or reputational damage. Any lapses in quality control could undermine consumer trust and weaken its competitive edge in the $451.7 billion nutraceutical market.

Compliance with U.S. FDA Regulations

In the United States, Nugevia products, classified as dietary supplements, fall under the Dietary Supplement Health and Education Act (DSHEA) of 1994, enforced by the FDA. The FDA requires that all health claims be substantiated with credible scientific evidence, and any claims related to Nugevia's benefits—such as mitochondrial support, mental clarity, or skin vitality—must avoid implying treatment or prevention of diseases, which would classify the products as drugs subject to stricter pre-market approval. Non-compliance, such as misleading labeling or unsubstantiated claims, could result in warning letters, product seizures, or injunctions. Additionally, Jupiter must ensure that JOTROL™, its proprietary resveratrol delivery system, complies with FDA's New Dietary Ingredient (NDI) notification requirements if deemed novel, a process that can take months and negatively impact the Company's ability to sell Nugevia products.

International Regulatory Variations

Global expansion introduces regulatory complexities. In the European Union, the European Food Safety Authority (EFSA) oversees nutraceuticals under the Novel Food Regulation (EU) 2015/2283. If JOTROL™ or other ingredients like NovaSOL® Astaxanthin are considered novel foods (not consumed in the EU before May 15, 1997), Jupiter must submit a detailed safety dossier, a costly and time-intensive process that could delay market entry. In markets like China or Japan, stringent pre-market approvals and ingredient restrictions may require reformulation or additional clinical studies. Failure to navigate these variations could limit Nugevia's global reach or result in costly reformulations, impacting Jupiter's revenue projections.

Post-Market Surveillance and Adverse Event Reporting

Nugevia products are subject to post-market surveillance, particularly in the U.S., where manufacturers must report serious adverse events to the FDA within 15 days under DSHEA. Even rare side effects linked to resveratrol or other ingredients like astaxanthin could trigger investigations, negative publicity, or product withdrawals. Jupiter must establish robust adverse event reporting systems and ensure transparency to mitigate legal and reputational risks. Failure to comply could lead to regulatory scrutiny, consumer lawsuits, or loss of market confidence, particularly given past skepticism about resveratrol's safety and efficacy at high doses.

Asian Business Development Activities

We have entered into service agreements in the areas of CMC, regulatory affairs and clinical trial management with companies with operations in Southeast Asia. These agreements are with companies that, we believe, have the knowledge and network in the Southeast Asian market. The agreements are further described in the section "Other Material Agreements". In addition, we are in active negotiations with Dominant Treasure Health Company Limited ("Dominant Treasure"), a BVI company. Dominant Treasure has demonstrated to us, through several company introductions, that they have business relationships, either directly or through affiliates, with many Southeast Asian pharmaceutical companies as well as companies involved in distribution and sales of TCM, Traditional Chinese Medicine. We are therefore planning to engage Dominant Treasure in active business development in China, Malaysia and Singapore as soon as we have financing in place for their engagement. Dominant Treasure has already introduced us to three Chinese companies, Beimei Pharma, http://en.beimeiyaoye.com, that specializes in pediatric medications, Sichuan Kelun Pharmaceutical Co., Ltd., a publicly traded company that is part of the Kelun Industrial Group, https://www.kelun.com/, and Tianjin Pharmaceuticals, https://en.pharm.com.cn/, that advocates the corporate core values of "Love, Integrity and Power". TCM products are run in a separate division within Tianjin. The Asian market is very large and hard to penetrate for a small company and we believe that our strategy with these agreements have the possibility to accelerate an out-licensing deal in the Southeast Asian territories. However, there are no assurances that this approach will be successful.

Our rationale for the strong approach into the Southeast Asian market is:

- Background: Asian countries are not accepting pharmaceutical products to be sold without clinical trial approvals based on trials conducted in an Asian population.
- The Company's strategy is to partner with organizations in the territory that can execute much more efficiently than trying to manage the process from USA.
- We have already received interest for our JOTROL™ product in the Asian market since resveratrol is listed as a Traditional Chinese Medicine.
- The need for a set up that can service this market is imperative for success.
- Strategic collaboration agreements have been executed to facilitate an expedited execution of an out-licensing agreement with one or more Chinese or other Southeast Asian pharmaceutical companies.
- The Company is too small, both financially as well as internal manpower, to manage developments in the territory.
- The Company has historically faced financial constraints that have, at times, limited its ability to fulfill certain commitments and complete clinical studies on its planned timeline.
- By utilizing equity as service payments, the company believes that it can get projects finalized without any significant cash outflow.
- The service agreements are therefore designed to be a win for both parties, assuming an increase in equity value, in case clinical studies and out-licensing activities will be successful in the territory.

Other Material Agreements

The agreement with a major pharmaceutical company, restricted by confidentiality, grants us data access to resveratrol toxicology studies through a letter of reference. Executed on May 2, 2017, it can only be terminated due to a material breach and there is no time limit on access to this study. The studies were conducted at Charles River Laboratories, and there are no payments associated with this agreement.

On December 15, 2024, the Company entered into a Strategic Services Agreement (the "Dominant Treasure Agreement") with Dominant Treasure Health Company Limited ("Dominant Treasure"). Pursuant to the terms of the Dominant Treasure Agreement, Dominant Treasure agreed to provide certain services to the Company to assist the Company in accelerating the development and distribution of the Company's products in the Southeast Asian market. In exchange for Dominant Treasure's services pursuant to the Dominant Treasure Agreement, the Company agreed to pay Dominant Treasure a one-time payment of $2,300,000 to be delivered after the closing of a minimum of $10,000,000 in gross proceeds from a public offering. In addition, if Dominant Treasure is involved in generating negotiations and conclusion of a distribution agreement for the Company in the countries of China (including Hong Kong), Singapore and Malaysia, the Company will pay Dominant Treasure a success fee of 5% of any upfront and/or milestone payments to be received by the Company. If such distribution agreement includes a royalty payment to the Company, Dominant Treasure will receive 5% of such royalty payment. The Dominant Treasure Agreement has a term of 36 months and may be terminated at any time upon mutual agreement of the parties.

Service Agreements - Southeast Asia

On June 3, 2024, the Company entered into three service agreements to expand in Southeast Asia; a CRO Services Agreement with Optimize Wellness Limited providing clinical trial guidance in China, Malaysia, and Singapore, a Regulatory Services Agreement with Regis Healthcare Group Limited providing regulatory strategy and guidance, and a Product Services Agreement with Longevity Technology Group Limited providing manufacturing guidance. Each of the 3 service agreements has a 3-year term and was paid for with an upfront issuance of 1,162,500 shares of common stock with a fair market value of $1.33 per share (3,487,500 in the aggregate, with an aggregate fair market value of $4,638,375) as pre-payment for three years of services, which were registered for resale as part of the initial public offering.

Legal Proceedings

From time to time, we are involved in various legal proceedings arising from the normal course of business activities. We are not presently a party to any litigation the outcome of which, we believe, if determined adversely to us, would individually or taken together have a material adverse effect on our business, operating results, cash flows or financial condition.

Facilities

Our corporate headquarters are located at 1001 North US Hwy 1, Suite 504, Jupiter, Florida 33477, where we lease approximately 1,206 rentable square feet of office space. This lease expires on May 31, 2026. Terms of the office lease provide for a base rent payment of $4,258 per month and a share of the building's operating expenses, such as taxes and maintenance, of $600 per month. In September 2021, we added an additional office located at 127 Main Street, Boston, Massachusetts 02129 for 120 rentable square feet of office space for our Boston-based employees and scientist to utilize as necessary.

We believe that these facilities are adequate for our current and near-term future needs.

Employees

As of December 31, 2025, we had a total of five full-time employees, two full-time consultants, three part-time consultants, and our six Scientific Advisory Board members. Of these, three were primarily engaged in research or product development and clinical activities.

ITEM 1A. RISK FACTORS

An investment in our securities carries a significant degree of risk. You should carefully consider the following risks, as well as the other information contained in this Annual Report on Form 10-K, including our historical financial statements and related notes included elsewhere in this Annual Report on Form 10-K, before you decide to purchase our securities. Any one of these risks and uncertainties has the potential to cause material adverse effects on our business, prospects, financial condition and operating results which could cause actual results to differ materially from any forward-looking statements expressed by us and a significant decrease in the value of our common shares. Refer to "Cautionary Statement Regarding Forward-Looking Statements."

We may not be successful in preventing the material adverse effects that any of the following risks and uncertainties may cause. These potential risks and uncertainties may not be a complete list of the risks and uncertainties facing us. There may be additional risks and uncertainties that we are presently unaware of, or presently consider immaterial, that may become material in the future and have a material adverse effect on us. You could lose all or a significant portion of your investment due to any of these risks and uncertainties.

Below is a summary of material risks, uncertainties and other factors that could have a material effect on the Company and its operations:

- Our substantial amount of indebtedness may adversely affect our cash flow and our ability to operate our business, remain in compliance with debt covenants and make payments on our indebtedness.
- Low trading volume in our common stock may limit or prevent our ability to draw on the Standby Equity Purchase Agreement to pay down the convertible promissory notes.
- We have not generated any meaningful revenue from product sales to date, have incurred significant net losses since our inception, and expect to continue to incur significant net losses for the foreseeable future;
- Our management has concluded that factors raise substantial doubt about our ability to continue as a going concern and our auditor has included an explanatory paragraph relating to our ability to continue as a going concern in its audit report for the fiscal years ended December 31, 2025 and 2024.
- We will require substantial additional capital to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our research and drug development programs or future commercialization efforts.
- Raising additional capital may cause substantial dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.
- The actual number of shares of common stock we will issue pursuant to the SEPA, if not terminated and if and when available, at any one time or in total, is uncertain.
- Our business and future prospects with the Nugevia brand and our pharmaceutical products are significantly dependent on our exclusive, worldwide license agreement with Aquanova. Any adverse development related to this license agreement could materially and adversely affect our operations, financial condition, and results of operations.
- We have entered into Service Agreements with the Asian Partners with respect to services to be provided by the Asian Partners to us in Asia for the clinical development of JOTROL™ in the Southeast Asian territory immediately following the completion of the initial public offering; the shares issued by us in advance for the specific services could have a material negative impact on our business, financial condition and operating results in case the Asian Partners' will not perform the services per the agreements.
- We entered into a Strategic Service Agreement with DOMINANT TREASURE HEALTH COMPANY LIMITED with respect to strategic services in Asia, the fees paid by the Company pursuant to which, are non-refundable and not tied to any milestones or performance, and the foregoing nature of such fees, could have a material negative impact on our business, financial condition and operating results.
- We have limited resources and are currently focusing the majority of our efforts on developing JOTROL™ for particular indications. As a result, we may fail to capitalize on other indications or product candidates that may ultimately have proven to be more profitable.
- We face significant competition and if our competitors develop and market technologies or products more rapidly than we do or that are more effective, safer or less expensive than the products we develop, our commercial opportunities will be negatively impacted.
- We may not be successful in our efforts to develop our proprietary drug delivery platform, JOTROL™, to build a pipeline of indications.
- The FDA, EMA and other comparable foreign regulatory authorities may not accept data from trials conducted in locations outside of their jurisdiction.
- We may face difficulties from changes to current regulations and future legislation.
- Our success is highly dependent on our ability to attract and retain highly skilled executive officers and employees; and
- The Company's failure to meet the continued listing requirements of The Nasdaq Capital Market could result in a delisting of its securities.

Risks Related to Our Financial Position, Need for Additional Capital and Limited Operating History

We are early in our development efforts, with a limited operating history, and we have no prescription products approved for commercial sale, which may make it difficult for you to evaluate our current business and likelihood of success and future viability.

We are an early clinical stage pharmaceutical company with a limited operating history upon which you can evaluate our business and prospects. We are advancing a therapeutic pipeline targeting CNS disorders and rare disease, while also expanding into the consumer longevity market with our Nugevia product line. We are developing one medication to treat rare diseases (MPS I and MELAS) as well as larger indications, Parkinson's Disease and MCI / early Alzheimer's disease, which is an unproven and highly uncertain undertaking and involves a substantial degree of risk.

We commenced operations in January 2016, have no prescription or therapeutic products approved for commercial sale and have not generated any revenue through our pharmaceutical operations. We initiated and completed our Phase I clinical trial for our sole product candidate, JOTROL™, in March 2021. Subject to additional discussions with and approval from FDA, we hope to use the results of this study as a cross-reference for other indications where JOTROL™ will be used in Phase IIa and potentially Phase III clinical trials. FDA accepted this cross-reference in the approval of the IND application for the Parkinson's Phase IIa trial. The Company has not discussed the use of cross-referencing in this manner with the FDA or other comparable regulatory authorities for any other indications, and FDA (or any comparable regulatory authorities) may preclude us from the use of cross-referencing with respect to the results of this study. As a result, we are presently unable to rely on potential cross-referencing besides in the already approved Parkinson's study.

Since our inception in 2016, we have devoted substantially all of our focus and financial resources to discovering, identifying and developing our product candidate, JOTROL™, including advancing our development program, conducting a preclinical study of our product candidate and initiating a clinical trial, organizing and staffing our company, business planning, raising capital and securing related intellectual property rights.

We have not yet demonstrated our ability to successfully complete efficacy clinical trials that can lead to a NDA submission, obtain marketing approvals, manufacture a commercial-scale product, or obtain a proposal for any out-licensing or distribution agreements. As a result, it may be more difficult for investors to accurately predict our likelihood of success and viability than it could be if we had a longer operating history.

In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors and risks frequently experienced by clinical-stage biopharmaceutical companies in rapidly evolving fields. We also may need to transition from a company with a research and development focus to a company capable of supporting commercial activities. We have not yet demonstrated an ability to successfully overcome such risks and difficulties, or to make such a transition. If we do not adequately address these risks and difficulties or successfully make such a transition, our business will suffer.

We have not generated any meaningful revenue from product sales to date, have incurred significant net losses since our inception, and expect to continue to incur significant net losses for the foreseeable future.

In 2025, the Company launched a new strategic initiative to introduce Nugevia, a consumer-focused product line centered on longevity and wellness. This initiative is intended to address growing demand for wellness solutions through the development of nutritional products. The Company completed product formulations and commenced initial direct-to-consumer sales in the fourth quarter of 2025. To date, however, the Company has not generated any meaningful revenue and has incurred significant net losses since inception. Operations have been funded primarily through private placements of common stock. The Company has not achieved profitability and continues to experience significant losses and cash flow deficits

For the fiscal years ended December 31, 2025 and 2024, we generated net revenues of $21,796 and $0, respectively from product sales and reported net losses of $8,644,897 and $2,439,625, respectively, and negative cash flow from operating activities of $5,413,736 and $3,911,004, respectively. As noted in our financial statements, as of December 31, 2025 and 2024, we had an accumulated deficit of $34,667,026 and $26,022,129, respectively.

Our product candidate, JOTROL™, recently completed Phase I clinical trial that commenced in December 2020. As a result, we expect that it will be several years, if ever, before we receive approval to commercialize our product and generate revenue from pharmaceutical product sales. Even if we succeed in receiving marketing approval for and commercializing of our approved product candidate, we expect that we will continue to incur substantial research and development and other expenses in order to discover, develop and market additional potential products.

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. The net losses we incur may fluctuate significantly from quarter to quarter such that a period-to-period comparison of our results of operations may not be a good indication of our future performance, particularly since we expect our expenses to increase if and when our product candidate progresses through clinical development as a product candidate in later stages of clinical development generally have higher development costs than those in earlier stages, primarily due to the increased size and duration of later-stage clinical trials. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to have our product candidates approved for marketing and to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our working capital, our ability to fund the development of our product candidate and our ability to achieve and maintain profitability and the performance of our stock.

Our management has concluded that factors raise substantial doubt about our ability to continue as a going concern and our auditor has included an explanatory paragraph relating to our ability to continue as a going concern in its audit report for the fiscal years ended December 31, 2025 and 2024.

Our management has concluded that our historical recurring losses from operations and negative cash flows from operations as well as our dependence on private equity and other financings raise substantial doubt about our ability to continue as a going concern and our auditor has included an explanatory paragraph relating to our ability to continue as a going concern in its audit report for the fiscal year ended December 31, 2025 and 2024.

Our financial statements do not include any adjustments that might result from the outcome of this uncertainty. These adjustments would likely include substantial impairment of the carrying amount of our assets and potential contingent liabilities that may arise if we are unable to fulfill various operational commitments. In addition, the value of our securities would be greatly impaired. Our ability to continue as a going concern is dependent upon generating sufficient cash flow from operations and obtaining additional capital and financing. If our ability to generate cash flow from operations is delayed or reduced and we are unable to raise additional funding from other sources, we may be unable to continue in business. For further discussion about our ability to continue as a going concern and our plan for future liquidity, see "Management's Discussion and Analysis of Financial Condition and Results of Operations—Ability to Continue as a Going Concern."

Our ability to generate revenue and achieve profitability depends significantly on our ability to achieve several objectives relating to the discovery, development and commercialization of our product candidates, if approved.

Our business depends entirely on the successful discovery, development, regulatory approval and commercialization of product candidates for therapeutic uses and/or the commercialization of products in our DTC Nugevia line. We have no prescription drug products approved for commercial sale and do not anticipate generating any revenue from sales of prescription drugs for the next several years, if ever. We have not generated meaningful revenue from Nugevia product sales to date.

Our ability to generate revenue and achieve profitability depends on successfully completing clinical development of the JOTROL™ program and future candidates, establishing relationships with CROs and clinical sites, initiating and completing clinical trials on time, ensuring acceptable safety and efficacy profiles for FDA or foreign regulatory approval, and obtaining timely marketing approvals. We must also comply with post-marketing commitments, develop scalable manufacturing processes, and secure reliable supply chains to meet clinical and market demands. Additionally, we need to launch commercially viable products, ensure continued safety post-approval, gain acceptance from patients, medical professionals, and payors, and secure adequate reimbursement. We must also develop new candidates, protect our intellectual property, defend against infringement claims, and enter favorable collaboration agreements. Further, we need additional funding, the ability to address competing therapies and market developments, manage costs, and attract and retain qualified personnel.

We may never be successful in achieving our objectives and, even if we do, we may never generate revenue that is significant or large enough to achieve profitability. 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 would decrease the value of our company and could impair our ability to maintain or further our research and development efforts, raise additional necessary capital, grow our business and continue our operations.

We may also experience delays in developing a sustainable, reproducible and scalable manufacturing process or transferring that process to commercial partners, which may prevent us from completing our clinical trials or commercializing our product candidates on a timely or profitable basis, if at all. Changes in the manufacturing process or facilities will require further comparability analysis and approval by the FDA before implementation, which could delay our clinical trials and product candidate development, and could require additional clinical trials, including bridging studies, to demonstrate consistent and continued safety and efficacy.

We will require substantial additional capital to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our research and drug development programs or future commercialization efforts.

As of December 31, 2025, we had $3,789,342 in cash. Our estimate as to how long we expect our existing cash and cash equivalents to be able to continue to fund our operations is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned.

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive and uncertain process that takes years to complete. Our operations have consumed substantial amounts of cash since inception, and we expect our expenses to increase in connection with our ongoing activities, particularly as we conduct clinical trials of, and seek marketing approval for, JOTROL™ as well as develop our proprietary drug delivery platform. Even if one or more of the product candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with sales, marketing, manufacturing and distribution activities. Our expenses could increase beyond expectations if we are required by the FDA, the European Medicines Agency (the "EMA") or other regulatory agencies to perform clinical trials or preclinical studies in addition to those that we currently anticipate. Other unanticipated costs may also arise. Because the design and outcome of our planned and anticipated preclinical studies and clinical trials are highly uncertain, we cannot reasonably estimate the actual amount of resources and funding that will be necessary to successfully complete the development and commercialization of any product candidate we develop. We are not permitted to market or promote JOTROL™, or any other product candidate, before we receive marketing approval from the FDA. We also incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in order to continue our operations.

Our future capital needs will hinge on multiple factors, including the scope, progress, and costs of researching and developing our product candidates through preclinical studies and clinical trials, as well as the timing and outcome of regulatory reviews. The number and nature of additional product candidates we pursue, along with costs for marketing, manufacturing, and distributing approved products, will also impact funding requirements. Revenue from potential commercial sales, expenses for building inventory, and costs of hiring staff to support growth will further influence our needs. Additionally, expenses for patent applications, intellectual property enforcement, and defending related claims, alongside costs to establish collaborations or in-license new technologies, will play a role. Competing products, milestone payments, royalties, and investments in businesses or technologies, as well as the costs of implementing internal systems and meeting public company compliance obligations, will also shape our financial demands. A change in the outcome of any of these or other factors with respect to the development of any of our product candidates could significantly change the costs and timing associated with the development of that product candidate.

We currently plan to initiate a Phase II clinical trial with JOTROL™ in patients with Parkinson's Disease, establish a presence in Southeast Asia through service agreements and advancing the manufacturing of JOTROL™ clinical trial supplies. in support of activities leading up to clinical trials in targeted indications. Remaining proceeds will be used for general research and development activities, working capital and other general corporate activities. Advancing the development of JOTROL™ program will require a significant amount of capital. Our cash and cash equivalents and grants will not be sufficient for us to fund our product candidates through the completion of its development, Phase III clinical trials, entire regulatory approval process and commercialization. We will need to raise additional capital to fund such activities.

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 future operating plans. 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 failure to raise capital as and when needed or on acceptable terms would have a negative impact on our financial condition and our ability to pursue our business strategy, and we may have to delay, reduce the scope of, suspend or eliminate one or more of our research-stage programs, clinical trials or future commercialization efforts.

Raising additional capital may cause substantial 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 revenues, we will be required to obtain further funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources, which may dilute our stockholders or restrict our operating activities. Adequate additional financing may not be available to us on acceptable terms, or at all. 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 may include liquidation or other preferences that adversely affect your rights as a 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 acquisitions, engaging in acquisition, merger or collaboration transactions, selling or licensing our assets, making capital expenditures, redeeming our stock, making certain investments, declaring dividends or encumbering our assets to secure future indebtedness. Such restrictions could adversely impact our ability to conduct our operations and execute our business plan.

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

The actual number of shares of common stock we will issue pursuant to the SEPA, if not terminated and if and when available, at any one time or in total, is uncertain.

Subject to the terms and conditions of the standby equity purchase agreement, dated October 24, 2025 (the "SEPA"), by and between the Company and YA II PN, LTD, a Cayman Islands exempt limited partnership ("Yorkville"), we issued two convertible notes to Yorkville in connection with advances under the SEPA. These convertible notes are convertible into shares of our common stock from time to time during their term. The number of shares of common stock that may be issued upon conversion of the convertible notes will depend on a number of factors, including the market price of our common stock at the time of conversion. As a result, we cannot predict the total number of shares that may ultimately be issued upon conversion of the convertible notes, which could result in substantial dilution to our existing stockholders.

Low trading volume in our common stock may limit or prevent our ability to draw on the Standby Equity Purchase Agreement.

We have entered into a SEPA pursuant to which Yorkville has committed to purchase up to $20 million of shares of our common stock, subject to certain conditions and limitations. The maximum amount of any individual advance notice under the SEPA is 100% of the average of the daily traded dollar volume of our common stock on Nasdaq during the five consecutive trading days immediately preceding an advance notice.

Accordingly, if the trading volume of our common stock is low during any such measurement period, the amount we may draw in any single advance, and the aggregate capital we can raise within any given timeframe, will be correspondingly reduced. There can be no assurance that our common stock will maintain sufficient trading volume to allow us to access the full commitment under the SEPA when needed. The amount of capital that may be raised under the SEPA will depend on market conditions, trading volumes, the price of our common stock, and the continued satisfaction of the applicable limitations and conditions under the SEPA. It is not possible to predict the actual number of shares we will sell under the SEPA or the actual gross proceeds resulting from those sales.

Our inability to utilize the SEPA could have a material adverse effect on our liquidity and financial condition.

Our substantial amount of indebtedness may adversely affect our cash flow and our ability to operate our business, remain in compliance with debt covenants and make payments on our indebtedness.

As of December 31, 2025, we had outstanding indebtedness in the principal amount of $6,000,000 and accrued interest of approximately $39,829. Our substantial level of indebtedness increases the possibility that we may be unable to generate sufficient cash to pay, when due, the principal of, interest on or other amounts due with respect to our indebtedness. Our indebtedness could have other important consequences to you as a stockholder. For example, it could:

- make it more difficult for us to satisfy our obligations with respect to our indebtedness and any failure to comply with the obligations of any of our debt instruments, including financial and other restrictive covenants, could result in an event of default under the debt instruments;
- make us more vulnerable to adverse changes in general economic, industry and competitive conditions and adverse changes in government regulation;
- require us to dedicate a substantial portion of our cash flow from operations to payments on our indebtedness, thereby reducing the availability of our cash flows to fund working capital, capital expenditures, acquisitions and other general corporate purposes;
- limit our flexibility in planning for, or reacting to, changes in our business and the industry in which we operate;
- place us at a competitive disadvantage compared to our competitors that have less debt; and
- limit our ability to borrow additional amounts for working capital, capital expenditures, acquisitions, debt service requirements, execution of our business strategy or other purposes.

Any of the above listed factors could materially adversely affect our business, financial condition and results of operations.

If we are at any time unable to generate sufficient cash flow from operations to service our indebtedness when payment is due, we may be required to attempt to renegotiate the terms of the instruments relating to the indebtedness, seek to refinance all or a portion of the indebtedness, or obtain additional financing. There can be no assurance that we would be able to successfully renegotiate such terms, that any such refinancing would be possible or that any additional financing could be obtained on terms that are favorable or acceptable to us, if at all. Any debt financing that is available could cause us to incur substantial costs and subject us to covenants that significantly restrict our ability to conduct our business. If we seek to complete additional equity financings, the interests of existing equity holders may be diluted.

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

Our net operating loss (NOL) carryforwards may be unavailable to offset future taxable income because of restrictions under U.S. tax law. Our NOLs generated in tax years ending on or prior to December 31, 2017 are only permitted to be carried forward for 20 taxable years under applicable U.S. federal tax law, and therefore could expire unused. Under tax legislation commonly referred to as the Tax Cuts and Jobs Act (Tax Act) as amended by the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), our federal NOLs generated in tax years beginning after December 31, 2017 may be carried forward indefinitely, but for taxable years beginning after December 31, 2021, the deductibility of federal NOLs generated in tax years beginning after December 31, 2017 is limited to 80% of our current year taxable income. It is uncertain if and to what extent various states will conform to the Tax Act. As of December 31, 2025, the Company had federal and state (post-apportioned basis) net operating losses ("NOLs") of $42.83 million, as well as federal orphan drug credit and research and development tax credit carryforwards of approximately $1.72 million. Approximately $22.1 million of the foregoing federal and state NOLs will expire at various dates from 2036 through 2045, if not limited by triggering events prior to such time.

In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (Code), if a corporation undergoes an "ownership change" (generally defined as a cumulative change in the corporation's ownership by "5% stockholders" that exceeds 50 percentage points over a rolling three-year period), the corporation's ability to use its pre-change NOLs and certain other pre-change tax attributes to offset its post-change taxable income may be limited. Similar rules may apply under state tax laws. We may have experienced such ownership changes in the past, and we may experience ownership changes in the future as a result of shifts in our stock ownership, some of which are outside our control. We have not conducted any studies to determine annual limitations, if any, that could result from such changes in ownership. Our ability to utilize our NOLs and certain other tax attributes could be limited by an "ownership change" as described above and consequently, we may not be able to utilize a material portion of our NOLs and certain other tax attributes, which could have a material adverse effect on our cash flows and results of operations.

Changes in U.S. tax laws and regulations and those which we are subject to in various tax jurisdictions could adversely affect our business, financial condition and results of operations.

We operate in multiple jurisdictions and are subject to tax laws and regulations of the U.S. federal, state and local and foreign governments. New income, sales, use, digital service or other tax laws, statutes, rules, regulations, or ordinances could be enacted at any time. Those enactments could harm our domestic and international business operations and our business, financial condition and results of operations. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. These events could require us to pay additional tax amounts on a prospective or retroactive basis, as well as require us to pay fines and/or penalties and interest for past amounts deemed to be due. Additionally, new, changed, modified or newly interpreted or applied tax laws could increase our compliance, operating and other costs, as well as the costs of our offerings. Further, these events could decrease the capital we have available to operate our business. Any or all of these events may harm our business, financial condition and results of operations.

If we expand the scale of our international business activities, any changes in the U.S. or foreign taxation of such activities may increase our worldwide effective tax rate and harm our business, financial condition and results of operations. We may be subject to taxation in several jurisdictions around the world with increasingly complex tax laws, the application of which can be uncertain. The amount of taxes we pay in these jurisdictions could increase substantially as a result of changes in the applicable tax principles, including increased tax rates, new tax laws or revised interpretations of existing tax laws and precedents. An increase in our tax liabilities could harm our liquidity and results of operations. In addition, the authorities in these jurisdictions could review our tax returns and impose additional tax, interest and penalties, and the authorities could claim that various withholding requirements apply to us or assert that benefits of tax treaties are not available to us, any of which may harm us and our results of operations.

Any shares of common stock we issue under the SEPA, if not terminated and if and when available, will further dilute our stockholders.

We have issued shares of our common stock to Yorkville pursuant to the SEPA and we may issue additional shares of our common stock under the SEPA in the future. These issuances have resulted, and any future issuances will result, in dilution to the ownership interests of our existing stockholders. The number of shares that may be issued under the SEPA is variable and depends on factors such as the prevailing market price of our common stock and any applicable discounts under the SEPA, and shares may be issued at prices below the market price, resulting in significant dilution.

Risks Related to the Launch of the Nugevia Brand

The launch of the Nugevia brand exposes the Company to a number of business and operational risks that could materially and adversely impact its business

The launch of the Nugevia brand exposes us to a number of risks that could materially and adversely affect our business, financial condition, and results of operations. Successfully introducing a new brand requires significant investment in marketing, product development, supply chain management, and regulatory compliance, and there can be no assurance that Nugevia will achieve market acceptance or generate anticipated sales. If we fail to execute the launch effectively, experience delays in product availability, or encounter challenges in maintaining product quality and regulatory standards, our ability to establish Nugevia as a recognized and trusted brand may be compromised.

Additionally, the introduction of Nugevia may provoke competitive responses from established market participants, potentially resulting in increased pricing pressure or heightened marketing costs. If the Nugevia brand does not gain sufficient traction or if we are unable to recover our investment in its development and promotion, our growth prospects and overall financial performance could be negatively impacted.

Our business and future prospects with the Nugevia brand and our pharmaceutical products are significantly dependent on our exclusive, worldwide license agreement with Aquanova. Any adverse development related to this license agreement could materially and adversely affect our operations, financial condition, and results of operations.

Our business and future prospects are significantly dependent on our exclusive, worldwide license agreement with Aquanova AG, a German company ("Aquanova") which grants us rights to develop, manufacture, distribute, and sell key products, including JOTROL™. Any adverse development related to this agreement could materially and adversely affect our operations, financial condition, and results of operations.

If the license agreement with Aquanova were to be terminated, limited, or materially altered, we could lose access to essential proprietary technologies, such as Aquanova's NovaSOL® formulation technology, which is critical for the bioavailability and effectiveness of our Nugevia brand. Disputes over contract terms, intellectual property rights, or performance obligations could result in costly litigation, delays in product development, or loss of commercialization rights. Additionally, our obligation to pay license fees and royalties under the license agreement represents a significant financial commitment, and any inability to meet these obligations could jeopardize our rights under the license agreement. The loss or impairment of this license would require us to seek alternative technologies or partners, which may not be available on favorable terms, if at all, and could delay or prevent the development and commercialization of our products.

Should we fail to maintain a productive relationship with Aquanova or if Aquanova experiences operational or financial difficulties, our ability to deliver products to market could be compromised, negatively impacting our growth prospects and competitive position.

If the Company or its suppliers fails to comply with FDA or other regulations, it could result in enforcement actions or delays in the Nugevia brand product launch.

The Company is subject to various federal, state, and local laws, regulations and administrative practices that affect its business. Our suppliers and contract manufacturers are also subject to such laws and regulations. The safety, formulation, manufacturing, processing, packaging, importation, labeling, promotion, advertising, and distribution of the Nugevia brand products are subject to regulation by several federal agencies, including the FDA, the FTC, the USDA, the CPSC and the EPA, as well as by various state and local agencies. If these laws and regulations were violated by our management, suppliers or distributors, we could be subject to regulatory enforcement action, public warning letters, product recalls, fines, penalties and sanctions, including injunctions against the future shipment and sale of products, restitution and disgorgement of profits, operating restrictions. In addition, other public and private actors are increasingly targeting supplement retailers and manufacturers with class action lawsuits for selling products that allegedly fail to adhere to the requirements of FDCA, DSHEA, and other federal and state statutes and requirements, including for failing to adhere to current GPMs, making false or misleading product statements, providing inaccurate ingredient identity and potency, and failing to control or disclose allergens, contaminants, residues and adulterants, as well as for state common and statutory laws regarding deceptive trade practices.

We could also be the target of claims relating to false or deceptive advertising in connection with the marketing and advertising of the products we sell, including under the auspices of the FTC, the consumer protection statutes of some states as well as certain non-government watchdog groups and class action law firms. In addition, the FDA has aggressively enforced its regulations with respect to structure/function claims (*e.g.,* "calcium builds strong bones"), nutrient content claims (*e.g.,* "high in antioxidants") and other claims that impermissibly suggest therapeutic benefits In addition, the number of private consumer class actions relating to false or deceptive advertising against cosmetic, food, beverage and nutritional supplement manufacturers has increased in recent years. These events could interrupt the marketing and sales of products in our stores, including our private label products, severely damage our brand reputation and public image, increase the cost of products in our stores, result in product recalls or litigation, and impede our ability to deliver merchandise in sufficient quantities or quality to our stores, which could result in a material adverse effect on our business, financial condition, results of operations and cash flows.

The global nutraceutical market is highly competitive, with many brands offering products that are similar to Nugevia. Failure to differentiate from competitors could limit market penetration and revenue potential.

The global nutraceutical market, valued at $458.55 billion in 2024, is highly competitive, with established players like Nestlé Health Science, Amway, and smaller niche brands vying for market share. Nugevia's reliance on resveratrol, despite JOTROL™'s potential for enhanced bioavailability, faces skepticism due to past studies questioning resveratrol's efficacy and may require additional clinical data. Convincing consumers and healthcare professionals of Nugevia's superior performance will require effective marketing. Failure to differentiate from competitors offering similar longevity or beauty-from-within products could limit market penetration and revenue potential.

The Company is dependent on certain proprietary supply-chain vulnerabilities with operational and supply chain risks.

The Company's dependence on proprietary technology like JOTROL™ and partnerships, such as with Aquanova for NovaSOL® Astaxanthin, introduces supply chain vulnerabilities. Disruptions in raw material availability, manufacturing delays, or quality control issues could hinder production timelines and product consistency. Scaling up manufacturing to meet demand while maintaining pharmaceutical-grade standards poses additional operational challenges. Any failure to deliver product in a timely manner could erode consumer trust and investor confidence.

If there are intellectual property disputes relating to the JOTROL™ technology, it could threaten Nugevia's market position

The Company's competitive edge hinges on its patented JOTROL™ technology. However, intellectual property disputes or challenges to JOTROL™ patent validity could threaten Nugevia's market position. Competitors may attempt to develop similar bioavailability-enhancing technologies, which circumvent the JOTROL™ patented technology. Furthermore, any adverse events linked to Nugevia's ingredients, even if rare, could result in product liability claims, damaging the brand's reputation and financial stability.

Risks Related to the Discovery, Development and Commercialization of Our Product Candidate

We are substantially dependent on the success of our lead product candidate, JOTROL™, which will be undergoing Phase II clinical trials, subject to FDA's review and agreement. If we are unable to complete development of, obtain approval for and commercialize JOTROL™ for one or more indications in a timely manner, our business will be harmed.

Our future success is dependent on our ability to timely and successfully complete clinical trials, obtain marketing approval for and successfully commercialize JOTROL™, our lead product candidate, through distribution deals with larger pharmaceutical companies. We are investing the majority of our efforts and financial resources in the research and development of JOTROL™. We have several pre-clinical trials and one completed Phase I clinical trial to evaluate the safety and tolerability of JOTROL™ in healthy volunteers. We are preparing for Phase II clinical trials. This will be our first clinical efficacy trial, and JOTROL™ has not previously been tested in humans with a specific disease although we can rely on data that exist for resveratrol. The reason for this is that once JOTROL™ is ingested the formulation excipients will be separated and it is only the active resveratrol that will be circulating in blood plasma. JOTROL™ will require additional clinical development, expansion of manufacturing capabilities, marketing approval from government regulators, substantial investment and significant marketing efforts to obtain established distributors before we can generate any revenues from product sales. We are not permitted to market or promote JOTROL™, or any other product candidate, before we receive marketing approval from the FDA and comparable foreign regulatory authorities, and we may never receive such marketing approvals.

The success of JOTROL™ will depend on several factors, including the following:

- the successful and timely completion of our clinical trials of JOTROL™;
- the initiation and successful patient enrollment and completion of additional clinical trials of JOTROL™ on a timely basis;
- maintaining and establishing relationships with CROs and clinical sites for the clinical development of JOTROL™;
- the frequency and severity of adverse events in clinical trials;
- demonstrating efficacy, safety and tolerability profiles that are satisfactory to the FDA, EMA or any comparable foreign regulatory authority for marketing approval;
- the timely receipt of any marketing approvals for JOTROL™ from applicable regulatory authorities;
- the extent of any required post-marketing approval commitments to applicable regulatory authorities;
- the maintenance of existing or the establishment of new supply arrangements with third-party drug product suppliers and manufacturers for clinical development and, if approved, commercialization of JOTROL™;
- obtaining and maintaining patent protection, trade secret protection and regulatory exclusivity, both in the United States and internationally;
- protecting our rights in our intellectual property portfolio;
- our ability to expand JOTROL™ into multiple indications;
- our ability to find partners handling all aspects of commercialization;
- the successful launch of commercial sales following any marketing approval;
- a continued acceptable safety profile following any marketing approval;
- the actual market-size, ability to identify patients and the demographics of patients eligible for our product candidates, which may be different than expected;
- commercial acceptance by patients, the medical community and third-party payors, particularly since the product candidates we develop may be novel; and
- our ability to compete with other therapies.

We do not have control over many of these factors, including certain aspects of clinical development and the regulatory submission process, potential threats to our intellectual property rights and the manufacturing, marketing, distribution and sales efforts of any future collaborator. If we are not successful with respect to one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize JOTROL™, which would materially harm our business. If we do not receive marketing approvals for JOTROL™, we may not be able to continue our operations.

In addition to JOTROL™, our prospects depend in part upon discovering, developing and commercializing product candidates in future programs, which may fail or suffer delays that adversely affect their commercial viability.

Our future operating results are dependent on our ability to successfully develop, obtain regulatory approval for and commercialize product candidates from our research programs, in addition to our lead product candidate, JOTROL™. However, research and development related to novel therapeutics is inherently risky. A product candidate can unexpectedly fail at any stage of preclinical and/or clinical development. The historical failure rate for product candidates is high due to risks relating to safety, efficacy, clinical execution, changing standards of medical care and other unpredictable variables. The results from preclinical testing or early clinical trials of a product candidate may not be predictive of the results that will be obtained in later stage clinical trials of the product candidate.

The success of other product candidates we may develop will depend on many factors, including the following:

- generating sufficient data to support the initiation or continuation of clinical trials;
- obtaining regulatory permission to initiate clinical trials;
- contracting with the necessary parties to conduct clinical trials;
- successful enrollment of patients in, and the completion of, clinical trials on a timely basis;
- the timely manufacture of sufficient quantities of a product candidate for use in clinical trials; and
- adverse events in clinical trials.

Even if we successfully discover and advance any other product candidates into clinical development, their success will be subject to all of the clinical, regulatory and commercial risks described elsewhere in this "Risk Factors" section. Accordingly, we cannot assure you that we will ever be able to discover, develop, obtain regulatory approval of, commercialize or generate significant revenue from any product candidates.

Clinical drug development involves a lengthy and expensive process with an uncertain outcome. The clinical trials of our product candidate may not demonstrate safety and efficacy to the satisfaction of the FDA, EMA or other comparable foreign regulatory authorities or otherwise produce positive results and the results of preclinical studies and early clinical trials may not be predictive of future results. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

Our lead product candidate, JOTROL™, is entering into Phase II clinical trials after completing a Phase I clinical trial in March 2021 and its risk of failure is high. It is impossible to predict when or if JOTROL™ or any product candidate that we develop will prove effective or safe in humans or will receive marketing approval. Before obtaining marketing approval from the FDA, EMA or other comparable foreign regulatory authorities for the sale of our product candidates, we must complete preclinical development and extensive clinical trials to demonstrate with substantial evidence the safety and efficacy of such product candidates.

Clinical testing is expensive, difficult to design and implement, can take many years to complete and its ultimate outcome is uncertain. We cannot guarantee that any of our clinical trials will be conducted as planned or completed on schedule, or at all. Clinical trials can fail at any stage of testing and failure may result from a multitude of factors, including, among other things, flaws in study design, dose selection issues, placebo effects, patient enrollment criteria and failure to demonstrate favorable safety or efficacy traits. The outcome of preclinical studies and early-stage clinical trials may not be predictive of the success of later clinical trials. For example, our product candidates may fail to show the desired safety and efficacy in clinical development despite positive results in preclinical studies or having successfully advanced through initial clinical trials. We may also discover that the half-life of our product candidates renders them unsuitable for the therapeutic applications we have chosen. As a result, we cannot assure you that any clinical trials that we conduct will demonstrate consistent or adequate efficacy and safety that is necessary to support marketing approval.

Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in preclinical testing and earlier-stage clinical trials, and we cannot be certain that we will not face similar setbacks. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their drugs. Furthermore, the failure of any of our product candidates to demonstrate safety and efficacy in any clinical trial could negatively impact the perception of our other product candidates and/or cause the FDA or other regulatory authorities to require additional testing before approving any of our product candidates.

We have experienced delays in completing our clinical trial research and may experience additional delays in initiating or completing additional clinical trials. We may also experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent receipt of marketing approval or our ability to commercialize our product candidates, including:

- receipt of feedback from regulatory authorities that requires us to modify the design of our clinical trials;
- clinical trial observations or results that require us to modify the design of our clinical trials;
- negative or inconclusive clinical trial results that may require us to conduct additional clinical trials or abandon certain drug development programs;
- obtaining approval from one or more institutional review boards (IRB);
- the number of patients required for clinical trials being larger than anticipated, enrollment in these clinical trials being slower than anticipated or participants dropping out of these clinical trials at a higher rate than anticipated;
- any failure or delay in reaching an agreement with CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- the suspension or termination of our clinical trials for various reasons, including non-compliance with regulatory requirements or a finding that our product candidates have undesirable side effects or other unexpected characteristics or risks;
- changes to clinical trial protocol;
- clinical sites deviating from trial protocol or dropping out of a trial;
- the cost of clinical trials of our product candidates being greater than anticipated;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates being insufficient or inadequate;
- subjects experiencing severe or unexpected drug-related adverse selection of clinical end points that require prolonged periods of clinical observation or analysis of the resulting data;
- a facility manufacturing our product candidates or any of their components being ordered by the FDA or comparable foreign regulatory authorities to temporarily or permanently shut down due to violations of current good manufacturing practice (cGMPs), regulations or other applicable requirements, or infections or cross-contaminations of product candidates in the manufacturing process;
- any changes to our manufacturing process that may be 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 (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; and
- regulators revising the requirements for approving our product candidates.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing in a timely manner, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may incur unplanned costs, be delayed in seeking and obtaining marketing approval, if we receive such approval at all, receive more limited or restrictive marketing approval, be subject to additional post-marketing testing requirements or have the drug removed from the market after obtaining marketing approval.

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

If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. Moreover, our product development costs will also increase if we experience delays in preclinical studies or clinical trials or in obtaining marketing approvals. We do not know whether any of our preclinical studies or clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. We may also determine to change the design or protocol of one or more of our clinical trials, which could result in increased costs and expenses and/or delays. Any delays in completing our clinical trials will increase our costs, slow down our product candidates development and approval process and jeopardize our ability to commence product sales and generate revenues.

In addition, many of the factors that cause, or lead to, termination or suspension of, or a delay in the commencement or completion of, clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate. Any delays to our clinical trials that occur as a result could shorten any period during which we may have the exclusive right to commercialize our product candidates and our competitors may be able to bring products to market before we do, and the commercial viability of our product candidates could be significantly reduced. Any of these occurrences may harm our business, financial condition and prospects significantly.

We have entered into Service Agreements with the Asian Partners with respect to services to be provided by the Asian Partners to us in Asia for the clinical development of JOTROL™ in the Southeast Asian territory immediately following the completion of the initial public offering; the shares issued by us in advance for the specific services could have a material negative impact on our business, financial condition and operating results in case the Asian Partners' will not perform the services per the agreements.

We have entered into service agreements for development of JOTROL™ in the Southeast Asian territory. The agreements are with three contracted companies, namely, Longevity Technology Group Limited, Regis Healthcare Group Limited, and Optimized Wellness Limited (collectively, the "Asian Partners") that will handle CMC, regulatory affairs and clinical trial management, respectively. As consideration for these services, on June 3, 2024, the Company issued 1,162,500 shares of common stock ("Issued Shares") to each of the Asian Partners with a fair market value of $1.33 per share (3,487,500 shares in aggregate, with an aggregate fair market value of $4,638,375), as pre-payment for three years of services. The Issued Shares are based on certain specified and agreed upon performances to be executed by each of the Asian Partners. However, if the Asian Partners fail to perform, or underperform, under their respective service agreements with the Company, their Issued Shares will still be issued and outstanding and registered for sale. If the Company tries to recover some or all of these Issued Shares, or the cash equivalent if the Issued Shares have been sold by the Asian Partners, based on any type of non-performance of the agreed services, there is no assurance that the Company's attempt to recover will be successful. Accordingly, the Company may be in a position where it issued shares to the Asian Partners under the service agreements even if the Asian Partners failed to perform, or underperform, without any ability to have the shares forfeited to the Company. The requirement by the Company to issue the Issued Shares under the service agreements, without any specific protection against non-performance, could have a material negative impact on our business, financial condition and operating results.

We entered into a Strategic Service Agreement with DOMINANT TREASURE HEALTH COMPANY LIMITED with respect to strategic services in Asia, the fees paid by the Company pursuant to which, are non-refundable and not tied to any milestones or performance, and the foregoing nature of such fees, could have a material negative impact on our business, financial condition and operating results.

The Company entered into a Strategic Service Agreement with DOMINANT TREASURE HEALTH COMPANY LIMITED ("Strategic Services Partner") to provide services to advance the business objectives of the Company in China and Southeast Asia. As consideration for these services, the Company paid $2,300,000 (the "Fees"). The Fees are non-refundable and are not based on performance by the Strategic Services Partner or milestones that must be reached by the Strategic Services Partner. Accordingly, if the Strategic Services Partner fails to perform, or underperforms, under the Strategic Service Agreement, the Company would still be obligated to pay the Fees and would not be entitled for any return of the Fees. Accordingly, the Company is without any ability to get its money back if the Strategic Services Partner fails to perform, or underperforms. The requirement by the Company to pay the Fees under the Strategic Service Agreement, regardless of any milestones or performance by Strategic Services Partner, and the non-refundable nature of such Fees could have a material negative impact on our business, financial condition and operating results.

Our product candidates may cause serious adverse events, toxicities or other undesirable side effects when used alone or in combination with approved products or investigational new drugs that may result in a safety or risk profile that could prevent regulatory approval, prevent market acceptance, limit their commercial potential or result in significant negative consequences.

We are developing a novel biologically active small molecule for neurological disorders. As a result, there is uncertainty as to the safety profile of the product candidates we are developing. In addition, our product candidates could be used in combination with certain other therapies which may have undesirable side effects. If our product candidates are associated with undesirable side effects or have unexpected characteristics in preclinical studies or clinical trials when used alone or in combination with other approved products or investigational new drugs we may need to interrupt, delay or abandon their development or limit development to more narrow 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. Treatment-related side effects could also affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. Any of these occurrences may prevent us from achieving or maintaining market acceptance of the affected product candidates and may harm our business, financial condition and prospects significantly.

Patients in our ongoing and planned clinical trials may in the future suffer other serious adverse events or other side effects not observed in our preclinical studies or previous clinical trials. JOTROL™ or other product candidates may be used in pediatric populations for which safety concerns may be particularly scrutinized by regulatory agencies. In addition, if JOTROL™ is studied in combination with other therapies, it may exacerbate adverse events associated with the therapy. Patients treated with JOTROL™ or our other product candidates may also be undergoing other therapies which can cause side effects or adverse events that are unrelated to our product candidates but may still impact the success of our clinical trials. The inclusion of critically ill patients in our clinical trials may result in deaths or other adverse medical events due to other therapies or medications that such patients may be using or due to the gravity of such patients' illnesses. For example, it is expected that some of the patients enrolled in our JOTROL™ clinical trial will die or experience major clinical events either during the course of our clinical trials or after participating in such trials.

If further serious adverse events or other side effects are observed in any of our current or future clinical trials, we may have difficulty recruiting patients to the clinical trials, patients may drop out of our trials, or we may be required to abandon the trials or our development efforts of that product candidate altogether. We, the FDA, EMA, other comparable regulatory authorities or an IRB may suspend clinical trials of a product candidate at any time for various reasons, including a belief that subjects in such trials are being exposed to unacceptable health risks or adverse side effects. Some potential therapeutics developed in the biotechnology industry that initially showed therapeutic promise in early-stage trials have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude the product candidate from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance due to its tolerability versus other therapies. Any of these developments could materially harm our business, financial condition and prospects. Further, if any of our product candidates obtains marketing approval, toxicities associated with such product candidates previously not seen during clinical testing may also develop after such approval and lead to a requirement to conduct additional clinical safety trials, additional contraindications, warnings and precautions being added to the drug label, significant restrictions on the use of the product or the withdrawal of the product from the market. We cannot predict whether our product candidates will cause toxicities in humans that would preclude or lead to the revocation of regulatory approval based on preclinical studies or early-stage clinical trials.

The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and the results of our clinical trials may not satisfy the requirements of the FDA, EMA or other comparable foreign regulatory authorities.

We will be required to demonstrate with substantial evidence through rigorous, well-designed, and well-controlled clinical trials that our product candidates are safe and effective for use in a diverse population before we can seek marketing approvals to commercialize any such product candidates. Success in preclinical studies and early-stage clinical trials does not mean that future clinical trials will be successful. For instance, we do not know whether JOTROL™ will perform in current or future clinical trials as JOTROL™ has performed in preclinical studies or earlier clinical trials. Product candidates in clinical trials may fail to demonstrate sufficient safety and efficacy to the satisfaction of the FDA, EMA and other comparable foreign regulatory authorities despite having progressed through preclinical studies. Regulatory authorities may also limit the scope of later-stage trials until we have demonstrated satisfactory safety, which could delay regulatory approval, limit the size of the patient population to which we may market our product candidates, or prevent regulatory approval.

In some instances, there can be significant variability in safety and efficacy results between different clinical trials of the same product candidates due to numerous factors, including changes in trial protocols, differences in size and type of the patient populations, differences in and adherence to the dose and dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. Patients treated with our product candidates may also be undergoing other therapies and may be using other approved products or investigational new drugs, which can cause side effects or adverse events that are unrelated to our product candidates. As a result, assessments of efficacy can vary widely for a particular patient, and from patient to patient and site to site within a clinical trial. This subjectivity can increase the uncertainty of, and adversely impact, our clinical trial outcomes.

We do not know whether any clinical trials we may conduct will demonstrate consistent or adequate efficacy and safety sufficient to obtain approval to market any of our product candidates.

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

We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials to such trial's conclusion as required by the FDA, EMA or other comparable foreign regulatory authorities. Patient enrollment is a significant factor in the timing of clinical trials. Our ability to enroll eligible patients may be limited or may result in slower enrollment than we anticipate.

We may encounter difficulties in identifying and enrolling subjects with a stage of disease appropriate for our planned clinical trials and monitoring such subjects adequately during and after treatment. 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. In addition, the process of finding and diagnosing subjects may prove costly. Further, the treating physicians in our clinical trials may also use their medical discretion in advising patients enrolled in our clinical trials to withdraw from our studies to try alternative therapies.

We expect patient enrollment to be affected because our competitors have ongoing clinical trials for programs that are under development for the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials could instead enroll in clinical trials of our competitors' programs. Patient enrollment for our current or any future clinical trials may be affected by other factors, including:

- size and nature of the patient population;
- perceived risks and benefits of novel, unproven approaches;
- severity of the disease under investigation;
- availability and efficacy of approved drugs for the disease under investigation;
- patient eligibility criteria for the trial in question as defined in the protocol;
- perceived risks and benefits of the product candidates under study;
- clinicians' and patients' perceptions as to the potential advantages of the product candidates being studied in relation to other available therapies, including any new products that may be approved or other product candidates being investigated for the indications we are investigating;
- patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment;
- the activities of KOLs and patient advocacy groups;
- proximity and availability of clinical trial sites for prospective patients; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion or, because they may have an advanced disease, will not survive the full terms of the clinical trials.

Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates and jeopardize our ability to obtain marketing approval for the sale of our product candidates. Furthermore, even if we are able to enroll a sufficient number of patients for our clinical trials, we may have difficulty maintaining participation in our clinical trials through the treatment and any follow-up periods.

We have limited resources and are currently focusing the majority of our efforts on developing JOTROL™ for particular indications. As a result, we may fail to capitalize on other indications or product candidates that may ultimately have proven to be more profitable.

We are currently focusing the majority of our resources and efforts on developing JOTROL™. As a result, because we have limited resources, we may forgo or delay the pursuit of opportunities for other indications or with other product candidates that may have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial drugs or profitable market opportunities. Our spending on current and future research and development activities for JOTROL™ may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target markets for JOTROL™, we may relinquish valuable rights to our product candidates or programs through collaboration, licensing or other strategic arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidates or program.

We face significant competition and if our competitors develop and market technologies or products more rapidly than we do or that are more effective, safer or less expensive than the products we develop, our commercial opportunities will be negatively impacted.

The biotechnology and biopharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary and novel products and product candidates. Our competitors have developed, are developing or may develop products, product candidates and processes competitive with our product candidate. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. We believe that a significant number of products are currently under development, and may become commercially available in the future, for the treatment of conditions for which we may attempt to develop product candidates.

We have competitors both in the United States and internationally, including major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies, emerging and start-up companies, universities and other research institutions. We also compete with other organizations to recruit management, scientists and clinical development personnel, which could negatively affect our level of expertise and our ability to execute our business plan. We will also face competition in establishing clinical trial sites, enrolling subjects for clinical trials and in identifying and in-licensing new product candidates.

We expect to face competition from existing products and products in development for each of our programs. Many of these current and potential competitors have significantly greater financial, manufacturing, marketing, drug development, technical and human resources and commercial expertise than we do. Large pharmaceutical and biotechnology companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients and manufacturing biotechnology 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 collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical and biotechnology companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make the product candidates that we develop obsolete. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies, as well as in acquiring technologies complementary to, or necessary for, our programs. As a result of all these factors, our competitors may succeed in obtaining approval from the FDA, EMA or other comparable foreign regulatory authorities or in discovering, developing and commercializing products in our field before we do.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer side effects, are more convenient, have a broader label, are marketed more effectively, are more widely reimbursed or are less expensive than any products that we may develop. Our competitors also may obtain marketing approval from the FDA, EMA or other comparable foreign regulatory authorities 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. Even if the product candidates we develop achieve marketing approval, they may be priced at a significant premium over competitive products if any have been approved by then, resulting in reduced competitiveness. Technological advances or products developed by our competitors may render our technologies or product candidates obsolete, less competitive or not economical. If we are unable to compete effectively, our opportunity to generate revenue from the sale of our products we may develop, if approved, could be adversely affected.

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

From time to time, we may publicly disclose preliminary, interim or topline data from our clinical trials, such as the interim data from our Phase I clinical trial of JOTROL™. These interim updates 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 topline results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remains subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available. In addition, we may report interim analyses of only certain endpoints rather than all endpoints. 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 changes between interim data and final data could significantly harm our business and prospects. Further, additional disclosure of interim data by us or by our competitors in the future could result in volatility in the price of our securities.

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 candidates or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. If the preliminary or topline data that we report differ from late, final or actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, JOTROL™ or any other product candidates may be harmed, which could harm our business, financial condition, results of operations and prospects.

We may not be successful in our efforts to develop our proprietary drug delivery platform, JOTROL™, to build a pipeline of indications.

A key element of our strategy is to leverage our proprietary drug delivery platform and our ability to expand our pipeline of indications. We are leveraging our proprietary drug delivery platform and capabilities to create precision medicines for neurological disorders with high levels of unmet need. Although our research and development efforts to date have resulted in a pipeline product candidate JOTROL™, this product candidate may not be safe and effective. In addition, although we expect that our proprietary drug delivery platform will allow us to develop a diverse pipeline across multiple therapeutic areas, we may not prove to be successful at doing so. Furthermore, we may also find that the uses of our proprietary drug delivery platform are limited because alternative uses of our therapeutics prove not to be safe or effective. Even if we are successful in building our pipeline, JOTROL™ may not be suitable for clinical development, including as a result of being shown to have harmful side effects or other characteristics that indicate that they are unlikely to receive marketing approval or achieve market acceptance. Further, because our product candidate and development programs are based on our proprietary drug delivery platform, adverse developments with respect to one of our programs may have a significant adverse impact on the actual or perceived likelihood of success and value of our other programs.

In addition, the biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies. Our future success will depend in part on our ability to maintain a competitive position with our approach. If we fail to stay at the forefront of technological change in utilizing our proprietary drug delivery platform to create and develop product candidates, we may be unable to compete effectively. Our competitors may render our approach obsolete or limit the commercial value of our product candidates, by advances in existing technological approaches or the development of new or different approaches, potentially eliminating the advantages in our drug delivery process that we believe we derive from our research approach and proprietary technologies. By contrast, adverse developments with respect to other companies that attempt to use a similar approach to our approach may adversely impact the actual or perceived value of our proprietary drug delivery platform and potential of our product candidates. If any of these events occur, we may be forced to abandon our development efforts for a program or programs, which would have a material adverse effect on our business and could potentially cause us to cease operations.

We may develop JOTROL™ and potentially other programs in combination with other therapies, which would expose us to additional risks.

We may develop JOTROL™ and potentially other programs, in combination with one or more currently approved therapies or therapies in development. Patients may not be able to tolerate JOTROL™ or any other product candidates in combination with other therapies or dosing of JOTROL™ in combination with other therapies may have unexpected consequences. Even if any of our product candidates were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA, EMA or other comparable foreign regulatory authorities could revoke approval of the therapy used in combination with any of our product candidates, or safety, efficacy, manufacturing or supply issues could arise with these existing therapies. In addition, it is possible that existing therapies with which our product candidates are approved for use could themselves fall out of favor. This could result in the need to identify other combination therapies for our product candidates or our own products being removed from the market or being less successful commercially.

We may also evaluate our product candidates in combination with one or more other therapies that have not yet been approved for marketing by the FDA, EMA or comparable foreign regulatory authorities. We will not be able to market and sell any product candidates in combination with any such unapproved therapies that do not ultimately obtain marketing approval.

If the FDA, EMA or other comparable foreign regulatory authorities do not approve or revoke their approval of these other therapies, or if safety, efficacy, commercial adoption, manufacturing or supply issues arise with the therapies we may choose to evaluate in combination with JOTROL™ or any other product candidate, we may be unable to obtain approval of or successfully market any one or all of the product candidates we develop.

Additionally, if the third-party providers of therapies or therapies in development used in combination with our product candidates are unable to produce sufficient quantities for clinical trials or for commercialization of our product candidate, or if the cost of combination therapies are prohibitive, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

The manufacture of drugs is complex, and our third-party manufacturers may encounter difficulties in production. If any of our third-party manufacturers encounter such difficulties, our ability to provide adequate supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or prevented.

Manufacturing drugs, especially in large quantities, is complex and may require the use of innovative technologies. Each lot of an approved drug product must undergo thorough testing for identity, strength, quality, purity and potency. Manufacturing drugs requires facilities specifically designed for and validated for this purpose, as well as sophisticated quality assurance and quality control procedures. Slight deviations anywhere in the manufacturing process, including filling, labeling, packaging, storage and shipping and quality control and testing, may result in lot failures or product recalls. When changes are made to the manufacturing process, we may be required to provide preclinical and clinical data showing the comparable quality and efficacy of the products before and after such changes. If our third-party manufacturers are unable to produce sufficient quantities for clinical trials or for commercialization as a result of these challenges, or otherwise, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

Our product candidates may not achieve adequate market acceptance among physicians, patients, healthcare payors and others in the medical community necessary for commercial success.

Even if our product candidates receive regulatory approval, they may not gain adequate market acceptance among physicians, patients, third-party payors and others in the medical community. The degree of market acceptance of any of our approved product candidates will depend on a number of factors, including:

- the efficacy and safety profile as demonstrated in clinical trials compared to alternative treatments;
- the timing of market introduction of the product candidates as well as competitive products;

- the clinical indications for which a product candidate is approved;
- restrictions on the use of product candidates in the labeling approved by regulatory authorities, such as boxed warnings or contraindications in labeling, or a risk evaluation and mitigation strategy, if any, which may not be required of alternative treatments and competitor products;
- the potential and perceived advantages of our product candidates over alternative treatments;
- the cost of treatment in relation to alternative treatments;
- the availability of an approved product candidate for use as a combination therapy;
- relative convenience and ease of administration;
- the willingness of the target patient population or their caregivers to try new therapies and of physicians to prescribe these therapies;
- the availability of coverage and adequate reimbursement by third-party payors, including government authorities;
- patients' willingness to pay for these therapies in the absence of such coverage and adequate reimbursement;
- the effectiveness of sales and marketing efforts;
- support from KOLs and patient advocacy groups;
- unfavorable publicity relating to our product candidates; and
- the approval of other new therapies for the same indications.

If any of our product candidates are approved but do not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors and patients, we may not generate or derive sufficient revenue from that product candidate and our financial results could be negatively impacted.

The patient population suffering from MPS I and MELAS syndrome is small and has not been established with precision. If the actual number of patients is smaller than we estimate, our potential revenue and ability to achieve profitability may be adversely affected. Because the target patient populations of our programs are small and the addressable patient population may be even smaller, we must be able to successfully identify patients and capture a significant market share to achieve profitability and growth.

MPS I and MELAS are rare, genetic neuromuscular disorders. We estimate that MPS I occurs in approximately one in every 100,000 live births and that the patient population is approximately 2,000 to 3,000 in the United States and approximately 4,000 in Europe. MELAS is one of the most common mitochondrial diseases, with an estimated incidence of 1 in 4000. We estimate that there are approximately 80,000 patients with MELAS in the United States.

Our estimates of the size of these patient populations are based on published studies. Given the small number of patients who have the diseases that we are targeting, it is critical to our ability to grow and become profitable that we continue to successfully identify patients with these rare diseases. The effort to identify patients with diseases we seek to treat is in early stages, and we cannot accurately predict the number of patients for whom treatment might be possible. Various factors may decrease the market size of our product and product candidates, including the severity of the disease, patient demographics and the response of patients' immune systems to our product candidates. If the results of these studies or our analysis of them do not accurately reflect the relevant patient population, our assessment of the market may be inaccurate, making it difficult or impossible for us to meet our revenue goals, or to obtain and maintain profitability.

Additionally, the potentially addressable patient population for each of our product candidates may be limited or may not be amenable to treatment with our product candidates, and new patients may become increasingly difficult to identify or gain access to, which would adversely affect our results of operations and our business. Further, even if we obtain significant market share for our product candidates, because the potential target populations are very small, we may never achieve profitability despite obtaining such significant market share.

Any product candidates we develop may become subject to unfavorable third-party coverage and reimbursement practices, as well as pricing regulations.

The availability and extent of coverage and adequate reimbursement by third-party payors including government health administration authorities, private health coverage insurers, managed care organizations and other third-party payors is essential for most patients to be able to afford expensive treatments. The initial targets in our pipeline are indications with small patient populations. For product candidates that are designed to treat smaller patient populations to be commercially viable, the reimbursement for such product candidates must be higher, on a relative basis, to account for the lack of volume. Accordingly, we will need to implement a coverage and reimbursement strategy for any approved product candidate that accounts for the smaller potential market size.

Sales of any of our product candidates that receive marketing approval will depend substantially, both in the United States and internationally, on the extent to which the costs of such product candidates will be covered and reimbursed by third-party payors. If reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize an adequate return on our investment. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not successfully commercialize any product candidate for which we obtain marketing approval.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. In the United States, for example, principal decisions about reimbursement for new products are typically made by the Centers for Medicare & Medicaid Services (CMS), an agency within the U.S. Department of Health and Human Services (HHS). CMS decides whether and to what extent a new product will be covered and reimbursed under Medicare, and private third-party payors often follow CMS's decisions regarding coverage and reimbursement to a substantial degree. However, one third-party payor's determination to provide coverage for a product candidate does not assure that other payors will also provide coverage for the product candidate or at the same level of reimbursement. As a result, the coverage determination process is often time-consuming and costly. This process will require us to provide scientific and clinical support for the use of our products to each third-party payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Further, such payors are increasingly challenging the price, examining the medical necessity and reviewing the cost effectiveness of medical product candidates. There may be especially significant delays in obtaining coverage and reimbursement for newly approved drugs. Third-party payors may limit coverage to specific product candidates on an approved list, known as a formulary, which might not include all FDA-approved drugs for a particular indication. We may need to conduct expensive pharmaco-economic studies to demonstrate the medical necessity and cost effectiveness of our products. Nonetheless, our product candidates may not be considered medically necessary or cost effective. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be.

Outside the United States, the commercialization of therapeutics is generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost containment initiatives in Europe, Canada and other countries has and will continue to put pressure on the pricing and usage of therapeutics such as our product candidates. In many countries, particularly the countries of the European Union (EU), medical product prices are subject to varying price control mechanisms as part of national health systems. In these countries, pricing negotiations with governmental authorities can take considerable time after a product receives marketing approval. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. In general, product prices under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for products but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. 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.

If we are unable to establish or sustain coverage and adequate reimbursement for any product candidates from third-party payors, the adoption of those products and sales revenue will be adversely affected, which, in turn, could adversely affect the ability to market or sell those product candidates, if approved. Coverage policies and third-party payor reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Our business entails a significant risk of product liability and if we are unable to obtain sufficient insurance coverage, such inability could have an adverse effect on our business and financial condition. If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our products.

Our business exposes us to significant product liability risks inherent in the development, testing, manufacturing and marketing of therapeutic treatments. We currently have product liability insurance that we believe is appropriate for our stage of development and may need to obtain higher levels prior to marketing any of our product candidates, if approved. Any insurance we have or may obtain may not provide sufficient coverage against potential liabilities. Furthermore, clinical trial and product liability insurance are becoming increasingly expensive. As a result, we may be unable to obtain sufficient insurance at a reasonable cost to protect us against losses caused by product liability claims that could have an adverse effect on our business and financial condition. Also, our insurance policies may 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 amount awarded by a court or negotiated in a settlement that exceeds our coverage limitations or that is not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

We may be sued if any of our product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing, or sale post-approval. 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, negligence, strict liability, or a breach of warranties. Claims could also be asserted under state consumer protection laws. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit testing and commercialization of our products. Even successful defense would require significant financial and management resources.

Regardless of the merits or eventual outcome, liability claims may result in:

- delays in the development of our product candidates;
- FDA, EMA or other regulatory authority investigation of the safety and effectiveness of our products, our manufacturing processes and facilities or our marketing programs;
- decreased or interrupted demand for our products;
- injury to our reputation;
- withdrawal of clinical trial participants and inability to continue clinical trials;
- initiation of investigations by regulators;
- 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;
- loss of revenue;
- exhaustion of any available insurance and our capital resources; and
- the inability to commercialize any products.

Risks Related to Regulatory Approval and Other Legal Compliance Matters

The regulatory approval processes of the FDA, EMA and other comparable foreign regulatory authorities are lengthy, time consuming and inherently unpredictable. If we are ultimately unable to obtain regulatory approval of our product candidates, we will be unable to generate product revenue and our business will be substantially harmed.

We currently have no products authorized for commercial distribution in either the United States, Europe or any other country. All of our product candidates require regulatory clearance or approval. We cannot begin marketing and selling product candidates until we obtain applicable authorizations from the applicable regulatory agencies.

Our product candidates are and will continue to be subject to extensive governmental regulations relating to, among other things, research, testing, development, manufacturing, safety, efficacy, approval, recordkeeping, reporting, labeling, storage, packaging, advertising and promotion, pricing, marketing and distribution of drugs. Rigorous preclinical testing and clinical trials and an extensive regulatory approval process must be successfully completed in the United States and in many foreign jurisdictions before a new drug can be approved for marketing. We are not permitted to market JOTROL™ or any other product candidates as medicines in the United States or other countries until we receive approval of an NDA from the FDA. Prior to submitting any NDA to the FDA for approval of JOTROL™ we will need to have completed our pre-clinical studies and clinical trials and demonstrate that JOTROL™ meets all applicable standards of identity, strength, quality, and purity throughout their expiration date. Successfully completing any clinical program and obtaining approval of an NDA is a complex, lengthy, expensive, and uncertain process, and the FDA (or other country medicines regulatory body) may delay, limit, or deny approval of product candidates for many reasons. Obtaining approval by the FDA, EMA and other comparable foreign regulatory authorities is costly, unpredictable, typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the type, complexity and novelty of the product candidates involved. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions, which may cause delays in the approval or the decision not to approve an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical, clinical or other data. Even if we eventually complete clinical testing and receive approval for our product candidates, the FDA, EMA and other comparable foreign regulatory authorities may approve our product candidates for a more limited indication or a narrower patient population than we originally requested or may impose other prescribing limitations or warnings that limit the product's commercial potential. We have not submitted for, or obtained, regulatory approval for any product candidate, and it is possible that none of our product candidates will ever obtain regulatory approval. Further, development of our product candidates and/or regulatory approval may be delayed for reasons beyond our control. We cannot provide any assurance that any product candidates we may develop will progress through required clinical testing and obtain the regulatory approvals necessary for us to begin selling them.

We have not conducted, managed or completed large-scale or pivotal clinical trials nor managed the regulatory approval process with the FDA or any other regulatory authority. As a result, applications for our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA, EMA or other comparable foreign regulatory authorities may disagree with the design, size, conduct, implementation or results of our clinical trials;
- the FDA, EMA or other comparable foreign regulatory authorities may determine that our product candidates are not safe and effective, are only moderately effective or have undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use;
- the population studied in the clinical trial may not be sufficiently broad or representative to assure efficacy and safety in the full population for which we seek approval;
- the FDA, EMA or other comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- we may be unable to demonstrate to the FDA, EMA or other comparable foreign regulatory authorities that our product candidate's risk-benefit ratio for its proposed indication is acceptable;
- the FDA, EMA or other comparable foreign regulatory authorities may conclude that our API or finished products do not meet all applicable standards of identity, strength, quality, and purity
- the FDA, EMA or other comparable foreign regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA, EMA or other comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process, as well as the unpredictability of the results of clinical trials, may result in our failing to obtain regulatory approval to market any of our product candidates, which would significantly harm our business, results of operations and prospects. Any delay or failure in seeking or obtaining required approvals would have a material and adverse effect on our ability to generate revenue from any particular product candidates we are developing and for which we are seeking approval. Furthermore, any regulatory approval to market a drug may be subject to significant limitations on the approved uses or indications for which we may market, promote and advertise the drug or the labeling or other restrictions. In addition, the FDA has the authority to require a REMS plan as part of approving an NDA, or after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug. These requirements or restrictions might include limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria and requiring treated patients to enroll in a registry. These limitations and restrictions may significantly limit the size of the market for the drug and affect reimbursement by third-party payors.

We are also subject to numerous foreign regulatory requirements governing, among other things, the conduct of clinical trials, manufacturing and marketing authorization, pricing and third-party reimbursement. The foreign regulatory approval process varies among countries, and generally includes all of the risks associated with FDA and EMA approval described above as well as risks attributable to the satisfaction of local regulations in foreign jurisdictions. Moreover, the time required to obtain approval may differ from that required to obtain FDA approval.

The FDA, EMA and other comparable foreign regulatory authorities may not accept data from trials conducted in locations outside of their jurisdiction.

Our clinical trials are planned for undertaking in the United States. We may choose to conduct additional clinical trials internationally. The acceptance of study data by the FDA, EMA or other comparable foreign regulatory authorities from clinical trials conducted outside of their respective jurisdictions may be subject to certain conditions. In cases where data from United States clinical trials are intended to serve as the basis for marketing approval in the foreign countries outside the United States, the standards for clinical trials and approval may be different. There can be no assurance that any United States or foreign regulatory authority would accept data from trials conducted outside of its applicable jurisdiction. If the FDA, EMA or any applicable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan, and which may result in our product candidates not receiving approval or clearance for commercialization in the applicable jurisdiction.

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

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion and reimbursement of the product candidate in those countries. However, a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the United States, including additional preclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

Obtaining foreign regulatory approvals and establishing and maintaining compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we or any future collaborator fail to comply with the regulatory requirements in international markets or fail to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our potential product candidates will be harmed.

The regulatory approval processes for any product candidates that target rare diseases, including MPS I and MELAS are uncertain.

Due to the lack of precedent, broad discretion of regulatory authorities, and a multitude of unique factors that impact the regulatory approval process, the likelihood of the approval of any product candidates that target rare diseases, such as MPS I and MELAS is uncertain, and we may not be able to anticipate, prepare for or satisfy requests or requirements from regulatory authorities, including completing and submitting planned Investigational New Drug (IND) and new drug applications (NDA) for our product candidates, in a timely manner, or at all. For example, MPS I is a rare disease for which there is only one FDA approved therapeutics. In addition, no therapies are currently approved for MELAS in the United States or the EU. Further, the FDA may determine, after evaluation of our data and analyses, that such data and analyses do not support an NDA submission, filing or approval. Due to this lack of predictability, we may not have the resources necessary to meet regulatory requirements and successfully complete a potentially protracted, expensive and wide-ranging approval process for commercialization of product candidates for rare diseases.

Even if our product candidates receive regulatory approval, they will be subject to significant post-marketing regulatory requirements and oversight.

Any regulatory approvals that we may receive for our product candidates will likely require on-going post-marketing surveillance to monitor the safety and efficacy of any such approved product. Any regulatory approval may also contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, and may include burdensome post-approval study or risk management requirements and regulatory inspection. For example, the FDA may require a REMS in order to approve our product candidates, which could entail requirements for a medication guide, physician training and 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 foreign regulatory authorities approve our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates 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 on-going compliance with cGMP regulations and GCPs for any clinical trials that we conduct post-approval. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA and other regulatory authorities for compliance with cGMP regulations and standards. If we or a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facilities where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. In addition, failure to comply with FDA and other comparable foreign regulatory requirements may subject our company to administrative or judicially imposed sanctions, including:

- restrictions on the products, manufacturers or manufacturing process;
- warning or untitled letters;
- civil and criminal penalties;
- injunctions;
- suspension or withdrawal of regulatory approvals, or debarment;
- product seizures, detentions, import refusals, or import alerts;
- voluntary or mandatory product recalls and publicity requirements;
- total or partial suspension of production; and
- imposition of restrictions on operations, including costly new manufacturing requirements.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates, if approved, and generate revenue. Furthermore, non-compliance by us or any future collaborator with regulatory requirements, including safety monitoring and with requirements related to the development of products for the pediatric population can also result in significant financial penalties.

We may not be able to obtain orphan drug designation or obtain or maintain orphan drug exclusivity for our product candidates and, even if we do, that exclusivity may not prevent the FDA, EMA or other comparable foreign regulatory authorities, from approving competing products.

Regulatory authorities in some jurisdictions, including the United States and the EU, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. However, there can be no assurances that we will be able to obtain orphan designations for any of our product candidates.

In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax credits for qualified clinical testing expenses, and user-fee waivers. In addition, if a product that has orphan drug designation subsequently receives the first FDA approval for the indication for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not subsequently approve another application, including a full NDA, to market the same drug for the same indication or use within the such rare disease indication for seven years, except in limited circumstances.

We intend to seek orphan drug designation for JOTROL™ in MPS I and may seek orphan drug designation for other product candidates. Even if we obtain orphan drug designation for a product candidate, we may not be able to obtain or maintain orphan drug exclusivity for that product candidate, nor can we guarantee that any orphan-drug-designated product candidate will obtain regulatory approval from FDA. Even if we obtain FDA approval, we may not be the first to obtain marketing approval of any product candidate for which we have obtained orphan drug designation for the same indication or use due to the uncertainties associated with developing pharmaceutical products. In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to ensure that we will be able to manufacture sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because drugs with different active moieties may be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve the same drug with the same active moiety for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care or the manufacturer of the product with orphan exclusivity is unable to maintain sufficient product quantity. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the product candidate any advantage in the regulatory review or approval process or entitles the product candidate to priority review.

Where appropriate, we plan to help expedite the product development and approval process by requesting that FDA or comparable foreign regulatory authorities designate product candidates for the use of accelerated registration or approval pathways. If we are unable to obtain such designations, we may be required to conduct additional preclinical studies or clinical trials beyond those that we contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary marketing approvals. Even if we receive an accelerated development designation from the FDA, if our confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous post-marketing requirements, the FDA may seek to withdraw accelerated approval.

Where possible, we plan to pursue accelerated development strategies in areas of high unmet need. We may seek an accelerated approval pathway for one or more of our product candidates. Under the accelerated approval provisions in the Federal Food, Drug, and Cosmetic Act, and the FDA's implementing regulations, the FDA may grant accelerated approval to a product candidate designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that the product candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is contingent on the sponsor's agreement to conduct post-approval confirmatory studies to verify and describe the drug's clinical benefit. Such studies must be commenced prior to or not later than the time of approval, and the sponsor must conduct such studies with due diligence. If such post-approval studies fail to confirm the drug's clinical benefit, or if the sponsor fails to conduct such studies with due diligence, the FDA may use expedited procedures to withdraw its approval of the drug.

Prior to seeking such accelerated approval, we will seek feedback from the FDA and will otherwise evaluate our ability to seek and receive such accelerated approval. There can be no assurance that after our evaluation of the feedback and other factors we will decide to pursue or submit an NDA for accelerated approval or any other form of expedited development, review or approval. Similarly, there can be no assurance that after subsequent FDA feedback we will continue to pursue or apply for accelerated approval or any other form of expedited development, review or approval, even if we initially decide to do so. Furthermore, if we decide to submit an application for accelerated approval or under another expedited regulatory designation (e.g., breakthrough therapy designation), there can be no assurance that such submission or application will be accepted or that any expedited development, review or approval will be granted on a timely basis, or at all. The FDA or other comparable foreign regulatory authorities could also require us to conduct further studies prior to considering our application or granting approval of any type. A failure to obtain accelerated approval or any other form of expedited development, review or approval for our product candidate would result in a longer time period to commercialization of such product candidate, could increase the cost of development of such product candidate and could harm our competitive position in the marketplace.

If our Nugevia nutritional supplement products do not have the effects intended or cause undesirable side effects, our business may suffer.

Although the ingredients in our current Nugevia supplement products are substances for which there is a history of human consumption, they also contain innovative ingredients or combinations of ingredients. Although we believe all of such products and the combinations of ingredients in them are safe when taken as directed, the products could have certain undesirable side effects if not taken as directed or if taken by a consumer that has certain medical conditions. In addition, such products may not have the effect intended if they are not taken in accordance with certain instructions, which include certain dietary restrictions. Furthermore, there can be no assurance that any of the products, even when used as directed, will have the effects intended or will not have harmful side effects in an unforeseen way or affect populations differently. If any of our products or products we develop or commercialize in the future are shown to be harmful or generate negative publicity from perceived harmful effects, our business, financial condition, results of operations and prospects would be harmed significantly.

Our competitors may develop nutritional supplement products that are less expensive, safer or otherwise more appealing, which may diminish or eliminate the commercial success of any potential product that we may commercialize.

If our competitors (most of whom are larger and have more resources than we do) develop and bring to market competing nutritional supplement products that are less expensive, safer or otherwise more appealing than our current Nugevia products and potential future products, or that reach the market before our products, we may not achieve commercial success. The market may choose to continue utilizing existing products for a number of reasons, including familiarity with or pricing of these existing products. The failure of any of Nugevia products to compete with products marketed by our competitors would impair our ability to generate revenue, which could have a material adverse effect on our future business, financial condition, results of operations, and cash flows. Our competitors may:

- develop and market products that are less expensive, safer, or otherwise more appealing than our products;
- commercialize competing products before we or our partners can launch our products; and
- initiate or withstand substantial price competition more successfully than we can.

Our Nugevia products are subject to regulatory requirements and failure to comply with any regulations could lead to significant penalties or claims, which could materially harm our financial condition and operating results.

For example, we are subject to FDA requirements, including for cGMPs for dietary supplements. Any failure by us or any contract manufacturer to comply with the cGMPs could negatively impact our reputation and ability to sell our products even after the situation has been resolved. In addition, FDA and other governmental authorities limit the types of claims that we can make about our products, including nutrition content claims, health claims, and therapeutic claims and otherwise regulate the marketing of our products. It is possible that our marketing materials, including testimonials about our products, may be significantly impacted by laws, rules, and regulations governing the marketing of our products and therefore might negatively impact our sales.

We may face difficulties from changes to current regulations and future legislation.

Governmental agencies throughout the world, including in the United States, strictly regulate the pharmaceutical, dietary and nutritional supplement and drug and medical product industries. Our business involves the clinical testing and development of drug product candidates and the marketing and sale of nutritional supplements.

Existing regulatory policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, and we may not achieve or sustain profitability.

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. For example, certain policies of the current U.S. administration may impact our business and industry, which could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict how current and future legislation, executive actions, and litigation, including the executive orders referenced below, will be implemented, and the extent to which they will impact our business, our clinical development, and the FDA's and other agencies' ability to exercise their regulatory authority, including FDA's pre-approval inspection and timely review of any regulatory filings or applications we submit to the FDA. If these executive actions impose constraints on FDA's ability to engage in oversight and implementation activities in the normal course or constraints on our business operations, including operations of our contractors, our business may be negatively impacted.

For example, in March 2010, the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the ACA), was passed, which substantially changed the way healthcare is financed by both the government and private insurers, and continues to significantly impact the U.S. pharmaceutical industry. Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA. For example, various portions of the ACA are currently undergoing legal and constitutional challenges in the United States Supreme Court. Although the Supreme Court has not yet ruled on the constitutionality of the ACA, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through May 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. We cannot predict how the Supreme Court will rule on these challenges, how future litigation will impact our business, or what other healthcare measures and regulations will ultimately be implemented at the federal or state level or the effect of any future legislation or regulation may have on our business.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, effective April 1, 2013, which will remain in effect through 2030. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our drugs, if approved, and accordingly, our financial operations.

Moreover, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several 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 drug products. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. At the federal level, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, in 2020, HHS and CMS issued various rules that are expected to impact, among others, price reductions from pharmaceutical manufacturers to plan sponsors under Part D, fee arrangements between pharmacy benefit managers and manufacturers, manufacturer price reporting requirements under the Medicaid Drug Rebate Program, including regulations that affect manufacturer-sponsored patient assistance programs subject to pharmacy benefit manager accumulator programs and Best Price reporting related to certain value-based purchasing arrangements. Multiple lawsuits have been brought against the HHS challenging various aspects of the rules. In January 2021, the Biden administration issued a "regulatory freeze" memorandum that directs department and agency heads to review new or pending rules of the prior administration. It is unclear whether these new regulations will be withdrawn or when they will become fully effective under the Biden administration. The impact of these lawsuits as well as legislative, executive, and administrative actions of the Biden administration on us and the pharmaceutical industry as a whole is unclear.

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

We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. 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.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for biotechnology products. We cannot be sure whether additional legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements. In addition, recent and potential future courts decisions and administrative law cases may result in additional legal challenges to regulations and guidance issued by federal regulatory agencies, including the FDA, that we have relied on and intend to rely on in the future. Any such challenges, if successful, could have a material impact on our business. In addition to potential changes to regulations and agency guidance as a result of legal challenges, these decisions may result in increased regulatory uncertainty and delays in and other impacts to the agency rulemaking process, any of which could adversely impact our business and operations. Additionally, our ability to develop and market new drug products may be impacted based on current or future litigation in the federal court system challenging the FDA's approval of other companies' drugs. Depending on the outcome of this type of litigation, our ability to develop new drug product candidates and to maintain approval of existing drug products could be at risk and our efforts to develop and market new drug products could be delayed, undermined or subject to protracted litigation.

Further, artificial intelligence (AI)-based platforms and tools are increasingly being used in the medical industry, including by regulatory authorities, such as the FDA to assist with the review of regulatory filings and other activities. With new and evolving AI comes a continually changing AI regulatory environment, which may create additional costs, challenges, and risks that could adversely impact our ability to timely develop and seek approval of our drug product candidates with FDA, or otherwise have a material adverse impact on our business.

Risks Related to Data Privacy and Security

We are subject to an evolving array of U.S. and foreign privacy, and data protection, and data security laws regulations, and standards, and any failure or perceived failure to comply could result in regulatory investigations, litigation, significant fines and penalties, operational restrictions, and reputational harm.

We collect and process personal information in the course of operating our business, including in connection with our clinical programs and the direct-to-consumer marketing and sale of our Nugevia products. In the United States, we may be subject to a patchwork of federal and state laws and regulations governing the privacy and security of personal information, including state breach notification laws, consumer privacy laws (for example, the California Consumer Privacy Act of 2018, as amended by the California Privacy Rights Act of 2020 (CCPA)), health information privacy laws, and federal and state consumer protection laws enforced by regulators such as the Federal Trade Commission and state attorneys general. Businesses that process personal information of consumers in several states are required, among other things, to make certain disclosures regarding their data collection, use, and sharing practices, and to honor requests from consumers to exercise rights over their personal information, including the right to opt out of certain disclosures and the right to limit the use of sensitive personal information. These requirements continue to expand and diverge across states, increasing the cost and complexity of compliance and the risk of civil penalties for violations thereof.

To the extent we act as a covered entity or business associate, we are subject to the Health Insurance Portability and Accountability Act of 1996, as amended, and its implementing regulations (collectively, HIPAA), which impose privacy, security, and breach notification obligations with respect to protected health information, as well as contractual requirements and potential civil and criminal penalties for violations. Even where our clinical trial data may benefit from limited exemptions under certain state consumer privacy laws, our broader activities, such as recruiting, employee information processing, and marketing, may still be in scope.

Internationally, the collection and use of health data and other personal information is governed in the EU by the General Data Protection Regulation (GDPR) and by certain EU Member State-level legislation. The GDPR extends its geographical scope to entities outside of the EU that offer goods or services to, or monitor the behavior of, individuals within the EU. While our clinical operations are currently based in the United States, we maintain significant business relationships with international partners, including our exclusive license agreement with Aquanova AG, a German company. To the extent personal information is exchanged in connection with these relationships, the GDPR and the UK General Data Protection Regulation (UK GDPR), may apply. Failure to comply with the GDPR may result in fines up to €20,000,000 or up to 4% of total worldwide annual turnover of the preceding financial year, whichever is higher, and other administrative penalties. The UK GDPR provides for fines of up to the greater of £17.5 million or 4% of global turnover. While the EU-U.S. Data Privacy Framework and other transfer mechanisms currently provide pathways for transatlantic data flows, these frameworks are subject to change and legal challenge, which may require us to implement additional safeguards at increased cost and with residual risk.

Furthermore, as we pursue our stated plans for international clinical trials, regulatory submissions to the EMA, out-licensing opportunities in European and Asian markets, and potential commercialization in foreign jurisdictions, we expect that we will become subject to additional data protection requirements in those jurisdictions. These may include, among others, data protection laws in China (the Personal Information Protection Law, or PIPL), Singapore (the Personal Data Protection Act, or PDPA), and Australia (the Privacy Act 1988), each of which imposes distinct compliance obligations, restrictions on cross-border data transfers, and significant penalties for noncompliance.

With the GDPR, CCPA, state comprehensive privacy laws, and other laws, regulations and other obligations imposing new and burdensome obligations, and with substantial uncertainty over the interpretation and application of these evolving requirements, we may face challenges in addressing their requirements and making necessary changes to our policies and practices, and may incur significant costs and expenses in an effort to do so. Additionally, our reliance on third parties, such as CROs, CMOs, clinical sites, vendors, or other service providers, creates additional risk and could have an adverse effect on our business and data if such parties fail to comply with applicable privacy and security requirements or our policies, or otherwise suffer a security incident. Any failure or perceived failure by us or our service providers to comply with applicable privacy or data protection obligations, or to protect personal information against unauthorized access, use, or disclosure, could result in investigations, enforcement actions, litigation (including class actions), significant fines and damages, the suspension of data processing, orders to change our practices, and reputational harm, any of which could adversely affect our business, financial condition, and results of operations.

Inadequate funding for the FDA, the U.S. Securities and Exchange Commission (SEC) and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

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

Disruptions at the FDA and other agencies 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, in recent years, the U.S. government shut down several times and certain regulatory agencies, such as the FDA and the SEC, had to furlough critical employees and stop critical activities. In addition, in 2025, the federal government implemented workforce reductions across the Department of Health and Human Services, including layoffs affecting FDA employees and resulting in a reduction in the FDA's full-time workforce. Although FDA review staff were described as exempt from direct cuts, the loss of personnel may have contributed to reported slowdowns, reduced responsiveness, and operational strain within the FDA. If a prolonged government shutdown or personnel reduction occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, in our operations as a public company, future government shutdowns or personnel reductions could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Our relationships with healthcare professionals, clinical investigators, CROs and third-party payors in connection with our current and future business activities may be subject to federal and state healthcare fraud and abuse laws, false claims laws, transparency laws, government price reporting, and health information privacy and security laws, which could expose us to significant losses, including, among other things, criminal sanctions, civil penalties, contractual damages, exclusion from governmental healthcare programs, reputational harm, administrative burdens and diminished profits and future earnings.

Healthcare providers and third-party payors play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, clinical investigators, CROs, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we research, as well as market, sell and distribute our products for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations may include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;

- the federal false claims laws, including the civil False Claims Act, which can be enforced by private citizens through civil whistleblower or qui tam actions, and civil monetary penalties laws, prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), prohibits, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH) and their implementing regulations, also imposes obligations, including mandatory contractual terms, on covered entities, which are health plans, healthcare clearinghouses, and certain health care providers, as those terms are defined by HIPAA, and their respective business associates and their subcontractors, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- the federal Physician Payments Sunshine Act requires applicable manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to annually report to CMS information regarding payments and other transfers of value to physicians, defined to include doctors, dentists, optometrists, podiatrists and chiropractors, and teaching hospitals as well as information regarding ownership and investment interests held by physicians and their immediate family members. Beginning in 2022, reporting obligations with respect to covered recipients will be expanded to include physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and anesthesiologist assistants, and certified nurse midwives for payments and transfers of value made during the previous year; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance regulations promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures, or drug pricing; state and local laws that require the registration of pharmaceutical sales and medical representatives; state laws that govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare and data privacy laws and regulations will involve substantial ongoing costs, and may require us to undertake or implement additional policies or measures. We may face claims and proceedings by private parties, and claims, investigations and other proceedings by governmental authorities, relating to allegations that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations, and it is possible that courts or governmental authorities may conclude that we have not complied with them, or that we may find it necessary or appropriate to settle any such claims or other proceedings. In connection with any such claims, proceedings, or settlements, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations. 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. Further, if any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

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

We are exposed to the risk that our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, suppliers and vendors may engage in misconduct or other improper activities. Misconduct by these parties could include failures to comply with FDA regulations, provide accurate information to the FDA, comply with federal and state health care fraud and abuse laws and regulations, accurately report financial information or data or disclose unauthorized activities to us. In particular, research, sales, marketing and business arrangements in the health care industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct by these parties could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a code of conduct, but it is not always possible to identify and deter misconduct by these parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations.

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

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

Although we maintain workers' compensation insurance to cover us for costs and expenses, we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of hazardous and flammable materials, including chemicals and biological materials.

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

Our business activities may be subject to the U.S. Foreign Corrupt Practices Act and similar anti-bribery and anti-corruption laws of other countries in which we operate, as well as U.S. and certain foreign export controls, trade sanctions, and import laws and regulations. Compliance with these legal requirements could limit our ability to compete in foreign markets and subject us to liability if we violate them.

Our business activities are subject to the U.S. Foreign Corrupt Practices Act of 1977, as amended (FCPA), the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate. These laws generally prohibit companies and their employees, agents, representatives, business partners, and third-party intermediaries from, directly or indirectly, offering, promising, giving or authorizing others to give anything of value, either directly or indirectly, to recipients in the public or private sector in order to influence official action or otherwise obtain or retain business. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, hospitals are owned and operated by the government, and doctors and other hospital employees would be considered foreign officials under the FCPA. Recently, the SEC and DOJ have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies.

We sometimes leverage third parties to assist with the conduct of our business abroad. We, our employees, agents, representatives, business partners and our third-party intermediaries may have direct or indirect interactions with officials and employees of government agencies or state-owned or affiliated entities and may be held liable for the corrupt or other illegal activities of these employees, agents, representatives, business partners or third-party intermediaries even if we do not explicitly authorize such activities. We cannot assure you that all of our employees, agents, representatives, business partners and third-party intermediaries will not take actions in violation of applicable law for which we may be ultimately held responsible. As we increase our international sales and business, our risks under these laws may increase.

These laws also require that we make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls and compliance procedures designed to prevent violations of anti-corruption laws. There is no certainty that all of our employees, agents, representatives, business partners and third-party intermediaries, or those of our affiliates, will comply with applicable laws and regulations, for which we may be ultimately held responsible.

Violations of these laws and regulations could result in whistleblower complaints, fines, severe civil or criminal sanctions, settlements, prosecution, enforcement actions, damages, adverse media coverage, investigations, loss of export privileges, disgorgement, and other remedial measures and prohibitions on the conduct of our business including our ability to offer our products in one or more countries. Responding to any investigation or action will likely result in a materially significant diversion of management's attention and resources and significant defense costs and other professional fees. As a general matter, investigations, enforcement actions and sanctions could damage our reputation, our brand, our international activities, our ability to attract and retain employees and our business, prospects, operating results and financial condition.

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

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

Our success is highly dependent on our ability to attract and retain highly skilled executive officers and employees.

To succeed, we must recruit, retain, manage and motivate qualified clinical, scientific, technical and management personnel, and we face significant competition for experienced personnel. We are highly dependent on the principal members of our management and scientific and medical staff, particularly Marshall Hayward, our Co-Founder and Chief Scientific Officer. If we do not succeed in attracting and retaining qualified personnel, particularly at the management level, it could adversely affect our ability to execute our business plan and harm our operating results. In particular, the loss of one or more of our executive officers could be detrimental to us if we cannot recruit suitable replacements in a timely manner. We do not maintain "key person" insurance for any of our executives or other employees. We could in the future have difficulty attracting and retaining experienced personnel and may be required to expend significant financial resources in our employee recruitment and retention efforts.

Many of the other biotechnology companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide higher compensation, more diverse opportunities and better prospects for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. If we are unable to continue to attract and retain high-quality personnel, the rate and success at which we can discover, develop and commercialize our product candidates will be limited and the potential for successfully growing our business will be harmed.

Additionally, we rely on our scientific founders and other scientific and clinical advisors and consultants to assist us in formulating our research, development and clinical strategies. These advisors and consultants are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. In addition, these advisors and consultants typically will not enter into non-compete agreements with us. If a conflict of interest arises between their work for us and their work for another entity, we may lose their services. Furthermore, our advisors may have arrangements with other companies to assist those companies in developing products or technologies that may compete with ours. In particular, if we are unable to maintain consulting relationships with our scientific founders or if they provide services to our competitors, our development and commercialization efforts will be impaired and our business will be significantly harmed.

If we are unable to establish sales or marketing capabilities or enter into agreements with third parties to sell or market our product candidates, we may not be able to successfully sell or market our product candidates that obtain regulatory approval.

We currently do not have and have never had a marketing or sales team. In order to commercialize any product candidates, if approved, we must build marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services for each of the territories in which we may have approval to sell or market our product candidates. We may not be successful in accomplishing these required tasks.

Establishing an internal sales or marketing team with technical expertise and supporting distribution capabilities to commercialize our product candidates will be expensive and time-consuming and will require significant attention of our executive officers to manage. Any failure or delay in the development of our internal sales, marketing and distribution capabilities could adversely impact the commercialization of any of our product candidates that we obtain approval to market, if we do not have arrangements in place with third parties to provide such services, which is our preferred marketing and sales strategy, on our behalf. Alternatively, if we choose to collaborate, either globally or on a territory-by-territory basis, 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 will be required to negotiate and enter into arrangements with such third parties relating to the proposed collaboration and such arrangements may prove to be less profitable than commercializing the product on our own. If we are unable to enter into such arrangements when needed, on acceptable terms, or at all, we may not be able to successfully commercialize any of our product candidates that receive regulatory approval, or any such commercialization may experience delays or limitations. If we are unable to successfully commercialize our approved product candidates, either on our own or through collaborations with one or more third parties, our future product revenue will suffer, and we may incur significant additional losses.

In order to successfully implement our plans and strategies, we will need to grow the size of our organization, and we may experience difficulties in managing this growth.

As of December 31, 2025, we had a total of five full-time employees, two full-time consultants and one part-time consultant, plus our six Scientific Advisory Board members. Of these, three were primarily engaged in research or product development and clinical activities. In order to successfully implement our development and commercialization plans and strategies, and as we transition into operating as a public company, we expect to hire additional managerial, operational, sales, marketing, financial and other personnel, as reflected in our organization chart represented in our Operation and Organization section. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, including the clinical, FDA, EMA and other comparable foreign regulatory agencies' review process for JOTROL™ and any other product candidates, while complying with any contractual obligations to contractors and other third parties we may have; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to successfully develop and, if approved, commercialize JOTROL™ and other product candidates will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services, including key aspects of our research and development, clinical development and manufacturing. We cannot assure you that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by third-party service providers is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain marketing approval of JOTROL™ and any other product candidates or otherwise advance our business. We cannot assure you that we will be able to manage our existing third-party service providers or find other competent outside contractors and consultants on economically reasonable terms, or at all.

If we are not able to effectively expand our organization by hiring new employees and/or engaging additional third-party service providers, we may not be able to successfully implement the tasks necessary to further develop and commercialize JOTROL™ and other product candidates and, accordingly, may not achieve our research, development and commercialization goals.

Risks Related to Cybersecurity and Information Technology Disruptions

Our information technology systems and those of any of our CROs, clinical sites, manufacturers, vendors, and other partners are subject to cybersecurity threats and other disruptions that could adversely affect our operations and the development and commercialization of our product candidates.

We and our third-party partners rely on information technology systems to conduct research and development, manage clinical and manufacturing operations, and support corporate functions. Despite the implementation of security measures designed to protect these systems, given their size and complexity and the increasing amounts of information maintained on our internal information technology systems, and those of our third-party CROs, contract development and manufacturing organizations ("CDMOs"), other contractors (including sites performing our clinical trials) and consultants, these systems are vulnerable to damage, disruption or unauthorized access arising from service interruptions, system malfunction, natural disasters, terrorism, war and telecommunication and electrical failures, as well as security breaches from inadvertent or intentional actions by our employees, contractors, consultants, business partners, and/or other third parties, or from cyber-attacks by malicious third parties. Such cyber-attacks may include supply chain attacks, the deployment of harmful malware, ransomware (including ransomware-as-a-service), denial-of-service attacks, social engineering, credential harvesting, business email compromise, and other means designed to affect service reliability and threaten the confidentiality, integrity and availability of information. The frequency, sophistication, and severity of such threats continue to increase and those of our third-party service providers remain at risk.

Any such incident may compromise our system infrastructure or lead to the loss, unavailability, destruction, alteration, prevention of access to, disclosure, or dissemination of, or damage or unauthorized access to, our data (including trade secrets or other confidential information, intellectual property, proprietary business information, and personal information) or data that is processed or maintained on our behalf, or other assets, which could result in financial, legal, business and reputational harm to us. We have also received phishing attacks, and companies have, in general, experienced an increase in phishing and social engineering attacks from third parties. The increase in remote and hybrid working arrangements further increases security threats.

A material cybersecurity incident or other significant disruption affecting us or our third parties could result in the loss, unavailability, alteration, or unauthorized access to confidential, proprietary, or personal information; liability, financial harm and reputational damage; increased costs, including incident response and remediation; regulatory investigations and enforcement actions; and the delay in development and commercialization of our product candidates. We cannot assure you that our data protection efforts and our investment in information technology, or the efforts or investments of CROs, CDMOs, consultants or other third parties, will prevent significant breakdowns or breaches in systems or other cyber incidents that cause loss, destruction, unavailability, alteration or dissemination of, or damage or unauthorized access to, our data and other data processed or maintained on our behalf or other assets that could have a material adverse effect upon our reputation, business, operations or financial condition.

In addition, the growing use of artificial intelligence and machine learning technologies, both by malicious actors seeking to circumvent security measures and by us and our service providers in the course of business operations, introduces new and evolving cybersecurity risks. AI-powered attacks may be more difficult to detect and may circumvent traditional security controls. Furthermore, if we or our third-party service providers use AI tools that process or have access to our confidential information, clinical trial data, or other sensitive data, the use of such tools could create additional vectors for data exposure if not properly secured and governed.

Notifications and follow-up actions related to a security incident could impact our reputation and cause us to incur significant costs, including legal expenses and remediation costs. We expect to incur significant costs in an effort to detect and prevent security incidents, and we may face increased costs and requirements to expend substantial resources in the event of an actual or perceived security incident. In addition, the SEC's cybersecurity disclosure rules require us to disclose material cybersecurity incidents and describe our cybersecurity risk management, strategy, and governance, which may increase the costs and complexity of managing cybersecurity events and could result in reputational harm if we are required to disclose a material incident.

While we maintain a cybersecurity risk management program and seek to implement and require appropriate security measures, we cannot eliminate all risk, and our insurance coverage may not be adequate to cover all losses or liabilities.. In addition, such insurance may not be available to us in the future on economically reasonable terms, or at all. Further, our insurance may not cover all claims made against us and could have high deductibles in any event, and defending a suit, regardless of its merit, could be costly and divert management attention.

In addition, we have recently launched our Nugevia direct-to-consumer nutraceutical business, which involves the collection, storage, and processing of consumer personal information, including names, shipping addresses, email addresses, and payment card data through our e-commerce platform. A security breach affecting our e-commerce systems or those of our third-party payment processors, fulfillment providers, or website hosting services could result in the unauthorized access to or theft of customer payment information and personal data, exposing us to liability under the Payment Card Industry Data Security Standard (PCI DSS), state consumer protection and data breach notification laws, and potential claims from affected consumers. Our direct-to-consumer marketing efforts may also rely on social media platforms and third-party brand ambassadors, and any security incident affecting those channels or relationships could harm our brand reputation and customer trust.

Our employees and executives may use artificial intelligence tools in ways that expose our confidential information, intellectual property, or clinical data to third parties, and the evolving regulatory and legal landscape around artificial intelligence could adversely affect our business.

Our employees and executives may use commercially available artificial intelligence tools, including generative AI platforms, in connection with their work. If our personnel inadvertently submit confidential information, proprietary research data, clinical trial data, or trade secrets to external AI platforms, that information may be exposed to third parties or incorporated into publicly accessible AI outputs, potentially compromising our intellectual property, our patent position, or our obligations under confidentiality agreements. The legal and regulatory framework governing AI tools remains uncertain and rapidly evolving, including with respect to ownership of AI-generated outputs and potential infringement of third-party intellectual property rights. We have not adopted a formal AI use policy, and any failure to manage these risks appropriately could have a material adverse effect on our business, financial condition, and results of operations.

Our operations are vulnerable to interruption by fire, earthquakes, power loss, telecommunications failure, terrorist activity, pandemics and other events beyond our control, which could harm our business.

Our facilities are located in Jupiter, Florida. We have not undertaken a systematic analysis of the potential consequences to our business and financial results from a major flood, blizzard, fire, earthquake, power loss, terrorist activity, pandemics or other disasters and do not have a recovery plan for such disasters. In addition, we do not carry sufficient insurance to compensate us for actual losses from interruption of our business that may occur, and any losses or damages incurred by us could harm our business. Also, our contract development and manufacturing organizations' (CDMOs) and suppliers' facilities are located in multiple locations where other natural disasters or similar events which could severely disrupt our operations, could expose us to liability and could have a material adverse effect on our business. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

A variety of risks associated with marketing our product candidates internationally could materially adversely affect our business.

We may seek regulatory approval of our product candidates outside of the United States and, accordingly, we expect that we will be subject to additional risks related to operating in foreign countries. These risks include navigating differing regulatory requirements and reimbursement systems, as well as coping with unexpected changes in tariffs, trade barriers, price and exchange controls, and other regulatory demands. We may also encounter economic challenges such as inflation or political instability in certain foreign markets. Compliance with local tax, employment, immigration, and labor laws for employees living or traveling abroad will be necessary, alongside managing foreign taxes, including payroll withholding.

Foreign currency fluctuations could increase our operating expenses and reduce revenue, adding further complexity to our international operations. We may experience difficulties in staffing and managing foreign operations, particularly in countries where labor unrest is more common than in the United States, leading to workforce uncertainty. There is also the potential for liability under the Foreign Corrupt Practices Act (FCPA) or similar foreign regulations. Enforcing our contractual and intellectual property rights may be challenging, especially in countries that do not provide the same level of protection as the United States. Additionally, production shortages could arise from disruptions in raw material supply or manufacturing capabilities abroad, and business interruptions could result from geopolitical actions such as war and terrorism. Collectively, these and other risks related to international operations could materially and adversely affect our ability to achieve or maintain profitable operations.

The certificate of incorporation, as amended, and amended and restated bylaws provides that state or federal court located within the state of Delaware will be the sole and exclusive forum for substantially all disputes between us and our stockholders, which could limit its stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or other employees.

Section IX of our certificate of incorporation, as amended, and Section 7.4 of our amended and restated bylaws provides that "unless the corporation consents in writing to the selection of an alternative forum, the sole and exclusive forum for (i) any derivative action or proceeding brought on behalf of the Corporation, (ii) any action asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee of the Corporation to the Corporation or the Corporation's stockholders, (iii) any action asserting a claim arising pursuant to any provision of the DGCL, or (iv) any action asserting a claim governed by the internal affairs doctrine shall be a state or federal court located in the county in which the principal office of the corporation in the State of Delaware is established, in all cases subject to the court's having personal jurisdiction over the indispensable parties named as defendants. Notwithstanding the foregoing, the exclusive forum provision will not apply to suits brought to enforce any liability or duty created by the Exchange Act of 1934, as amended, the Securities Act of 1933, as amended, or any claim for which the federal courts have exclusive or concurrent jurisdiction." Therefore, the exclusive forum provision in our certificate of incorporation, as amended, and our amended and restated bylaws will not relieve us of our duty to comply with the federal securities laws and the rules and regulations thereunder, and stockholders will not be deemed to have waived our compliance with these laws, rules and regulations.

This exclusive forum provision may limit a stockholder's ability to bring a claim in a judicial forum of its choosing for disputes with us or our directors, officers or other employees, which may discourage lawsuits against us or our directors, officers or other employees. In addition, stockholders who do bring a claim in the state or federal court in the State of Delaware could face additional litigation costs in pursuing any such claim, particularly if they do not reside in or near Delaware. The state or federal court of the State of Delaware may also reach different judgments or results than would other courts, including courts where a stockholder would otherwise choose to bring the action, and such judgments or results may be more favorable to us than to our stockholders. However, the enforceability of similar exclusive forum provisions in other companies' certificates of incorporation have been challenged in legal proceedings, and it is possible that a court could find this type of provision to be inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings. If a court were to find the exclusive forum provision contained in our certificate of incorporation, as amended, and our amended and restated bylaws to be inapplicable or unenforceable in an action, we might incur additional costs associated with resolving such action in other jurisdictions.

By purchasing our common stock, you are bound by the fee-shifting provision contained in our amended and restated bylaws, which may discourage you to pursue actions against us and could discourage stockholder lawsuits that might otherwise benefit the Company and its stockholders.

Section 7.4 of our amended and restated bylaws provides that "if any action is brought by any party against another party, relating to or arising out of these Bylaws, or the enforcement hereof, the prevailing party shall be entitled to recover from the other party reasonable attorneys' fees, costs and expenses incurred in connection with the prosecution or defense of such action."

Our amended and restated bylaws provide that for this section, the term "attorneys' fees" or "attorneys' fees and costs" means the fees and expenses of counsel to the Company and any other parties asserting a claim subject to Section 7.4 of the amended and restated bylaws, which may include printing, photocopying, duplicating and other expenses, air freight charges, and fees billed for law clerks, paralegals and other persons not admitted to the bar but performing services under the supervision of an attorney, and the costs and fees incurred in connection with the enforcement or collection of any judgment obtained in any such proceeding.

We adopted the fee-shifting provision to eliminate or decrease nuisance and frivolous litigation. We intend to apply the fee-shifting provision broadly to all actions except for claims brought under the Exchange Act and Securities Act.

There is no set level of recovery required to be met by a plaintiff to avoid payment under this provision. Instead, whoever is the prevailing party is entitled to recover the reasonable attorneys' fees, costs and expenses incurred in connection with the prosecution or defense of such action. Any party who brings an action, and the party against whom such action is brought under Section 7.4 of our amended and restated bylaws, which could include, but is not limited to former and current stockholders, Company directors, officers, affiliates, legal counsel, expert witnesses and other parties, are subject to this provision. Additionally, any party who brings an action, and the party against whom such action is brought under Section 7.4 of our amended and restated bylaws, which could include, but is not limited to former and current stockholders, Company directors, officers, affiliates, legal counsel, expert witnesses and other parties, would be able to recover fees under this provision.

In the event you initiate or assert a claims against us, in accordance with the dispute resolution provisions contained in our amended and restated Bylaws, and you do not, in a judgment prevail, you will be obligated to reimburse us for all reasonable costs and expenses incurred in connection with such claim, including, but not limited to, reasonable attorney's fees and expenses and costs of appeal, if any. Additionally, this provision in Section 7.4 of our amended and restated bylaws could discourage stockholder lawsuits that might otherwise benefit the Company and its stockholders.

THE FEE SHIFTING PROVISION CONTAINED IN THE AMENDED AND RESTATED BYLAWS IS NOT INTENDED TO BE DEEMED A WAIVER BY ANY HOLDER OF COMMON STOCK OF THE COMPANY'S COMPLIANCE WITH THE U.S. FEDERAL SECURITIES LAWS AND THE RULES AND REGULATIONS PROMULGATED THEREUNDER. THE FEE SHIFTING PROVISION CONTAINED IN THE AMENDED AND RESTATED BYLAWS DO NOT APPLY TO CLAIMS BROUGHT UNDER THE EXCHANGE ACT AND SECURITIES ACT.

Risks Related to Our Intellectual Property

Our worldwide exclusive license agreement with Aquanova for JOTROL™ is critical to our business. If we were to lose the license agreement, it could disrupt our ability to commercialize our Nugevia product line or pharmaceutical drug candidates.

We hold a worldwide license for JOTROL™, utilizing Aquanova's proprietary micellar technology. Aquanova jointly owns with us an international patent filed on January 29, 2017, titled "Resveratrol Solubilization Product for Pharmaceutical Purposes" (PCT/EP2017/051659). The patent, with a priority date of June 16, 2016, and an expiration in 2036, has been examined by the International Preliminary Examining Authority of the Patent Cooperation Treaty (PCT). All 15 claims were deemed novel, inventive, and industrially applicable, leading to the patent's approval in the United States, select European Union countries, Japan, China, and Hong Kong.

The JOTROL™ license agreement with Aquanova is critical to our operations, as JOTROL™ is a proprietary, enhanced resveratrol formulation that has demonstrated the potential for significantly improved bioavailability. Termination or loss of this license agreement would significantly disrupt our ability to commercialize our Nugevia product line or pharmaceutical drug candidates. Such a disruption could delay our development and commercialization efforts, resulting in a material adverse effect on our business, financial condition, and operational results.

Our success depends on our ability to protect our intellectual property and our proprietary technologies.

Our commercial success depends in part on our ability to obtain and maintain patent protection and trade secret protection for JOTROL™ and other product candidates, proprietary technologies and their uses as well as our ability to operate without infringing upon 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. We also seek to protect our proprietary position by acquiring or in-licensing relevant issued patents or pending applications from third parties.

Pending 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 or the patent applications of our licensor will result in additional 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 and our licensor's 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. These uncertainties and/or limitations in our ability to properly protect the intellectual property rights relating to our product candidates could have a material adverse effect on our financial condition and results of operations

Obtaining and maintaining patent protection involves significant risks and uncertainties. The USPTO and foreign patent agencies require strict compliance with procedural, documentary, fee payment, and other provisions during the patent process, and noncompliance can lead to the abandonment or lapse of a patent or application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. There is no guarantee that patent applications will result in issued patents. Even if granted, patents may be challenged, invalidated, modified, revoked, circumvented, or deemed unenforceable, potentially offering no competitive advantage. Competitors, often with substantially greater resources and significant investments in competing technologies, may seek or already hold patents that could limit, interfere with, or eliminate our ability to develop, use, and sell our potential product candidates. Additionally, public policy pressures on the U.S. government and international bodies may push to restrict patent protection scopes for successful disease treatments due to global health concerns. Furthermore, patent laws in countries outside the United States may be less favorable to patentees compared to those upheld by U.S. courts, enabling foreign competitors to more easily create, develop, and market competing products.

The patent prosecution process is also expensive and time-consuming, and we and our licensor 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 or our licensor 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, 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.

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 adversely affected.

The patent position of biopharmaceutical companies generally is 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 and those of our licensor 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 or in-license 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 patents that we own or in-license 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 or the patents of our licensors 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, and our patents or the patents of our licensor may be challenged in the courts or patent offices in the United States and abroad. 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 (PGR) and inter partes review (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 or the patents of our licensor may become subject to post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge our priority of invention or other features of patentability with respect to our patents and patent applications and those of our licensor. Such challenges may result in loss of patent rights, loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our 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 or the patents and patent applications of our licensor is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

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

The future strength of our intellectual property protection is uncertain, as IP rights have inherent limitations and may not fully safeguard our business or competitive position. For instance, others may develop similar products that fall outside the scope of our patents, or we or our licensors may not have been the first to invent or file for certain technologies. Competitors could independently develop or replicate our technologies without infringing our rights, and some of our pending patent applications may never be granted. Additionally, research conducted by others in countries where we lack patent protection could lead to competing products in key markets. We may also fail to develop new patentable technologies, be adversely affected by third-party patents, or choose to rely on trade secrets that others later patent. Any of these outcomes could materially harm our business, operations, and future prospects.

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

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

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

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

Although no third-party has asserted a claim of patent infringement against us as of the date of this Annual Report, others may hold proprietary rights that could prevent our product candidates from being marketed. These claims could be alleged to cover JOTROL™ in certain treatment indications. While we believe that these patents are difficult to enforce and that we would have valid defenses to these claims of patent infringement, we cannot be certain that we would prevail in any dispute and we cannot be certain how an adverse determination would affect our business.

It is possible that a third party may assert a claim of patent infringement directed at any of our product candidates. Any patent-related legal action against us claiming damages and seeking to enjoin commercial activities relating to our products, treatment indications, or processes could subject us to significant 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, treatment indications, 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 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 a 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.

We may in the future pursue invalidity proceedings with respect to third-party patents. The outcome following legal assertions of invalidity is unpredictable. Even if resolved in our favor, these legal proceedings may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such 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 proceedings adequately. Some of these third parties may be able to sustain the costs of such proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent proceedings could compromise our ability to compete in the marketplace. If we do not prevail in the patent proceedings the third parties may assert a claim of patent infringement directed at our product candidates.

We may not be successful in obtaining or maintaining necessary rights to our product candidates through acquisitions and in-licenses.

Many pharmaceutical companies, biotechnology companies, and academic institutions may have patents and patent applications potentially relevant to our business. We may find it necessary or prudent to obtain licenses to such patents from such third-party intellectual property holders, for example, in order to avoid infringing these third-party patents. We may also require licenses from third parties for certain technologies for use with future product candidates. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary for our product candidates. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or product candidate, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We may be involved in lawsuits to protect or enforce our patents or our licensor's patents, which could be expensive, time consuming and unsuccessful. Further, our issued patents or our licensor's 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 or in-license 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 or the patent of our licensor 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 lack of novelty, obviousness, lack of sufficient written description, non-enablement, or obviousness-type double patenting. 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). The outcome following legal assertions of invalidity and/or 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, our licensor, and the patent examiners are 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 or the patents and patent applications of our licensor, which may, nonetheless, ultimately be found to affect the validity or enforceability of a 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 technology or proprietary drug delivery platform, or any product candidates that we may develop. Such a loss of patent protection would have a material adverse impact on our business, financial condition, results of operations and prospects.

In addition, if the breadth or strength of protection provided by our patents and patent applications or the patents and patent applications of our licensor is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

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. 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. 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, the issuance of a patent does not give us the right to practice the patented invention. Third parties may have blocking patents that could prevent us from marketing our own patented product and practicing our own patented technology.

Intellectual property litigation may lead to unfavorable publicity that harms our reputation and causes the market price of our common stock 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 or those of our licensor. 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, 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 patent and the patents we might obtain or license in the future.

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

We may also 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, one or more of our U.S. patents or those of our licensor may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984 (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.

Filing, prosecuting and defending patents in all countries throughout the world would 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, the patents of our licensors, 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 our licensor's patents or marketing of competing products in violation of our proprietary rights. 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 or the patents of our licensors at risk of being invalidated or interpreted narrowly and our patent applications or the patent applications of our licensor 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.

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

We intend to use registered or unregistered trademarks for JOTROL™ and Nugevia, to brand and market ourselves and our products. Our trademarks applications for JOTROL™ and Nugevia, may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our financial condition or results of operations.

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

We rely on trade secrets, unpatented know-how, and proprietary information to maintain our competitive edge, taking steps like entering confidentiality agreements with third parties and invention agreements with employees, consultants, and advisors, but there is no guarantee these agreements are fully executed or will prevent breaches. Enforcing claims against illegal disclosure or misappropriation of trade secrets is costly, time-consuming, and uncertain, especially as some courts, both in the U.S. and abroad, may be reluctant to protect trade secrets, and third parties could independently obtain or develop similar information, using it to compete against us without restriction. Failure to secure patent protection before disclosure or to maintain confidentiality could diminish the value of our proprietary information, jeopardize patentability, and harm our competitive position.

Our Nugevia product line may have limited intellectual property protection, which could make it easier for competitors to replicate our products and harm our competitive position. Our Nugevia product line operates outside the scope of our pharmaceutical license with Aquanova AG and may have different or lesser intellectual property protections than JOTROL™. The nutraceutical and dietary supplement industry is highly competitive, with relatively low barriers to entry. Unlike our pharmaceutical product candidate JOTROL™, which benefits from patent protection, the Nugevia product line may rely primarily on trade secrets, trade dress, and trademarks for intellectual property protection. These forms of intellectual property are generally more difficult to enforce than patents and may not provide the same level of exclusivity or protection against competitors. Competitors may be able to develop and market substantially similar products without infringing our intellectual property rights. As a result, we may be unable to prevent competitors from eroding our market share in the nutraceutical space, which could have a material adverse effect on our business, financial condition, and results of operations related to the Nugevia product line.

We may be subject to claims that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets.

We enter into non-disclosure and confidentiality agreements with third parties, such as scientific collaborators, CROs, manufacturers, consultants, and potential partners, to protect proprietary information, but we may face litigation if a third party claims we or our employees breached these agreements by misusing or disclosing their trade secrets. Defending such claims, regardless of merit, could incur significant legal costs, divert employee resources, cause negative publicity, and potentially halt commercialization of our product candidates. Even if successful, litigation could be costly, distract management, and risk compromising our confidential information during discovery, while larger adversaries with greater resources may sustain complex intellectual property litigation more effectively. Such disputes could lead to substantial damages, delay development efforts, and hinder our ability to raise funds, materially impacting our business, financial condition, and prospects.

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.

Our rights to develop and commercialize our technology and product candidates may be subject, in part, to the terms and conditions of licenses granted to us by others.

We have entered into a license agreement with Aquanova pursuant to which we have acquired the exclusive right to certain patents and patent applications in micellar technologies that revolutionizes the bioavailability profile of resveratrol to treat certain rare diseases and Alzheimer's disease by eliminating the severe gastro-intestinal side effects experienced at effective dose levels of resveratrol. We may enter into additional license agreements in the future with others to advance our research or allow commercialization of product candidates. These and other licenses may not provide exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and products in the future.

In addition, subject to the terms of any such license agreements, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement, and defense of patents and patent applications covering the technology that we license from third parties. In such an event, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced, and defended in a manner consistent with the best interests of our business. If our licensor fails to prosecute, maintain, enforce, and defend such patents, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any of our products that are subject of such licensed rights could be adversely affected.

Our licensor may have relied on third-party consultants or collaborators or on funds from third parties such that our licensor are not the sole and exclusive owners of the patents we in-licensed. If other third parties have ownership rights to our in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

It is possible that we may be unable to obtain additional licenses at a reasonable cost or on reasonable terms, if at all. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to redesign our technology, product candidates, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could harm our business, financial condition, results of operations, and prospects significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our current technology, manufacturing methods, product candidates, or future methods or products resulting in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant.

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

Disputes with our licensor. Aquanova, or potential licensors, particularly regarding our complex licensing agreement with Aquanova, may arise over issues such as the scope of rights granted, potential infringement of the licensor's intellectual property not covered by the agreement, our ability to sublicense or assign rights, our diligence obligations, or the inventorship, ownership, and priority of inventions created jointly with licensors or partners. These disagreements could lead to interpretations that narrow our rights to intellectual property or increase our financial and operational obligations, significantly impacting our business, financial condition, and prospects. If licensors conclude we have breached these agreements, they may terminate them, stripping us of the ability to develop and commercialize affected products. Termination or failure of underlying patents to provide intended exclusivity could allow competitors to market identical products, severely harming our competitive position, business, and operational outcomes.

The patent protection and patent prosecution for some of our product candidates may be dependent on third parties.

While we normally seek to obtain the right to control prosecution, maintenance and enforcement of the patents relating to our product candidates, there may be times when the filing and prosecution activities for patents relating to our product candidates are controlled by our licensor, potential licensors or collaboration partners. If any of our licensor, potential licensors or collaboration partners fail to prosecute, maintain and enforce such patents and patent applications in a manner consistent with the best interests of our business, including by payment of all applicable fees for patents covering our product candidates, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, our ability to develop and commercialize those product candidates may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products. In addition, even where we have the right to control patent prosecution of patents and patent applications we have licensed to and from third parties, we may still be adversely affected or prejudiced by actions or inactions of our licensees, our licensors and their counsel that took place prior to the date upon which we assumed control over patent prosecution.

Intellectual property discovered through government funded programs may be subject to federal regulations such as "march-in" rights, certain reporting requirements and a preference for U.S.-based companies. Compliance with such regulations may limit our exclusive rights and limit our ability to contract with non-U.S. manufacturers.

We have patent applications, in addition to the in-licensed patent from Aquanova, that were generated through the use of U.S. government funding or grants, and may acquire or license in the future intellectual property rights that have been generated through the use of U.S. government funding or grants. Pursuant to the Bayh-Dole Act of 1980, the U.S. government has certain rights in inventions developed with government funding. These U.S. government rights include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right, under certain limited circumstances, to require us to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third-party if it determines that: (1) adequate steps have not been taken to commercialize the invention; (2) government action is necessary to meet public health or safety needs; or (3) government action is necessary to meet requirements for public use under federal regulations (also referred to as "march-in rights"). If the U.S. government exercised its march-in rights in our future intellectual property rights that are generated through the use of U.S. government funding or grants, we could be forced to license or sublicense intellectual property developed by us or that we license on terms unfavorable to us, and there can be no assurance that we would receive compensation from the U.S. government for the exercise of such rights. The U.S. government also has the right to take title to these inventions if the grant recipient fails to disclose the invention to the government or fails to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us to expend substantial resources. In addition, the U.S. government requires that any products embodying any of these inventions or produced through the use of any of these inventions be manufactured substantially in the United States. This preference for U.S. industry may be waived by the federal agency that provided the funding if the owner or assignee of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. industry may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property.

Risks Related to Our Dependence on Third Parties

We rely, and expect to continue to rely, on third parties to conduct our clinical trials and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research and studies, which may harm our business.

We rely on third parties, such as CROs, clinical data management organizations, medical institutions, and clinical investigators, to conduct our clinical trials for JOTROL™ and other product candidates, as we lack the ability to independently manage these trials. These third parties, who are not our employees, play a significant role in trial execution and data analysis, but we have limited control over their resource allocation, and they may prioritize other entities, including competitors, or terminate engagements, potentially delaying our drug development. Despite reduced control, we remain responsible for ensuring trials comply with GCP standards enforced by the FDA and EMA, and failure to meet these or cGMP requirements for trial products could render data unreliable, necessitating additional trials and delaying marketing approvals. Performance failures by these third parties or distributors, who handle drug storage and distribution for our Company, could further hinder clinical development, approval, or commercialization, leading to losses and reduced revenue potential.

We contract with Aquanova and Catalent for the production of JOTROL™ for our ongoing clinical trial and other product candidates, and expect to continue to do so for additional clinical trials and ultimately for commercialization. This reliance on Aquanova and Catalent increases the risk that we will not have sufficient quality and quantities of our product candidates or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We lack the internal infrastructure to manufacture our product candidates for development and commercialization, relying entirely on Aquanova and Catalent to manufacture our preclinical and clinical trial supplies of JOTROL™. Currently, we depend on these companies as our only third-party manufacturer while evaluating possible other suppliers, but switching manufacturers could delay our supply chain, impacting JOTROL™'s development and increasing costs. Without long-term supply agreements, we purchase drug products on a purchase order basis, leaving us vulnerable to suppliers ceasing or altering terms at any time. An unexpected loss of supply due to manufacturing, storage, or other issues could disrupt, delay, or terminate ongoing clinical trials, requiring us to restart or repeat studies.

Our reliance on third-party manufacturers for commercial supply, if our product candidates gain marketing approval, introduces risks such as failure to meet our schedule or specifications, prioritization of other products by contractors, termination of agreements at inconvenient times, or breaches of contract. Additional risks include non-compliance with current Good Manufacturing Practices (cGMPs), mislabeling of clinical supplies, delayed delivery to trial sites or commercial vendors, and misappropriation of our proprietary information, including trade secrets. These issues could lead to clinical trial interruptions, lost sales, or compromised intellectual property, significantly affecting our operations.

We are developing our supply chain by establishing framework agreements with CDMOs to secure necessary quantities of active pharmaceutical ingredients and drug products. However, we may fail to establish these agreements or ensure redundant supply to mitigate disruptions. Our CDMOs' compliance with cGMP regulations and other regulatory requirements is critical, as their failure to meet FDA, EMA, or similar standards could prevent or revoke manufacturing approvals, forcing us to seek alternative facilities. Such transitions would require new regulatory inspections, delaying development, approval, or market entry of our product candidates.

Non-compliance by us or our manufacturers with regulations could result in sanctions like fines, injunctions, civil penalties, approval withdrawals, license revocations, product seizures, or criminal prosecutions, all of which could severely impact our product supply and business. Our dependence on third-party manufacturers may reduce future profit margins and hinder our ability to commercialize approved product candidates in a timely and competitive manner.

We rely on Catalent Pharmaceutical Services, Inc. as our sole manufacturer for JOTROL™ clinical trial supplies, and any disruption to this relationship could significantly delay our clinical development programs. We currently rely on Catalent Pharmaceutical Services, Inc. as our sole contract manufacturer for JOTROL™ clinical trial supplies. We do not have a backup manufacturer for JOTROL™, and establishing relationships with alternative manufacturers would require significant time and resources, including the need to transfer manufacturing technology and obtain regulatory approval for any new manufacturing facility. If Catalent is unable or unwilling to continue manufacturing JOTROL™ for any reason, including due to capacity constraints, regulatory compliance issues, natural disasters, business disruptions, financial difficulties, or a change in Catalent's business priorities, we may be unable to obtain sufficient quantities of JOTROL™ to conduct our clinical trials on schedule or at all. Any delay or inability to obtain clinical trial supplies could significantly delay our clinical development programs, increase our costs, and have a material adverse effect on our business, financial condition, and prospects.

We rely on third parties, including a network of collaborators and brand ambassadors, an advertising agency, and social media content creators to help promote and accelerate sales of our recently launched Nugevia product line, and our business could be adversely affected if these third parties fail to comply with applicable FDA (and other) regulatory requirements or are ineffective in their ability to help promote the Nugevia products to customers.

We depend in part on collaborators, social media content creators, two celebrity brand ambassadors, and other third parties to help drive traffic to our website and the sale of our products. As a result, our ability to maintain and increase commercial interest in our Nugevia products is not entirely within our control, and it is possible that these third parties may fail to successfully or meaningfully help drive sales of our products. Further, a failure by these third parties to comply with FDA, FTC, or other applicable regulatory requirements, such as requirements regarding the promotion, marketing and sale of our products, could result in regulatory enforcement action by FDA (or other governmental authorities) or other adverse events, which could interrupt the marketing and sales of our products, severely damage our brand reputation and public image, increase the cost of our products, result in product recalls, market withdrawals or litigation and impede our ability to deliver our products, any of which could result in a material adverse effect on our business, financial condition and results of operations.

We may rely on third-party manufacturers and distributors for our Nugevia product line, and any failure by these third parties to perform could adversely affect our business.

To the extent we rely on third-party manufacturers or distributors for the production and distribution of our Nugevia products, our business could be adversely affected if these third parties fail to meet their contractual obligations, experience manufacturing delays or disruptions, fail to comply with applicable regulatory requirements, or otherwise fail to perform satisfactorily. Any such failures could result in product shortages, delays in product delivery, quality control issues, or regulatory enforcement actions, any of which could harm our reputation, reduce sales of our Nugevia products, and have a material adverse effect on our business, financial condition, and results of operations.

Our reliance on third parties may require 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 third parties in the course of our business, we may share our proprietary technology and confidential information, including trade secrets, with them. We seek to protect our proprietary technology, in part, by entering into confidentiality agreements, and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our collaborators, advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information. 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 trade secrets, 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 engage in future acquisitions or strategic partnerships, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

We may periodically explore acquisition opportunities and strategic partnerships, such as licensing or acquiring complementary products, intellectual property, technologies, or businesses. These endeavors carry significant risks, including increased operating expenses and cash needs, assumption of additional debt or liabilities, and the issuance of equity securities. Integrating acquired operations, intellectual property, or personnel may pose challenges, diverting management's focus from existing programs. Retaining key employees, maintaining critical business relationships, and uncertainties about the other party's prospects, products, or regulatory approvals present further risks. Additionally, we may fail to generate sufficient revenue from acquired technologies or products to achieve our objectives or offset acquisition and maintenance costs. In addition, if we undertake acquisitions or pursue partnerships in the future, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense.

If we decide to establish collaborations, but are not able to establish those collaborations on commercially reasonable terms, we may have to alter our development and commercialization plans.

Our drug development programs and potential commercialization of product candidates require significant additional funding, which may lead us to pursue collaborations to enhance capabilities, accelerate research, or out-license rights for certain indications. These relationships could involve non-recurring charges, increased expenditures, issuance of dilutive securities, or management disruptions. We face intense competition in securing collaborators, and the complex, time-consuming negotiation process depends on factors like the collaborator's resources, expertise, and evaluation of clinical trial results, regulatory approval likelihood, market potential, manufacturing complexities, competing drugs, intellectual property uncertainties, and general market conditions. Alternative candidates or technologies may be deemed more attractive, and our early-stage candidates may not be viewed as viable for collaboration, potentially limiting our ability to form partnerships.

If we cannot secure collaborations on acceptable terms or at all, we may need to curtail development, delay programs, reduce marketing efforts, or fund activities independently, requiring additional capital that may not be available. Recent consolidations among large pharmaceutical companies have reduced potential collaborators, and even successful collaborations may impose restrictions on future agreements. Failure to secure sufficient funds or partnerships could hinder our ability to develop or commercialize product candidates, impacting our ability to generate revenue.

We may enter into collaborations with third parties for the development and commercialization of product candidates. If those collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates.

Collaborations with third parties for the development or commercialization of our product candidates involve limited control over the resources and efforts our collaborators dedicate, posing risks such as inadequate performance, deprioritization, or termination of programs due to clinical trial outcomes, strategic shifts, acquisitions, or competing priorities. Collaborators may delay trials, underfund programs, abandon candidates, or develop competing products, potentially undermining our candidates' success. Exclusive rights granted to collaborators could restrict our ability to partner with others, and their failure to properly manage our intellectual property may invite litigation or jeopardize proprietary information. Disputes, termination of agreements, or non-compliance with laws by collaborators could delay development, necessitate additional capital, or lead to costly legal proceedings, while their control over shared intellectual property may limit our exclusivity. Additionally, reliance on a network of expert advisors for our development efforts carries the risk that these experts may cease collaboration, hindering our ability to address muscle disease needs and develop our proprietary delivery platform.

Even if we are able to commercialize our product candidates, the products may not receive coverage and adequate reimbursement from third-party payers, which could harm our business.

Our ability to commercialize any products successfully will depend, in part, on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government authorities, private health insurers, health maintenance organizations and third-party payers. Patients who are prescribed medications for the treatment of their conditions generally rely on third-party payers to reimburse all or part of the costs associated with their prescription drugs. Coverage and adequate reimbursement from government health care programs, such as Medicare and Medicaid, and private insurers are essential to new product acceptance of any approved product. In the event we obtain marketing approval, patients are unlikely to use our product candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our product candidates. A key trend in the United States healthcare industry and elsewhere is cost containment. Government authorities and other third-party payers have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. We cannot be sure that coverage and adequate reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If coverage and reimbursement are not available or are available only at limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval. There may also be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or comparable foreign regulatory authorities. Moreover, obtaining coverage does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sales and distribution. Interim reimbursement levels for new drugs, if applicable, may also be insufficient to cover our costs, and may only be temporary.

Risks Related to Ownership of Our Securities

The Company's failure to meet the continued listing requirements of The Nasdaq Capital Market could result in a delisting of its securities.

Our common stock is currently listed for trading on The Nasdaq Stock Market LLC ("Nasdaq"). On March 21, 2025, the Company received a written notice from the Listing Qualifications Department of Nasdaq indicating that the Company was not in compliance with the minimum bid price requirement set forth under Nasdaq Listing Rule 5550(a)(2) (the "Minimum Bid Price Requirement"), as the closing bid price of the Company's common stock was below $1.00 per share for 30 consecutive business days.. Listing Rule 5550(a)(2) requires the registrant to maintain a minimum bid price of $1.00 USD per share for its securities listed on the NASDAQ, and Listing Rule 5810(c)(3)(A) provides that a failure to meet the minimum bid price requirement exists if the deficiency continues for a period of 30 consecutive business days. Based on the closing bid price of the Company's shares for the 30 consecutive business days prior to that notice (February 6, 2025 through March 20, 2025), the Company did not meet the Minimum Bid Price Requirement.

Subsequently, on February 26, 2026, the Company received additional written notices (the "Notices") from Nasdaq indicating that the Company is not in compliance with (i) the Minimum Bid Price Requirement and (ii) the minimum market value of listed securities requirement set forth under Nasdaq Listing Rule 5550(b)(2) (the "MVLS Requirement"). Based on the closing bid price of the Company's common stock for the 30 consecutive business days prior to the Notices (January 13, 2026 through February 25, 2026), the Company did not meet the Minimum Bid Price Requirement. In addition, based on Nasdaq's review of the Company's market value of listed securities for the 30 consecutive business days ended February 26, 2026, the Company did not meet the MVLS Requirement.

Pursuant to Nasdaq Listing Rules 5810(c)(3)(A) and 5810(c)(3)(C), the Company has 180 calendar days, or until August 25, 2026, to regain compliance with both the Minimum Bid Price Requirement and the MVLS Requirement. To regain compliance with the Minimum Bid Price Requirement, the Company's common stock must have a closing bid price of at least $1.00 per share for a minimum of 10 consecutive business days (or such longer period, up to 20 consecutive business days, as Nasdaq may require). To regain compliance with the MVLS Requirement, the Company's market value of listed securities must be at least $35 million for a minimum of 10 consecutive business days.

If the Company does not regain compliance with the Minimum Bid Price Requirement by August 25, 2026, the Company may be eligible for an additional 180-day compliance period, provided that it meets all other initial listing standards for The Nasdaq Capital Market, other than the Minimum Bid Price Requirement, and provides written notice of its intention to cure the deficiency, including, if necessary, by effecting a reverse stock split. If the Company does not regain compliance with the MVLS Requirement within the applicable compliance period, Nasdaq will provide notice that the Company's common stock is subject to delisting. In such event, the Company may appeal the delisting determination to a hearings panel.

The receipt of the Notices has no immediate effect on the listing of the Company's common stock, and the common stock will continue to trade on Nasdaq under the symbol "JUNS" during the applicable compliance periods. The Company intends to actively monitor its compliance with Nasdaq continued listing requirements and may consider available options to regain compliance, including, without limitation, effecting a reverse stock split. However, there can be no assurance that the Company will be successful in regaining or maintaining compliance with the Nasdaq continued listing requirements.

If Nasdaq delists the Company's common stock, the Company's liquidity and market price could be affected.

Our common stock is currently listed on Nasdaq. If we do not regain compliance, our common stock may begin trading on an over-the-counter market, such as the OTCQB or the OTC Pink. Trading on such markets is characterized by lower trading volumes, fewer market makers and greater price volatility compared to trading on a national securities exchange. As a result, a delisting could reduce the liquidity of our common stock, result in decreased institutional investor interest and may impair a stockholder's ability to sell or purchase shares of our common stock. In addition, delisting could impair our ability to raise additional capital.

The price of our common stock could be subject to rapid and substantial volatility.

There have been instances of extreme stock price run-ups followed by rapid price declines and strong stock price volatility with recent initial public offerings, especially among those with relatively smaller public floats. As a relatively small-capitalization company with relatively small public float, we may experience greater stock price volatility, extreme price run-ups, lower trading volume and less liquidity than large-capitalization companies. In particular, the common stock may be subject to rapid and substantial price volatility, low volumes of trades and large spreads in bid and ask prices. Such volatility, including any stock-run up, may be unrelated to our actual or expected operating performance and financial condition or prospects, making it difficult for prospective investors to assess the rapidly changing value of our common stock.

In addition, if the trading volumes of our common stock are low, persons buying or selling in relatively small quantities may easily influence prices of our common stock. This low volume of trades could also cause the price of our common stock to fluctuate greatly, with large percentage changes in price occurring in any trading day session. Holders of our common stock may also not be able to readily liquidate their investment or may be forced to sell at depressed prices due to low volume trading. Broad market fluctuations and general economic and political conditions may also adversely affect the market price of our common stock. As a result of this volatility, investors may experience losses on their investment in our common stock. A decline in the market price of our common stock also could adversely affect our ability to sell additional shares or common stock or other securities and our ability to obtain additional financing in the future. No assurance can be given that an active market in our common stock will develop or be sustained. If an active market does not develop, holders of our common stock may be unable to readily sell the common stock they hold or may not be able to sell their common stock at all.

A "short squeeze" due to a sudden increase in demand for shares of our common stock could lead to extreme price volatility in shares of our common stock.

Investors may purchase shares of our common stock to hedge existing exposure or to speculate on the price of our common stock. Speculation of the price of our common stock may lead to long and short exposures. To the extent aggregate short exposure exceeds the number of shares of our common stock available for purchase on the open market, investors with short exposure may have to pay a premium to repurchase shares of our common stock for delivery to lenders of our common stock. Those repurchases may in turn, dramatically increase the price of our common stock until additional shares of our common stock are available for trading or borrowing. This is often referred to as a "short squeeze." A proportion of our common stock has been, and may continue to be, traded by short sellers which may increase the likelihood that our common stock will be the target of a short squeeze. A short squeeze could lead to volatile price movements in shares of our common stock that are unrelated or disproportionate to our operating performance and, once investors purchase the shares of our common stock necessary to cover their short positions, the price of our common stock may rapidly decline. Investors that purchase shares of our common stock during a short squeeze may lose a significant portion of their investment.

The market price of our common stock may be volatile, and you could lose all or part of your investment.

The market price of our common stock may fluctuate significantly due to factors often beyond our control and unrelated to our operating performance, including the timing and results of preclinical studies and clinical trials for our product candidates or those of competitors, the success or announcements of competitive products, regulatory actions, changes in our growth rate compared to competitors, developments or disputes over patents or proprietary rights, key personnel changes, significant acquisitions or collaborations, changes in financial estimates or analyst recommendations, market conditions in the pharmaceutical and biotechnology sectors, changes in healthcare payment systems, additional financing efforts, sales of our stock by insiders or other stockholders, and general economic, political, industry, and market conditions. The limited public float of our stock may increase price volatility, and the stock market, particularly for pharmaceutical and biotechnology companies, has historically experienced extreme price and volume fluctuations, which could lead to substantial losses for investors. Any of these risks could materially and adversely affect our stock price.

If securities or industry analysts do not publish research or reports, or if they publish adverse or misleading research or reports, regarding us, our business or our market, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that securities or industry analysts publish about us, our business or our market. We do not currently have and may never obtain research coverage by securities or industry analysts. If no or few securities or industry analysts commence coverage of us, the stock price would be negatively impacted. In the event we obtain securities or industry analyst coverage, if any of the analysts who cover us issue adverse or misleading research or reports regarding us, our business model, our intellectual property, our stock performance or our market, or if our operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or our guidance.

Our operating results may fluctuate significantly due to factors such as variable upfront and milestone payments from license or collaboration agreements, changes in stock-based compensation expenses driven by stock price volatility, and costs related to research and development, clinical trial enrollment, and manufacturing. Additional factors include expenditures for acquiring new technologies, outcomes and timing of clinical trials for JOTROL™ or other product candidates, competition, regulatory delays, demand variability, reimbursement policies, and our ability to commercialize products or maintain partnerships. Global economic and political volatility, unforeseen disruptions, and accounting changes may further contribute to fluctuations. These factors make our future operating results unpredictable, rendering period-to-period comparisons unreliable and potentially causing our results or guidance to fall below analyst or investor expectations, which could lead to a substantial decline in our stock price, even if we meet previously stated guidance

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

As of December 31, 2025, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 59% of our common stock. These stockholders, acting together, may be able to control matters requiring stockholder approval. For example, they may be able to control elections of directors, amendments of our organizational documents or approval of any merger, sale of assets or other major corporate transactions. This concentration of ownership control may delay, discourage or prevent a change of control, including unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders, entrench our management and board of directors or delay or prevent a merger, consolidation, takeover or other business combination involving us that other stockholders may desire. The interests of this group of stockholders may not always coincide with your interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the prevailing market price for our common stock.

Our common stock may be subject to the "penny stock" rules in the future. It may be more difficult to resell securities classified as "penny stock."

Our common stock may be subject to "penny stock" rules (generally defined as non-exchange traded stock with a per-share price below $5.00) in the future. While our common stock is not currently considered "penny stock" since it is listed on the Nasdaq, if we are unable to maintain that listing and our common stock is no longer listed on the Nasdaq, unless we maintain a per-share price above $5.00, our common stock will become "penny stock." These rules impose additional sales practice requirements on broker-dealers that recommend the purchase or sale of penny stocks to persons other than those who qualify as "established customers" or "accredited investors." For example, broker-dealers must determine the appropriateness for non-qualifying persons of investments in penny stocks. Broker-dealers must also provide, prior to a transaction in a penny stock not otherwise exempt from the rules, a standardized risk disclosure document that provides information about penny stocks and the risks in the penny stock market. The broker-dealer also must provide the customer with current bid and offer quotations for the penny stock, disclose the compensation of the broker-dealer and its salesperson in the transaction, furnish monthly account statements showing the market value of each penny stock held in the customer's account, provide a special written determination that the penny stock is a suitable investment for the purchaser, and receive the purchaser's written agreement to the transaction.

Legal remedies available to an investor in "penny stocks" include the ability to seek cancellation of the purchase and a refund of the investment if the stock was sold in violation of federal or state securities laws, such as the requirements outlined above. Additionally, if the "penny stock" was sold through fraudulent means, the investor may have the right to pursue legal action against the individuals or firms responsible for the fraud, seeking damages for any losses incurred. These requirements may have the effect of reducing the level of trading activity, if any, in the secondary market for a security that becomes subject to the penny stock rules. The additional burdens imposed upon broker-dealers by such requirements may discourage broker-dealers from effecting transactions in our securities, which could severely limit the market price and liquidity of our securities. These requirements may restrict the ability of broker-dealers to sell our common stock and may affect your ability to resell our common stock.

Many brokerage firms will discourage or refrain from recommending investments in penny stocks. Most institutional investors will not invest in penny stocks. In addition, many individual investors will not invest in penny stocks due, among other reasons, to the increased financial risk generally associated with these investments. For these reasons, penny stocks may have a limited market and, consequently, limited liquidity. We can give no assurance at what time, if ever, our common stock will not be classified as a "penny stock" in the future.

If the benefits of any proposed acquisition do not meet the expectations of investors, stockholders or financial analysts, the market price of our Common Stock may decline.

If the benefits of any proposed acquisition do not meet the expectations of investors or securities analysts, the market price of our common stock prior to the closing of the proposed acquisition may decline. The market values of our common stock at the time of the proposed acquisition may vary significantly from their prices on the date the acquisition target was identified.

In addition, broad market and industry factors may materially harm the market price of our common stock irrespective of our operating performance. The stock market in general has experienced price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of the particular companies affected. The trading prices and valuations of these stocks, and of our securities, may not be predictable. A loss of investor confidence in the market for retail stocks or the stocks of other companies which investors perceive to be similar to us could depress our stock price regardless of our business, prospects, financial conditions or results of operations. A decline in the market price of our securities also could adversely affect our ability to issue additional securities and our ability to obtain additional financing in the future.

Changes in accounting principles and guidance, or their interpretation, could result in unfavorable accounting charges or effects, including changes to our previously filed financial statements, which could cause our stock price to decline.

We prepare our financial statements in accordance with GAAP. These principles are subject to interpretation by the SEC and various bodies formed to interpret and create appropriate accounting principles and guidance. A change in these principles or guidance, or in their interpretations, may have a significant effect on our reported results and retroactively affect previously reported results.

As an "emerging growth company" under the JOBS Act, we are permitted to rely on exemptions from certain disclosure requirements.

As an "emerging growth company" under the JOBS Act, we are permitted to rely on exemptions from certain disclosure requirements, which we intend to utilize. For as long as we maintain this status, we are not required to obtain an auditor's report on our internal control over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act. Additionally, we are exempt from complying with any Public Company Accounting Oversight Board requirements regarding mandatory audit firm rotation or providing a supplement to the auditors' report with additional information about the audit and financial statements, such as an auditor discussion and analysis. Furthermore, we are not obligated to submit certain executive compensation matters to stockholder advisory votes, including "say-on-pay" and "say-on-frequency" votes, nor are we required to disclose specific executive compensation details, such as the correlation between executive compensation and company performance or comparisons of the chief executive officer's compensation to the median employee compensation.

As an emerging growth company under the JOBS Act, we have elected to use the extended transition period for adopting new or revised accounting standards, delaying compliance until required for private companies. This may make our financial statements less comparable to those of companies adhering to these standards. We will remain an emerging growth company until the earliest of: (i) annual gross revenue reaching $1.235 billion; (ii) the market value of our non-affiliate-held common stock reaching $700.0 million as of the last business day of our most recently completed second fiscal quarter; (iii) issuing over $1.0 billion in non-convertible debt in the prior three years; or (iv) the fifth anniversary of our initial public offering. Relying on these exemptions may reduce the attractiveness of our securities, potentially leading to a less active trading market and increased price volatility.

If we are unable to maintain effective internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports and have an adverse effect on the value of our securities.

As a public company, we are required to maintain internal control over financial reporting and to report any material weaknesses in such internal control. Further, we are required to report any changes in internal controls on a quarterly basis. In addition, we are required to furnish a report by management on the effectiveness of internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act. We will design, implement, and test the internal controls over financial reporting required to comply with these obligations. If we identify material weaknesses in our internal control over financial reporting, if we are unable to comply with the requirements of Section 404 in a timely manner or assert that our internal control over financial reporting is effective, or if our independent registered public accounting firm is unable to express an opinion as to the effectiveness of its internal control over financial reporting when required, investors may lose confidence in the accuracy and completeness of our financial reports and the value of our securities could be negatively affected. We also could become subject to investigations by the Commission or other regulatory authorities, which could require additional financial and management resources

As an emerging growth company, our auditor will not be required to attest to the effectiveness of our internal controls.

Our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting while we are an emerging growth company. This means that the effectiveness of our financial operations may differ from our peer companies in that they may be required to obtain independent registered public accounting firm attestations as to the effectiveness of their internal controls over financial reporting and we are not. While our management will be required to attest to internal control over financial reporting and we will be required to detail changes to our internal controls on a quarterly basis, we cannot provide assurance that the independent registered public accounting firm's review process in assessing the effectiveness of our internal controls over financial reporting, if obtained, would not find one or more material weaknesses or significant deficiencies. Further, once we cease to be an emerging growth company and cease to be a smaller reporting company (as described below), we will be subject to independent registered public accounting firm attestation regarding the effectiveness of our internal controls over financial reporting. Even if management finds such controls to be effective, our independent registered public accounting firm may decline to attest to the effectiveness of such internal controls and issue a qualified report.

We believe we will be considered a smaller reporting company and will be exempt from certain disclosure requirements, which could make our Common Stock less attractive to potential investors.

We qualify as a "smaller reporting company" under Rule 12b-2 of the Exchange Act, defined as an issuer (not an investment company, asset-backed issuer, or majority-owned subsidiary of a non-smaller reporting company parent) with either: a public float of less than $250 million as of the last business day of its most recently completed second fiscal quarter, or, for initial registration statements, a public float of less than $250 million within 30 days of filing, or annual revenues of less than $100 million with a public float of zero or less than $700 million for the most recent fiscal year with audited financial statements. As a smaller reporting company, we benefit from scaled disclosure requirements, including no Compensation Discussion and Analysis in proxy statements, providing only two years of financial statements, and omitting the selected financial data table. These reduced disclosures may make our common stock less attractive to investors, potentially impacting our stockholders' ability to sell shares.

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

As a public company, we incur significant legal, accounting, and compliance costs, particularly under the Sarbanes-Oxley Act, which requires effective disclosure and financial controls. These obligations demand substantial management time and increase our legal and financial expenses, including challenges in obtaining directors' and officers' liability insurance, potentially hindering our ability to attract qualified board members. Compliance with Section 404 of the Sarbanes-Oxley Act requires evaluating and testing our internal controls over financial reporting, and, after our emerging growth company or smaller reporting company status ends, obtaining an auditor's attestation. This necessitates additional accounting staff and resources. Failure to comply with Section 404, or identification of material weaknesses in our controls, could lead to SEC sanctions, investigations, or a decline in our securities' value. Delays or disruptions in implementing enhanced systems and controls may impair our ability to prepare accurate financial statements, potentially affecting our internal control effectiveness, auditor reports, and access to capital markets.

Shares eligible for future sale may adversely affect the market.

From time to time, certain of our stockholders may be eligible to sell all or some of their shares of common stock by means of ordinary brokerage transactions in the open market pursuant to Rule 144 promulgated under the Securities Act, subject to certain limitations. In general, pursuant to Rule 144, non-affiliate stockholders may sell freely after six months, subject only to the current public information requirement. Affiliates may sell after six months, subject to the Rule 144 volume, manner of sale (for equity securities), current public information, and notice requirements. Of the approximately 34,446,455 shares of our common stock and 1,626,037 restricted stock units outstanding as of December 31, 2025, 6,350,000 shares are tradable without restrictions. Given the limited trading of our common stock, resale of even a small number of shares of our common stock pursuant to Rule 144 or an effective registration statement may adversely affect the market price of our common stock.

Anti-takeover provisions contained in our certificate of incorporation, as amended, and amended and restated bylaws, as well as provisions of Delaware law, could impair a takeover attempt.

Our Certificate of Incorporation and amended bylaws include provisions that could delay or prevent changes in control or management without board approval, such as prohibiting cumulative voting in director elections, limiting minority stockholders' ability to elect candidates, and granting the board exclusive authority to fill director vacancies, preventing stockholder appointments. The board can issue preferred stock with terms set without stockholder approval, potentially diluting hostile acquirers, and directors are protected by limited liability and indemnification provisions. Only the board's majority can call special stockholder meetings, and removing directors requires a two-thirds stockholder vote. Advance notice requirements for nominating directors or proposing matters at meetings may deter potential acquirers from pursuing control. These provisions could delay hostile takeovers or management changes, potentially limiting opportunities for stockholders to receive a premium for their securities and affecting the price investors are willing to pay.

We may be subject to securities litigation, which is expensive and could divert management attention.

The market price of our common stock may be volatile and, in the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. This risk is especially relevant for us because biotechnology companies have experienced significant stock price volatility in recent years and we may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

We have never paid dividends on our common stock and have no plans to do so in the future.

Holders of shares of our common stock are entitled to receive such dividends as may be declared by our board of directors. To date, we have paid no cash dividends on our shares of common stock and we do not expect to pay cash dividends on our common stock in the foreseeable future. We intend to retain future earnings, if any, to provide funds for operations of our business. Therefore, any return investors in our common stock may have will be in the form of appreciation, if any, in the market value of their shares of common stock. See "Dividend Policy."

We will indemnify and hold harmless our officers and directors to the maximum extent permitted by Delaware law.

Our certificate of incorporation provides that we will indemnify and hold harmless our officers and directors against claims arising from our activities, to the maximum extent permitted by Delaware law. If we were called upon to perform under our indemnification obligations, then the portion of our assets expended for such purpose would reduce the amount otherwise available for our business.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 1C. CYBERSECURITY

Cybersecurity Risk Management and Strategy

The cybersecurity risk management program, processes and strategy described in this section are limited to the personal and business information belonging to or maintained by the Company (collectively, "Confidential Information"), our own third-party critical systems and services supporting or used by the Company (collectively, "Critical Systems"), and service providers.

We will develop and implement a cybersecurity risk management program intended to protect the confidentiality, integrity, and availability of our Confidential Information and Critical Systems. Our cybersecurity risk management program will be integrated into our overall enterprise risk management program and includes a cybersecurity incident response plan.

Our cybersecurity risk management program shall include:

- risk assessments designed to help identify material cybersecurity risks to our Confidential Information, Critical Systems and the broader enterprise information technology environment;
- a security team principally responsible for managing (i) our cybersecurity risk assessment processes, (ii) our security controls, and (iii) our response to cybersecurity incidents;
- cybersecurity awareness and spear-phishing resistance training of our employees, and senior management;
- a cybersecurity incident response plan that includes procedures for responding to cybersecurity incidents; and
- a vendor management policy for service providers.

We have not identified risks from known cybersecurity threats, including as a result of any prior cybersecurity incidents, that have materially affected or are reasonably likely to materially affect us, including our operations, business strategy, results of operations, or financial condition.

Cybersecurity Governance

Our executive management team, along with our managed information technology service provider, is responsible for assessing and managing risks from cybersecurity threats to the Company, including our Confidential Information and Critical Systems. The team has primary responsibility for our overall cybersecurity risk management program. Our management team works closely with our information technology service provider.

Our management team meets with our information technology service provider periodically to discuss then-current cybersecurity issues, which may include efforts to prevent, detect, mitigate, and remediate cybersecurity risks and incidents through various means, including threat intelligence and other information obtained from governmental, public or private sources, and external service providers engaged by us; and alerts and reports produced by security tools deployed in the information technology environment including a spear-phishing report.

Our Board considers cybersecurity risk as part of its risk oversight function and oversight of cybersecurity and other information technology risks.

Our Board oversees management's implementation of our cybersecurity risk management program. Our executive management team is responsible for updating the Board, as necessary, regarding significant cybersecurity incidents.

Our Board also receives periodic reports from management on our cybersecurity risks and cybersecurity risk management program.

ITEM 2. PROPERTIES

Our corporate headquarters are located at 1001 North US Hwy 1, Suite 504, Jupiter, Florida 33477, where we lease approximately 1,206 rentable square feet of office space. This lease expires on May 31, 2026. Terms of the office lease provide for a base rent payment of $4,258 per month and a share of the building's operating expenses, such as taxes and maintenance, of $600 per month. In September 2021, we added an additional office located at 127 Main Street, Boston, Massachusetts 02129 for 120 rentable square feet of office space for our Boston-based employees and scientist to utilize as necessary.

We believe that these facilities are adequate for our current and near-term future needs.

ITEM 3. LEGAL PROCEEDINGS

From time to time, we are involved in various legal proceedings arising from the normal course of business activities. We are not presently a party to any litigation the outcome of which, we believe, if determined adversely to us, would individually or taken together have a material adverse effect on our business, operating results, cash flows or financial condition. Defending such proceedings is costly and can impose a significant burden on management and employees. The results of any current or future litigation cannot be predicted with certainty, and regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources, and other factors.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our common stock is listed on The Nasdaq Capital Market and its stock symbol is "JUNS." The closing price of our common stock on The Nasdaq Capital Market on March 30, 2026 was $0.3248.

Holders

As of March 31, 2026, there were 36,281,252 shares of common stock issued and outstanding, and we had approximately 29 holders of record of our common stock. The number of record holders does not include beneficial owners of common stock whose shares are held in the names of banks, brokers, nominees or other fiduciaries.

Dividends

We have not declared or paid any cash dividends on our common stock since our inception, and do not currently anticipate paying cash dividends in the foreseeable future. We intend to retain future earnings, if any, for reinvestment in the development and expansion of our business.

Securities Authorized for Issuance Under Equity Compensation Plans

The Company's stockholders approved the 2016 Equity Incentive Plan ("2016 Plan") on January 4, 2016. Under the 2016 Plan, as modified, 8,437,500 shares of common stock are authorized for issuance to employees, officers, directors, consultants. The 2016 Plan authorizes the grant of nonqualified stock options and incentive stock options, restricted stock awards, restricted stock units, stock appreciation rights, under the 2016 Plan. The Company does not intend to make any grants under the 2016 Plan.

The Board of Directors and stockholders of the Company approved the 2021 Equity Incentive Plan (the "2021 Plan") on September 17, 2021. Under the 2021 Plan, 1,125,000 shares of common stock are authorized for issuance to employees, directors and independent contractors (except those performing services in connection with the offer or sale of the Company's securities in a capital raising transaction, or promoting or maintaining a market for the Company's securities. The 2021 Plan authorizes equity-based and cash-based incentives for participants. On July 22, 2022, the Board of Directors increased the shares authorized in the 2021 Plan, increasing the plan to 1,710,000. The Company does not intend to make any grants under the 2021 Plan.

The Board of Directors and stockholders of the Company approved the 2023 Equity Incentive Plan (the "2023 Plan") on October 4, 2023. Under the 2023 Plan, 4,012,785 shares of common stock are authorized for issuance to employees, directors and independent contractors (except those performing services in connection with the offer or sale of the Company's securities in a capital raising transaction, or promoting or maintaining a market for the Company's securities) of the Company or its subsidiaries. As of March 31, 2026, there were 1,047,135 shares available for issuance under the 2023 Plan.

The Board of Directors and stockholders of the Company approved the 2025 Equity Incentive Plan (the "2025 Plan") on December 19, 2025. Under the 2025 Plan, 5,250,000 shares of common stock are authorized for issuance to employees, directors and independent contractors (except those performing services in connection with the offer or sale of the Company's securities in a capital raising transaction, or promoting or maintaining a market for the Company's securities) of the Company or its subsidiaries. As of March 31, 2026, there were 5,250,000 shares available for issuance under the 2025 Plan.

Recent Sales of Unregistered Securities

Name	Date	Type	Type of Award	Quantity	Price
A service provider	April 23, 2025	Granted	Common Stock	78,186	$ 0.64
A service provider	April 23, 2025	Granted	Common Stock	25,000	$ 0.64

The above issuances/sales were made pursuant to an exemption from registration as set forth in Section 4(a)(2) of the Securities Act and/or Rule 506 of Regulation D promulgated under the Securities Act.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Transfer Agent

The Company's transfer agent is Equiniti Trust Company. The transfer agent's address is 1110 Centre Pointe Curve, Suite 101, Mendota Heights, Minnesota 55120, and its telephone number is (800) 401-1957.

ITEM 6. [RESERVED]

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Special Note Regarding Forward-Looking Statements

All statements other than statements of historical fact included in this Annual Report on Form 10-K, including, without limitation, statements under "Management's Discussion and Analysis of Financial Condition and Results of Operations" regarding the Company's financial position, business strategy and the plans and objectives of management for future operations, are forward-looking statements. When used in this Annual Report on Form 10-K, words such as "anticipate," "believe," "estimate," "expect," "intend" and similar expressions, as they relate to us or the Company's management, identify forward-looking statements. Such forward-looking statements are based on the beliefs of management, as well as assumptions made by, and information currently available to, the Company's management. Actual results could differ materially from those contemplated by the forward-looking statements as a result of certain factors detailed in our filings with the SEC.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the financial statements and the notes thereto contained elsewhere in this Annual Report on Form 10-K. Certain information contained in the discussion and analysis set forth below includes forward-looking statements that involve risks and uncertainties. Unless the context otherwise requires, "JNS," "we," "us," "our," or the "Company" refers to Jupiter Neurosciences, Inc.

Business Overview

Jupiter Neurosciences, Inc. is a clinical stage research and development pharmaceutical company located in Jupiter, Florida. The Company is advancing a therapeutic pipeline targeting CNS disorders and rare diseases, while also expanding into the consumer longevity market with its Nugevia product line. Both efforts are powered by JOTROL™, Jupiter's proprietary, enhanced resveratrol formulation that has demonstrated potential for improved bioavailability compared to standard resveratrol. The Company's therapeutic development pipeline is focused broadly on CNS disorders, presently with a planned Phase IIa clinical study in Parkinson's disease. The Company's Nugevia product line brings clinical-grade science to the supplement space, supporting mental clarity, healthy-looking skin, and longevity.

The Company completed preclinical studies at the University of Miami for Parkinson's Disease in 2021. These studies used a validated mouse model to mimic human disease characteristics. The promising results have led the Company to initiate a Phase IIa clinical trial for Parkinson's Disease, which received final IND approval by the FDA in November of 2025 and is expected to start in the second quarter of 2026, with results anticipated 12 months later. The Company also aims to investigate other CNS indications, such as MCI and Alzheimer's disease, following the Parkinson's study.

The Company believes, based on pre-clinical and clinical studies, that high doses of resveratrol are necessary for potential therapeutic effects. Currently available resveratrol products cannot reach these levels without causing severe gastrointestinal side effects. Human studies evaluating resveratrol in Alzheimer's patients (Turner et al 2015) and Friedreich's Ataxia patients (Yu et al 2015) indicate the concentration of resveratrol at its peak (CMax) measured in blood plasma should be 300 ng/ml or higher for a potential therapeutic effect. A Phase 1 study with 500mg of resveratrol as a maximum dose in the JOTROL™ formulation showed levels of resveratrol exceeding 800 ng/ml without generating any severe adverse events (AAPS Open 2022). Resveratrol was shown in the Turner Alzheimer's study to cross the blood-brain barrier, possibly indicating a potential for positive effects on oxidative stress and inflammation. Subsequent analysis published in Molecular Science 2025 (Mousa et al) further indicates that resveratrol may have an impact on neurodegeneration and neuroinflammation in Alzheimer's patients.

Over the past two years, JOTROL™ has garnered significant interest from Asian organizations. This interest is partly due to resveratrol's use in Asian herbal medicines, recent patent approvals in Hong Kong and China, and China's list of rare disease indications where JOTROL™ could be applicable. Additionally, recent publications in the Journal of Alzheimer's Disease and AAPS Open, along with the projected growth of the Traditional Chinese Medicine market, have contributed to this interest.

The Company has entered service agreements with firms in Hong Kong to accelerate product development in Southeast Asia. These agreements aim to leverage local expertise and networks to facilitate market entry and potential out-licensing deals. The Company entered into an agreement with Dominant Treasure Health to expand its business development in China, Malaysia, and Singapore, aiming to penetrate the large and challenging Asian market.

During 2025, the Company launched Nugevia, a premium line of longevity and performance supplements to support longevity, mental clarity and skin vitality. The Nugevia brand targets the growing consumer demand for science-backed wellness solutions, leveraging Jupiter's proprietary JOTROL™ technology—a resveratrol-based platform with an improvement in bioavailability profile of resveratrol.

Nugevia's initial product line features three core formulations, each targeting a major aspect of wellness and longevity:

Product Name	Focus Area	Target Consumer Benefit
GLO	Skin beauty	Support skin beauty and healthy appearance
MND	Cognitive performance	Supports mental clarity, cognitive resilience
PWR	Mitochondrial and physical health	Maintains energy, endurance, muscle recovery

Nugevia's formulations are built on Jupiter's patented JOTROL™ micellar delivery platform, which has shown potential for significantly enhanced bioavailability and serves as the foundation for the company's clinical-stage CNS therapies. The debut products—GLO, MND, and PWR—are formulated to support wellness and longevity through synergistic ingredient combinations, all optimized for absorption via the JOTROL™ system.

On October 24, 2025, the Company entered into a Standby Equity Purchase Agreement (the "SEPA") and related Registration Rights Agreement with YA II PN, Ltd. ("Yorkville"), providing the Company the right, but not the obligation, to sell up to $20.0 million of common stock from time to time, subject to customary conditions, including an effective resale registration statement. In connection with the SEPA, Yorkville agreed to provide up to $6.0 million of pre-paid advances via convertible promissory notes. On October 27, 2025, the Company received $3,720,000 and issued a $4.0 million note (7% original issue discount, "OID"). A second $1,860,000 tranche was received in December 2025, upon registration effectiveness and receipt of stockholder approval, against a $2.0 million note (7% OID). The notes bear interest at 8% (increasing to 18% upon default), mature on October 24, 2026, and are convertible at $1.50 per share, subject to proportional anti-dilution and price-protection adjustments (not below a contractual floor). Beginning January 7, 2026, and monthly thereafter, the Company must repay one-tenth (1/10) of the then-outstanding principal plus accrued interest (a 5% premium applies to cash repayments). Installments may be satisfied via SEPA advances without the premium, and SEPA proceeds must be applied first to repay the notes until they are repaid in full. On February 20, 2026, the Company and Yorkville entered into an Omnibus Amendment (the "Amendment"). Among other changes, the Amendment revises the terms of the convertible promissory notes to defer the commencement of monthly installment payments to April 1, 2026, effectively providing an extension of approximately three months.

In December 2024, we received gross proceeds of $11 million in a registered public offering ("Public Offering") of 2,750,000 shares of our common stock at a price of $4.00 per share for gross proceeds of $11 million before deducting underwriting discounts and other related expenses. In connection with the Public Offering, the Company's common stock was registered under Section 12(b) of the Exchange Act and began trading on The Nasdaq Capital Market under the symbol "JUNS."

Financial Position

For the fiscal years ended December 31, 2025 and 2024, we generated net revenues of $21,796 and $0, respectively from product sales and reported net losses of $8,644,897 and $2,439,625, respectively, and negative cash flow from operating activities of $5,413,736 and $3,911,004, respectively. As noted in our financial statements, as of December 31, 2025 and 2024, we had an accumulated deficit of $34,667,026 and $26,022,129, respectively. There is substantial doubt regarding our ability to continue as a going concern as a result of our historical recurring losses and negative cash flows from operations as well as our dependence on private equity and financings. See "Risk Factors—We have a history of operating losses, our management has concluded that factors raise substantial doubt about our ability to continue as a going concern and our auditor has included an explanatory paragraph relating to our ability to continue as a going concern in its audit report for the fiscal years ended December 31, 2025 and 2024."

Results of Operations

Year Ended December 31, 2025 Compared to Year Ended December 31, 2024

Revenue

There was net revenue of $21,796 during the year ended December 31, 2025. Net revenue consisted of product sales from the Company's Nugevia consumer product line, which launched in the second half 2025. Gross sales were $24,874, offset by discounts of $1,777 and returns of $1,301. Cost of goods sold through commercial products was $4,231, resulting in gross profit of $17,565. There was no revenue from product sales during the years ended December 31, 2024 as Nugevia was launched in 2025.

Research and Development Expenses

Research and development ("R&D") expenses were $2,086,574 for the year ended December 31, 2025, compared to $492,660 for the year ended December 31, 2024. The increase is driven primarily by $810,019 in consulting and professional fees, $438,425 in payroll and stock-based compensation, and $345,470 in clinical trial supplies and miscellaneous costs as the Company prepared for initiation of its Phase IIa Parkinson's disease trial.

R&D expenses related to the development of JOTROL™, which is the platform product used in each indication defined in our product pipeline.

General and Administrative Expenses

General and administrative expenses were $6,839,712 for the year ended December 31, 2025 compared to $2,598,622 for the year ended December 31, 2024, an increase of $4,241,090 or approximately 163%. The increase is primarily related to the increase in employee salaries of approximately $1,730,902, consulting and professional services of approximately $908,363, investor relations of approximately $472,923, and other general and administrative costs of $1,108,902.

Interest Expense

Interest expenses were $66,020 for the year ended December 31, 2025, compared to $248,366 for the year ended December 31, 2024, decrease of $182,346, or approximately 73%. During 2024, interest expense included $147,705 related to the combined convertible Notes I, II, and III, and $15,013 related to the amortization of debt discounts. In 2025, interest expense is primarily attributable to accrued interest on the SEPA and interest expense on our corporate credit card and the note payable to our Chief Executive Officer, Christer Rosén, which was repaid during 2025.

Gain on Change in Fair Value of Convertible Notes

The 2025 convertible promissory notes issued in connection with the SEPA were marked to market, and the change in fair value of the convertible notes was recorded as a gain of $281,932 in the year ended December 31, 2025.

Loss on Change in Fair Value of Derivative Liability

As of December 31, 2024 and at each quarter end during the year, the variable conversion options embedded in our convertible notes were marked to market, and the change in fair value of the derivative was recorded as a loss of $53,257. These notes were fully paid off in the year ended December 31, 2024.

Gain on Extinguishment of Debt

During the year ended 2024, the Senior Secured Convertible Note was amended several times with materially different economics and subsequently paid off, thus requiring for the recording of debt as an extinguishment and re-recording the debt with the amended terms. This resulted in a gain on extinguishment of debt in the year ended December 31, 2024 of $857,723.

Liquidity and Capital Resources; Plan of Operations

As of December 31, 2025, we had cash and cash equivalents of $3,789,342. Our cash equivalents are held in high yield savings account. Since inception, we have incurred net losses and negative cash flows from operations. On December 31, 2025, we had an accumulated deficit of $34,667,026.

Historically, we have financed our operations primarily by selling common stock and convertible debt. On October 24, 2025, the Company entered into a Standby Equity Purchase Agreement ("SEPA") and related Registration Rights Agreement with YA II PN, Ltd. ("Yorkville"), providing the Company the right, but not the obligation, to sell up to $20.0 million of common stock from time to time, subject to customary conditions, including an effective resale registration statement. In connection with the SEPA, Yorkville agreed to provide $6.0 million of pre-paid advances via convertible promissory notes. During the year ended December 31, 2025, the company received aggregate proceeds of $5,100,000, which is net of $420,000 of issuance discounts and $480,000 of financing costs associated with the transaction. During the year ended December 31, 2025, the Company received aggregate proceeds of $22,251 from sales of common stock under the SEPA which were used to pay interest on the convertible promissory notes.

On December 2, 2024, the Company priced its initial public offering of 2,750,000 shares of common stock at a price of $4.00 per share. The offering closed on December 4, 2024, and the Company started trading on the Nasdaq Capital Market under the ticker symbol "JUNS". The Company sold 2,750,000 shares of its Common Stock to the underwriters and yielded proceeds of $9,725,213, net of underwriters and other fees of $1,274,787.

For the fiscal years ended December 31, 2025 and 2024, we generated net revenues of $21,796 and $0, respectively from product sales and reported net losses of $8,644,897 and $2,439,625, respectively, and negative cash flow from operating activities of $5,413,736 and $3,911,004, respectively. As noted in our financial statements, as of December 31, 2025 and 2024, we had an accumulated deficit of $34,667,026 and $26,022,129, respectively. There is substantial doubt regarding our ability to continue as a going concern as a result of our historical recurring losses and negative cash flows from operations as well as our dependence on private equity and financings. See "Risk Factors—We have a history of operating losses, our management has concluded that factors raise substantial doubt about our ability to continue as a going concern and our auditor has included an explanatory paragraph relating to our ability to continue as a going concern in its audit report for the fiscal years ended December 31, 2025 and 2024."

Our failure to raise capital as and when needed could have a negative impact on our financial condition and our ability to pursue our business strategies. We anticipate that we will need to raise substantial additional capital, the requirements of which will depend on many factors, including:

- the scope, rate of progress and costs of our drug delivery, preclinical development activities, laboratory testing and clinical trials for our drug candidate;
- the number and scope of clinical programs we decide to pursue;
- the scope and costs of manufacturing development and commercial manufacturing activities;
- the extent to which we acquire or in-license other drug candidate and technologies;
- the cost, timing and outcome of regulatory review of our drug candidate;
- the cost and timing of establishing sales and marketing capabilities, if our drug candidate receives marketing approval;
- the costs of preparing, filing and prosecuting patent applications, obtaining, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- our efforts to enhance operational systems and our ability to attract, hire and retain qualified personnel, including personnel to support the development of our drug candidate;
- the costs associated with being a public company; and
- the cost associated with commercializing our drug candidate, if it receives marketing approval.

If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Any future debt financing into which we enter may impose upon us additional covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, repurchase our common stock, make certain investments and engage in certain merger, consolidation or asset sale transactions. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders. If we are unable to raise additional funds when needed, we may be required to delay, reduce, or terminate some or all of our development programs and clinical trials. We may also be required to sell or license to other parties rights to develop or commercialize our drug candidate that we would prefer to retain.

See "Risk Factors" for additional risks associated with our capital requirements.

Cash Flows for the Years Ended December 31, 2025 and 2024

The following table shows a summary of our cash flows for the years ended December 31, 2025 and 2024.

	Fiscal Years Ended December 31,	
	2025	**2024**
Net cash used in operating activities	$ (5,413,736)	$ (3,911,004)
Net cash provided by investing activities	-	-
Net cash provided by financing activities	$ 5,433,568	$ 7,652,036
Net increase (decrease) in cash	$ 19,832	$ 3,741,032
Cash - beginning of the period	$ 3,769,510	$ 28,478
Cash - end of the period	$ 3,789,342	$ 3,769,510

Net Cash Used in Operating Activities:

Net cash used in operating activities was $5,413,736 for the year ended December 31, 2025, compared to $3,911,004 for the year ended December 31, 2024, representing an increase in cash used of $1,502,732, primarily driven by a higher net loss of $8,644,897 in 2025 compared to $2,439,625 in 2024. This increase was partially offset by higher non-cash addbacks, including an increase of $577,608 in stock-based compensation (from $1,840,908 to $2,418,516), an increase of $712,054 in amortization of prepaid contracts (from $54,612 to $766,666), and $222,521 of stock-based payments related to financing activities associated with the SEPA and the convertible promissory notes, partially offset by a $281,932 gain on the change in fair value of convertible notes in 2025 with no comparable activity in 2024. These impacts were further offset by the absence of prior year non-cash items, including an $857,723 gain on extinguishment of debt, a $53,257 loss on change in fair value of derivative liability, and $43,288 of amortization of debt discounts, along with working capital changes.

Net Cash Used in Investing Activities:

No net cash was provided by or used in investing activities during the years ended December 31, 2025 and 2024.

Net Cash Provided by Financing Activities:

Net cash provided by financing activities was $5,433,568 for the year ended December 31, 2025, compared to $7,652,036 for the year ended December 31, 2024, representing a decrease of $2,218,468, primarily due to the absence of $9,725,213 in IPO proceeds, net of costs, in 2025 compared to 2024. This decrease was partially offset by $5,580,000 in proceeds from the issuance of convertible promissory notes, net of costs, issued in connection with the SEPA in 2025, a $2,102,797 reduction in repayments of notes payable, and lower related party note repayments of $37,552, partially offset by a $150,000 decrease in proceeds from the sale of common stock and a $138,500 decrease in related party note proceeds.

Off-balance sheet financing arrangements

We have no obligations, assets or liabilities which would be considered off-balance sheet arrangements. We do not participate in transactions that create relationships with unconsolidated entities or financial partnerships, often referred to as variable interest entities, which would have been established for the purpose of facilitating off-balance sheet arrangements. We have not entered into any off-balance sheet financing arrangements, established any special purpose entities, guaranteed any debt or commitments of other entities, or purchased any non-financial assets.

Asian Business Development Activities

The Company initiated business development activities in the Asian region beginning in October of 2021. The Company has a strong strategic interest in accelerating the drug development and potential commercialization efforts of JOTROL™ in this market. Our Chairman & CEO, Christer Rosén, presented in person, our company's status and pipeline at the BIOHK 2023 in Hong Kong in September of 2023. The presentation led to several follow-on meetings, and we have recently agreed to service agreements in the areas of business development, CMC (Chemistry, Manufacturing, and Controls), regulatory affairs and clinical trial management. These agreements are further described in the section "Other Material Agreements". The Asian market is very large and hard to penetrate for a small company and we believe that our strategy with these agreements is cost effective and have the possibility to accelerate an out-licensing deal in the Southeast Asian territories. However, there are no assurances that this approach will be successful.

The agreements executed are very similar in nature that include an equity investment in our company by the other party and in turn the company issued equity in form of shares of common stock, in lieu of cash, for 3 years of services from each company.

The Company believes these agreements to be favorable for both parties based on the cash position of the company and the need for these activities to be executed and enabling the possibility of a one or more out-licensing agreements in the territory.

Contractual obligations

We do not have any long-term capital lease obligations, operating lease obligations or long-term liabilities, except as follows:

On April 30, 2021, the Company executed a lease agreement for office space in Jupiter, Florida. The term of the lease is sixty-one months commencing May 1, 2021 rent free until June 1, 2021. Fixed annual rent amounts are as follows:

Lease Period	Annual Fixed Rent
6/1/2021-5/31/2022	$ 45,396
6/1/2022-5/31/2023	$ 46,758
6/1/2023-5/31/2024	$ 48,158
6/1/2024-5/31/2025	$ 49,608
6/ l/2025-5/31/2026	$ 51,096

Standby Equity Purchase Agreement and Convertible Promissory Notes

On October 24, 2025, we entered into the SEPA with Yorkville. Pursuant to the SEPA, we have the right, but not the obligation, to issue and sell to Yorkville, from time to time, up to $20.0 million of shares of our Common Stock (the "SEPA Shares"), subject to certain limitations and conditions set forth in the SEPA.

In addition, pursuant to the SEPA, we may request, and Yorkville may, in its sole discretion, elect to provide, one or more prepaid advances (each, a "Prepaid Advance" and collectively, the "Prepaid Advances"), pursuant to which Yorkville would advance funds to us and we would issue to Yorkville a promissory note evidencing such Prepaid Advance. We requested, and Yorkville funded, two Prepaid Advances in an aggregate amount of $6.0 million as described below. Each Prepaid Advance is expected to be repaid through the issuance of SEPA Shares at a price per share determined in accordance with the terms of the SEPA, which is generally based on a discount to the prevailing market price of our common stock during a specified pricing period, unless earlier repaid in cash at our option, subject to the terms of the SEPA. Accordingly, the number of SEPA Shares issuable upon settlement of any Prepaid Advance will depend on the market price of our Common Stock at the time of such settlement and cannot be determined at the time such Prepaid Advance is made or thereafter until settlement.

As consideration for Yorkville's commitment to purchase common stock at the Company's direction pursuant the SEPA, the Company (i) paid to Yorkville a cash "structuring fee" in the amount of $25,000 and (ii) upon execution of the SEPA, issued to Yorkville 131,909 Commitment Shares, which have a total aggregate dollar value equal to $200,000, or 1.0% of Yorkville's $20.0 million aggregate purchase commitment under the SEPA (each Commitment Share valued at approximately $1.5162 per share, representing the VWAP on October 23, 2025, the trading day immediately prior to the date of execution of the SEPA, rounded to the nearest whole share).

In connection with the SEPA, and subject to the conditions set forth therein, Yorkville provided us with a Prepaid Advance of $6.0 million, funded in two tranches, in exchange for our issuance of convertible promissory notes (each, a "Convertible Note" and collectively, the "2025 Convertible Notes" or "2025 Notes"). On October 27, 2025, we received the first tranche of the Prepaid Advance in the amount of $3,720,000 and issued to Yorkville a Convertible Note in the principal amount of $4.0 million (the "First Convertible Note"), which was issued with an original issue discount of 7.0%. The First Convertible Note is initially convertible into shares of our Common Stock at a fixed conversion price of $1.50 per share.

Subsequently, upon satisfaction of the applicable conditions, on December 23, 2025 we received the second tranche of the Prepaid Advance in the amount of $1,860,000 and issued to Yorkville a Convertible Note in the principal amount of $2.0 million (the "Second Convertible Note"), which was issued with an original issue discount of 7.0% and is initially convertible into shares of our common stock at a fixed conversion price of $1.50 per share.

Interest accrues on the outstanding balance of each Convertible Note at a rate of 8% per annum, subject to an increase to 18% upon the occurrence of certain events of default, and each Convertible Note matures on October 24, 2026.

We and Yorkville also entered into a registration rights agreement (the "Registration Rights Agreement"), pursuant to which we agreed to file with the U.S. Securities and Exchange Commission (the "SEC") a registration statement registering the resale by Yorkville of the SEPA Shares, including SEPA Shares issuable upon settlement of the Prepaid Advances. On November 26, 2025, we filed a registration statement on Form S-1 (File No. 333-291832) with the SEC (the "Registration Statement") for the resale by Yorkville of 10,000,000 SEPA Shares, which was declared effective by the SEC on December 11, 2025.

As of the date of this Annual Report, we have issued and sold approximately 1.1 million SEPA Shares to Yorkville pursuant to the SEPA, including SEPA Shares issued in connection with the settlement of Prepaid Advances and upon conversion of the Convertible Notes, for aggregate net proceeds to us of approximately $625,748. We may continue to issue SEPA Shares to Yorkville pursuant to the SEPA, including in connection with any outstanding or future Prepaid Advances or conversions of Convertible Notes, subject to the terms and conditions of the SEPA.

Senior Secured Note

On April 11, 2022, the Company entered into a securities purchase agreement (the "Purchase Agreement") with an accredited investor for the sale of the Company's convertible notes. Pursuant to the terms of the Purchase Agreement, on April 11, 2022, the Company received aggregate gross proceeds of $1,000,000 and issued (i) a 10% Original Issue Discount Senior Secured Convertible Note in the principal amount of $1,111,111.11 (the "Note" or "Note II") and (ii) 514,403 shares of common stock, par value $0.0001 per share (the "Shares"), of the Company.

The Note. The aggregate principal amount of the Note is $1,111,111, and the Company received gross proceeds of $1,000,000 after giving effect to the original issue discount of 10%. The Note bore interest at a rate of 10% per year, payable monthly in arrears, and mature 12 months from issuance.

On April 29, 2024, the Company, the Holder of the Note II and the CEO entered into an amendment in which the CEO agreed to exchange 685,867 shares issued to the Holder in exchange for his related party notes that accrued interest at 3% that are due from the Company in an aggregate principal amount of $266,667 and the Holder agreed to forfeit all rights to all additional future shares from the Company that would of become due upon a qualified offering as well as the conversion option. Therefore, the principal amount of the note was increased to $1,377,778 and the exchange debt follows the requirements of Note II. In addition, the Holder agreed to extend the note maturity date to August 11, 2024. The note shall be designated as a 10% original issue discount secured note ("Senior Secured Note") moving forward. The Senior Secured Note and interest will become due and payable upon the earliest of the maturity date or upon the occurrence of a qualified event. The note is recorded on the balance sheet under note payable. As a result of the conversion feature of the note being removed the Company recorded a one-time gain on the modification of the debt of $951,868 and a new derivative liability of $407,494 was recorded related to the Senior Secured Note.

On August 8, 2024, the Company, and the Holder of the Senior Secured Note entered into an amendment to extend the maturity date of the Senior Secured Note to October 11, 2024.

On November 15, 2024, the Company, and the Holder of the Senior Secured Note entered into an amendment to extend the maturity date of the Senior Secured Note to December 10, 2024. During December 2024, the Company fully repaid the Senior Secured Note pursuant to the terms in the amount of $2,102,797. On April 29, 2024, the Company, the Holder of the Note II and the CEO entered into an amendment in which the CEO agrees to exchange 685,867 shares issued to the Holder in exchange for his related party notes that accrued interest at 3% that are due from the Company in an aggregate principal amount of $266,667 and the Holder agreed to forfeit all rights to all additional future shares from the Company that would of become due upon a qualified offering as well as the conversion option. Therefore, the principal amount of the note was increased to $1,377,778 and the exchange debt follows the requirements of Note II. In addition, the Holder agreed to extend the note maturity date to August 11, 2024. The note shall be designated as a 10% original issue discount secured note ("Senior Secured Note") moving forward. The Senior Secured Note and interest will become due and payable upon the earliest of the maturity date or upon the occurrence of a qualified event. The note is recorded on the balance sheet under note payable. As a result of the conversion feature of the note being removed the Company recorded a one-time gain on the modification of the debt of $951,868 and a new derivative liability of $407,494 was recorded related to the Senior Secured Note.

During December 2024, the Company fully repaid the Senior Secured Note pursuant to the terms in the amount of $2,102,797.

The Shares. In connection with the issuance of Note II, the Company issued 514,403 shares of common stock to the holder with a fair market value of $2.16 per share (aggregate value of $1,111,111) as additional consideration for the holder lending $1,000,000 to the Company. The 514,403 shares have a relatively fair value of $310,000.

The Purchase Agreement related to the Note was amended to provide that upon closing, the purchaser will receive 133.33% coverage (i.e. the face amount of the Note, i.e., $1,111,111.11 divided by the lesser of (i) the price/share of the last issuance of solely common stock (including options) of the Company, i.e., $5.00/share or (ii) the price per share of common stock (or if units are issued in the Qualified Offering, the price of units sold in the Qualified Offering), in shares of common stock of the Company (or if units are issued in the Qualified Offering, units). The number of shares to be received at closing shall be determined by using clause (i) above.

In light of the foregoing, the holder shall receive an additional number of shares of common stock, such that it shall have received the number of shares of common stock of the aggregate value of $1,111,111 divided by the lesser of (i) the price/share of the last issuance of solely common stock (including options) of the Company, i.e., $5.00/share or (ii) the price per share of common stock (or if units are issued in the Qualified Offering, the price of units sold in the Qualified Offering), in shares of common stock of the Company (or if units are issued in the Qualified Offering, units) ("Share True Up"). The Share True Up was forfeited as a result of the April 29, 2024 agreement.

Ancillary Agreements. In connection with the Company's obligations under the Note, the Company entered into a security agreement and intellectual property security agreement with the holder, pursuant to which the Company granted a security interest on all assets of the Company, including all intellectual property of the Company, for the benefit of the holders, to secure the Company's obligations under the Note and the other transaction documents. In addition, the holder was granted piggyback registration rights for the shares of common stock issued under the Purchase Agreement and shares of common stock issuable upon conversion of the Note (collectively, "Registrable Securities"). At any time while there are any Registrable Securities of holder outstanding, if the Company proposes to register any of its securities either for its own account or for the account of other security holders (other than a registration statement relating solely to employee benefit plans on Form S-8 or a Commission Rule 145 transaction on Form S-4), the holder is entitled to include its Registrable Securities in the registration. Notwithstanding, the Company and underwriters in an underwritten registration may exclude some or all of the Registrable Securities from the underwritten registration if the underwriters believe that including the Registrable Securities would adversely affect the underwritten offering.

At any time within the 12 months closing, upon any issuance by the Company or any of its subsidiaries of debt or common stock or common stock equivalents for cash consideration, indebtedness or a combination of units thereof, other than in an underwritten public offering (a "Subsequent Financing"), the investor will have the right to participate up to its investment amount in the Note, but not more than 25% of the Subsequent Financing, on the same terms, conditions and price provided for in the Subsequent Financing.

Until the Company has consummated a Qualified Offering which results in a listing of the common stock onto a national securities exchange, if the Company engages in any future financing transactions with a third-party investor, if the holder determines that the terms of the subsequent investment are preferable in any respect to the terms of the securities of the Company issued to the Holder pursuant to the terms of the Purchase Agreement, the holder will have the right to amend and restate such securities to include the preferable term or terms.

Notes Payable, related party

The Company's Chief Executive Officer (CEO) has loaned the Company working capital since inception. The balance of the loans to the CEO as of December 31, 2024 was $146,432. The loan was due on demand and accrues interest at 3% per year. Accrued interest relating to the loan was $1,064 as of December 31, 2024, and is included in accrued interest on the accompanying 2024 balance sheets. The Company fully settled the debt in 2025 by repaying a total of $150,782, $146,432 in principal and $4,350 in accrued interest. The Company repaid a total of $100,000 during the year ended December 31, 2024, $83,880 in principal and $16,120 in accrued interest.

On April 29, 2024, the Company, the Holder of the Note II and the CEO entered into an amendment in which the CEO agreed to exchange 685,869 shares issued to the Holder in exchange for his related party notes that accrued interest at 3% that are due from the Company in an aggregate principal amount of $266,667 and the Holder agreed to forfeit all rights to all additional future shares from the Company that would have become due upon a qualified offering and the conversion feature of the note. In addition, the Holder agreed to extend the note maturity date to August 11, 2024. The note shall be designated as a 10% original issue discount secured note ("Senior Secured Note") moving forward. The note and interest will become due and payable upon the earliest of the maturity date or upon the occurrence of a qualified event.

Other Related Party Transactions

Accrued compensation includes partially accrued salaries to executives since inception. Since inception, executive salaries have been paid in cash when the Company's cash flow has permitted such payment.

On March 15, 2024, a former executive agreed to forgive $100,000 of accrued compensation in exchange for 49,605 options to purchase common stock and 7,500 restricted stock units, The options to purchase common stock have a strike price of $1.33. The option had a grant date fair value of $50,000. The Company recorded a gain on the forgiveness of accrued compensation in the amount of $40,000.

As of December 31, 2025 and 2024, $64,105 was due to a Company wholly owned by the Company's Chief Financial Officer, who also is an option holder, respectively. The amount is included in accrued compensation on the Company's balance sheets.

Share Issuances

On June 3, 2024, the Company issued 1,162,500 shares of common stock to each of Optimize Wellness Limited, Regis Healthcare Group Limited, and Longevity Technology Group Limited (collectively, "Asian Partners") with a fair market value of $1.33 per share (3,487,500 shares in aggregate, with an aggregate fair market value of $4,638,375), as pre-payment for 3 years of services.

On June 3, 2024, the Company sold 112,500 shares of common stock to the Asian Partners for $1.33 per share, with each Selling Stockholder purchasing 37,500 shares of common stock.

On December 2, 2024, the Company priced its initial public offering of 2,750,000 shares of common stock at a price of $4.00 per share. The offering closed on December 4, 2024, and the Company started trading on the Nasdaq Capital Market under the ticker symbol "JUNS". The Company sold 2,750,000 shares of its Common Stock to the underwriters and yielded proceeds of $9,725,213, net of underwriters and other fees of $1,274,787.

Upon the closing of the offering on December 4, 2024, the outstanding principle and all unpaid accrued interest, totaling $109,216, of the Notes I converted into an aggregate of 227,447 share of common stock of the Company at $2.80, which is 70% of the offering price of $4.00.

On April 23, 2025, the Company issued 103,186 shares of common stock, with an aggregate fair value of $66,000, as consideration for services rendered related to media and investor relations activities, strategic communications support, enhancement to the Company's market visibility and shareholder engagement. The fair value of the shares issued was determined based on the market price of the Company's common stock at the date of issuance and is included general and administrative expenses in the accompanying 2024 condensed consolidated statement of operations.

Effective June 22, 2025, the Company entered into an amendment with a warrant holder for a warrant to purchase 109,376 shares of Common Stock. The amendment extended the warrant's exercise period through August 31, 2025, and clarified the exercise mechanism applicable to the warrant. The effects of the warrant modification were de minimis.

On July 16, 2025 the Company entered into an amendment with a warrant holder who holds 1,249,999 warrants that clarified the exercise mechanisms. Concurrently with the amendment, the warrant holder exercised the warrants via a cashless exercise and received 913,299 shares of Common Stock. Pursuant to the amendment, the Company agreed to issue the warrant holder 86,700 shares of Common Stock.

On August 12, 2025, the Company received an exercise notice from a warrant holder who holds 109,376 warrants. The warrant was exercised via a cashless exercise, and the warrant holder received 30,547 shares of Common Stock. Pursuant to the amended warrant agreement, the Company agreed to issue the warrant holder 56,954 shares of Common Stock.

On October 24, 2025, As consideration for Yorkville's commitment to purchase common stock at the Company's direction pursuant the SEPA, the Company issued to Yorkville 131,909 Commitment Shares, which have a total aggregate dollar value equal to $200,000, or 1.0% of Yorkville's $20.0 million aggregate purchase commitment under the SEPA (each Commitment Share valued at approximately $1.5162 per share, representing the VWAP on October 23, 2025, the trading day immediately prior to the date of execution of the SEPA, rounded to the nearest whole share).

Recent Developments

On October 24, 2025, we entered into the SEPA with Yorkville. Pursuant to the SEPA, we have the right, but not the obligation, to issue and sell to Yorkville, from time to time, up to $20.0 million of shares of our Common Stock (the "SEPA Shares"), subject to certain limitations and conditions set forth in the SEPA.

In addition, pursuant to the SEPA, we may request, and Yorkville may, in its sole discretion, elect to provide, one or more prepaid advances (each, a "Prepaid Advance" and collectively, the "Prepaid Advances"), pursuant to which Yorkville would advance funds to us and we would issue to Yorkville a promissory note evidencing such Prepaid Advance. We requested, and Yorkville funded, two Prepaid Advances in an aggregate amount of $6.0 million as described below. Each Prepaid Advance is expected to be repaid through the issuance of SEPA Shares at a price per share determined in accordance with the terms of the SEPA, which is generally based on a discount to the prevailing market price of our common stock during a specified pricing period, unless earlier repaid in cash at our option, subject to the terms of the SEPA. Accordingly, the number of SEPA Shares issuable upon settlement of any Prepaid Advance will depend on the market price of our Common Stock at the time of such settlement and cannot be determined at the time such Prepaid Advance is made or thereafter until settlement.

As consideration for Yorkville's commitment to purchase common stock at the Company's direction pursuant the SEPA, the Company (i) paid to Yorkville a cash "structuring fee" in the amount of $25,000 and (ii) upon execution of the SEPA, issued to Yorkville 131,909 Commitment Shares, which have a total aggregate dollar value equal to $200,000, or 1.0% of Yorkville's $20.0 million aggregate purchase commitment under the SEPA (each Commitment Share valued at approximately $1.5162 per share, representing the VWAP on October 23, 2025, the trading day immediately prior to the date of execution of the SEPA, rounded to the nearest whole share).

In connection with the SEPA, and subject to the conditions set forth therein, Yorkville provided us with a Prepaid Advance of $6.0 million, funded in two tranches, in exchange for our issuance of convertible promissory notes (each, a "Convertible Note" and collectively, the "2025 Convertible Notes" or "2025 Notes"). On October 27, 2025, we received the first tranche of the Prepaid Advance in the amount of $3,720,000 and issued to Yorkville a Convertible Note in the principal amount of $4.0 million (the "First Convertible Note"), which was issued with an original issue discount of 7.0%. The First Convertible Note is initially convertible into shares of our Common Stock at a fixed conversion price of $1.50 per share.

Subsequently, upon satisfaction of the applicable conditions, on December 23, 2025 we received the second tranche of the Prepaid Advance in the amount of $1,860,000 and issued to Yorkville a Convertible Note in the principal amount of $2.0 million (the "Second Convertible Note"), which was issued with an original issue discount of 7.0% and is initially convertible into shares of our common stock at a fixed conversion price of $1.50 per share.

Interest accrues on the outstanding balance of each Convertible Note at a rate of 8% per annum, subject to an increase to 18% upon the occurrence of certain events of default, and each Convertible Note matures on October 24, 2026.

We and Yorkville also entered into a registration rights agreement (the "Registration Rights Agreement"), pursuant to which we agreed to file with the U.S. Securities and Exchange Commission (the "SEC") a registration statement registering the resale by Yorkville of the SEPA Shares, including SEPA Shares issuable upon settlement of the Prepaid Advances. On November 26, 2025, we filed a registration statement on Form S-1 (File No. 333-291832) with the SEC (the "Registration Statement") for the resale by Yorkville of 10,000,000 SEPA Shares, which was declared effective by the SEC on December 11, 2025.

As of the date of this Annual Report, we have issued and sold approximately 1.1 million SEPA Shares to Yorkville pursuant to the SEPA, including SEPA Shares issued in connection with the settlement of Prepaid Advances and upon conversion of the Convertible Notes, for aggregate net proceeds to us of approximately $625,748. We may continue to issue SEPA Shares to Yorkville pursuant to the SEPA, including in connection with any outstanding or future Prepaid Advances or conversions of Convertible Notes, subject to the terms and conditions of the SEPA.

On December 2, 2024, the Company priced its initial public offering of 2,750,000 shares of common stock at a price of $4.00 per share. The offering closed on December 4, 2024, and the Company started trading on the Nasdaq Capital Market under the ticker symbol "JUNS". The Company sold 2,750,000 shares of its Common Stock to the underwriters and yielded proceeds of $9,725,213, net of underwriters and other fees of $1,274,787.

Critical Accounting Policies

Basis of Presentation

The financial statements of the Company have been prepared in accordance with generally accepted accounting principles in the United States of America ("US GAAP").

Business Segments

The Company uses the "management approach" to identify its reportable segments in accordance with ASC 280, Segment Reporting. The management approach requires companies to report segment financial information consistent with the information regularly reviewed by the Chief Operating Decision Maker ("CODM") for purposes of making operating decisions and assessing performance.

The Company's Chief Executive Officer serves as the CODM. The CODM evaluates financial performance and allocates resources based on the operating results of the Company's reportable segments. Effective October 1, 2025, the Company operates through two reportable segments: (i) its premium nutritional supplements, and (ii) pharmaceutical operations focused on drug candidates for CNS.

The CODM assesses segment performance primarily based on segment net loss (income). Selling, general and administrative expenses are directly attributable to segments or allocated based on reasonable and consistently applied methodologies. Corporate and other expenses that are not allocated to reportable segments consist primarily of public company costs, certain executive compensation, certain stock-based compensation, interest income (expense), other income (expense), and income taxes.

The identification of two reportable segments reflects the manner in which the CODM reviews financial information and allocates resources. Prior-period information has been recast to conform to the current presentation.

Use of Estimates

Preparing financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that materially affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and revenues and expenses during the reported period. Actual results could differ from those estimates, and those estimates may be material.

Changes in estimates are recorded in the period in which they become known. The Company bases its estimates on historical experience and other assumptions, which include both quantitative and qualitative assessments that it believes to be reasonable under the circumstances.

Significant estimates during the years ended December 31, 2025 and 2024, respectively, include valuation of stock-based compensation, uncertain tax positions, valuation of debt instruments, and the valuation allowance on deferred tax assets.

Research and Development

Research and development costs are expensed as incurred. Costs for certain development activities, such as clinical trials, are recognized based on an evaluation of the progress to completion of specific tasks using data such as subject enrollment, monitoring visits, clinical site activations, or information provided to us by our vendors with respect to their actual costs incurred. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the financial statements as prepaid or accrued research and development expense, as the case may be. Total research and development costs for the fiscal years ended December 31, 2025 and 2024 were $2,086,574 and $492,660, respectively.

Stock-Based Compensation

The Company records stock-based compensation equal to the grant date fair value of the stock awards issued. For stock options issued to employees, non-employees and members of our board of directors for their services on our board of directors, the Company estimates the grant-date fair value of options using the Black-Scholes option pricing model. The use of the Black-Scholes option pricing model requires management to make assumptions with respect to the expected term of the option, the expected volatility of the common stock consistent with the expected life of the option, risk-free interest rates, and, for grants prior to our initial public offering, the value of the common stock. For awards subject to time-based vesting, the Company recognized stock-based compensation expense, on a straight-line basis over the requisite service period, which is generally the vesting term of the award. As of December 31, 2025 and 2024, stock-based compensation expenses totaled $2,418,516 and $1,840,908, respectively, and includes expenses associated with shares issued to service providers and warrant holders.

Clinical Trial Expenses

As part of the process of preparing our financial statements, the Company is required to estimate expenses resulting from obligations under contracts with vendors, clinical research organizations and consultants and under clinical site agreements in connection with conducting clinical trials. The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided under such contracts. The Company's objective is to reflect the appropriate trial expenses in the financial statements by matching those expenses with the period in which services are performed and efforts are expended. The Company accounts for these expenses according to the progress of the trial as measured by patient progression and the timing of various aspects of the trial. The Company determines accrual estimates based on estimates of services received and efforts expended that take into account discussion with applicable personnel and outside service providers as to the progress or state of consummation of trials. During the course of a clinical trial, the Company adjusts the clinical expense recognition if actual results differ from its estimates. The Company makes estimates of the accrued expenses as of each balance sheet date based on the facts and circumstances known at that time. The clinical trial accruals are dependent upon the timely and accurate reporting of contract research organizations and other third-party vendors. Although the Company does not expect the estimates to be materially different from amounts actually incurred, understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low for any particular period.

Convertible Notes with and without Embedded Derivative Liabilities

The Company has entered into convertible notes, some of which contain variable conversion options, whereby the outstanding principal and accrued interest may be converted, by the holder, into shares of common stock at a fixed discount to the price of the common stock at or around the time of conversion upon certain trigger events. The Company evaluates all its financial instruments to determine if those contracts or any potential embedded components of those contracts qualify as derivatives. This accounting treatment requires that the carrying amount of any derivatives be recorded at fair value at issuance and marked-to-market at each balance sheet date. In the event that the fair value is recorded as a liability, as is the case with the Company, the change in the fair value during the period is recorded as either other income or expense. Upon conversion, exercise or repayment, the respective derivative liability is marked to fair value at the conversion, repayment, or exercise date and then the related fair value amount is reclassified to other income or expense as part of gain or loss on debt extinguishment.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Reference is made to pages F-1 through F-26 comprising a portion of this Annual Report on Form 10-K.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

As previously reported in the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 21, 2025, which disclosure is incorporated herein by reference, on April 16, 2025, Assurance Dimensions, LLC resigned as the Company's independent registered public accounting firm, and the Audit Committee of the Board of Directors approved the engagement of Cherry Bekaert LLP as the Company's new independent registered public accounting firm, effective as of April 16, 2025.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Disclosure controls are procedures that are designed with the objective of ensuring that information required to be disclosed in our reports filed under the Exchange Act, such as this Annual Report on Form 10-K, is recorded, processed, summarized, and reported within the time period specified in the SEC's rules and forms. Disclosure controls are also designed with the objective of ensuring that such information is accumulated and communicated to our management, including the Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. Our management evaluated, with the participation of our Chief Executive Officer and Chief Financial Officer (our "Certifying Officers"), the effectiveness of our disclosure controls and procedures as of December 31, 2025, pursuant to Rule 13a-15(b) under the Exchange Act. Based upon that evaluation, our Certifying Officers concluded that, as of December 31, 2025, our disclosure controls and procedures were ineffective due to a deficiency in our ability to adequately segregate responsibility over financial transaction processing and reporting. Based on the number of personnel available to serve the Company's accounting function, management believes we are not able to adequately segregate responsibility over financial transaction processing and reporting. Further, the Company does not have a formal internal control environment in place and operating effectively.

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

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined under Exchange Act Rules 13a-15(f) and 14d-14(f). Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

All internal control systems, no matter how well designed, have inherent limitations and may not prevent or detect misstatements. Therefore, even those systems determined to be effective can only provide reasonable assurance with respect to financial reporting reliability and financial statement preparation and presentation. In addition, projections of any evaluation of effectiveness to future periods are subject to risk that controls become inadequate because of changes in conditions and that the degree of compliance with the policies or procedures may deteriorate.

Management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2025. In making the assessment, management used the criteria issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO – 2013) in Internal Control-Integrated Framework. Based on its assessment, management concluded that, as of December 31, 2025, our Company's internal control over financial reporting was deficient due to our inability to adequately segregate responsibility over financial transaction processing and reporting. Based on the number of personnel available to serve the Company's accounting function, management believes we are not able to adequately segregate responsibility over financial transaction processing and reporting. Further, the Company does not have a formal internal control environment in place and operating effectively. As such, we have identified these issues as material weaknesses in our internal control over financial reporting and we may identify additional material weaknesses in the future that may cause us to fail to meet our reporting obligations or result in material misstatements of our financial statements. If our remediation of such material weaknesses is not effective, or if we fail to develop and maintain an effective system of internal controls and internal control over financial reporting, our ability to produce timely and accurate financial statements or comply with applicable laws and regulations could be materially and adversely affected and the market price of our common stock could be negatively affected, which could require additional financial and management resources.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) during the most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

During the year ended December 31, 2025, no director or officer of the Company adopted, modified, or terminated a "Rule 10b5-1 trading arrangement" or a "non-Rule 10b5-1 trading arrangement" as each term is defined in Item 408(a) of Regulation S-K.[4]

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Officers and Directors

The following table sets forth the names and ages of the members of our Board of Directors and our executive officers and the positions held by each. Our Board of Directors elects our executive officers annually by majority vote. Each director's term continues until his or her successor is elected or qualified at the next annual meeting, unless such director earlier resigns or is removed. In addition, the following table sets forth the names and ages of the members of our Science Advisory Board.

Name	Age	Position
Executive Officers and Directors:		
Christer Rosén	74	Chairman of Board, Chief Executive Officer and Director
Saleem Elmasri	40	Chief Financial Officer and Secretary
Marshall Hayward, Ph.D.	71	Chief Scientific Officer and Director
Alexander Rosén	35	Chief Administrative Officer
Alison D. Silva	47	President, Chief Business Officer, and Director
Nicholas H. Hemmerly	43	Independent Director
Julie Kampf	64	Independent Director
Allison W. Brady	55	Independent Director
Holger Weis	63	Independent Director

Biographical information concerning our executive officers and directors listed above is set forth below.

Executive Officers

Christer Rosén. Mr. Rosén, 74, is our Co-Founder and has served as our Chief Executive Officer and Chairman of our Board of Directors since June 2015. From January 1998 through March 2015, Mr. Rosén founded and served as the Chief Executive Officer and Chairman of EffRx Pharmaceuticals. Mr. Rosén together with Marshall Hayward, our Chief Scientific Officer, held the same positions at EffRx, where Mr. Rosen invented, and led the development through FDA and EU approvals of a drug treating osteoporosis, Binosto®. Binosto® is distributed in several parts of the world and gave Mr. Rosén a full insight into all aspects of pharmaceutical development, regulatory paths and distribution. He has decades of entrepreneurial experience and has founded, funded, and created start-ups in industries ranging from entertainment, hospitality, information technology, nutritional retail and pharmaceuticals. Mr. Rosén is a graduate of Malmo Trade Schools/Lund University, Sweden, with a degree in Computer Sciences in 1971. We believe Mr. Rosén is qualified to serve as Chairman of our Board of Directors due to his extensive experience in the pharmaceutical industry and as an entrepreneur.

Saleem Elmasri. Mr. Elmasri, 40, has served as our Chief Financial Officer and Secretary since January 1, 2023. Since September 2020, he has served as Managing Partner at Titan Advisory Services LLC, a boutique advisory firm focused on providing collaborative and customized financial operations and CFO services to early-stage companies. Since November 2025, Mr. Elmasri has served as chief financial officer for both Drugs Made In America Acquisition Corp. and Drugs Made In America Acquisition II Corp. He previously served as a director of Liberty Star Uranium & Metals Corp. from August 2023 to December 2025, where he served on the nominating, compensation, and audit committees. Mr. Elmasri also served as a director of Trans American Aquaculture, Inc. from March 2024 to December 2024, where he was chair of the audit committee. He also served as chief financial officer for Bright Green Corporation from February 2022 to December 2024. From September 2020 to April 2021, Mr. Elmasri was a consultant to DLA LLC, a professional services firm providing clients internal audit, accounting advisory, and corporate finance services. From June 2019 to August 2020, he was Managing Director at DLA LLC. From September 2007 to March 2018, Mr. Elmasri worked as Senior Director for Pine Hill Group LLC, a boutique accounting and transaction advisory firm, From March 2018 to June 2019, he worked as Senior Director for Pine Hill Group LLC, a boutique accounting and transaction advisory firm. From September 2007 to March 2018, Mr. Elmasri worked as Senior Manager for PricewaterhouseCoopers LLP ("PwC"), a Big-4 Accounting and Global Professional Services firm. Mr. Elmasri is a CPA and seasoned business professional who has a passion for delivering meaningful and measurable value to clients through practical solutions. He has over 15 years of experience in financial and management consulting. Mr. Elmasri began his career at PwC and worked on several of the firm's Fortune 500 clients, primarily focused on the Life Sciences and Pharmaceutical industry. From PwC, he transitioned to lead advisory practices at boutique consulting firms, specializing in transaction and complex accounting advisory. Mr. Elmasri received B.S. degrees in Accounting and Finance from Rutgers University in 2007.

Marshall Hayward, Ph.D. Dr. Hayward, 71, is one of our Co-Founders, serves as our Chief Scientific Officer, and has served as a member of our Board of Directors since 2015. Since 2013, Dr. Hayward has served as the founder and managing member of Marshall Hayward Associates LLC. From 2003 to 2013, Dr. Hayward served as the Chief Scientific Officer of EffRx Pharmaceuticals, where he was instrumental in all aspects of the development and approvals of the Binosto® product. Dr. Hayward received a Ph.D. in Biochemistry from the University of Illinois at Urbana-Champaign in 1982, where he conducted postdoctoral research in molecular biology. Dr. Hayward received a B.S. degree (in Biochemistry with High Honor) from the Honors College of Michigan State University in 1977. Dr. Hayward does not hold, and has not previously held, any directorships in any reporting companies. We believe Dr. Hayward is qualified to serve on our Board of Directors due to his extensive experience in the pharmaceutical industry and scientific background.

Alexander Rosén. Mr. Rosén, 35, is a Co-Founder and our Chief Administrative Officer and has been with Jupiter Neurosciences, Inc. since its inception. Previously, Mr. Rosén held the position of Head of Administration at X-Vax Technology, Inc. from November 2020 to June 2021. From February 2019 to November 2020, Mr. Rosén served as the Controller at X-Vax Technology, Inc. Mr. Rosén attended Halmstad University, Sweden from 2009 to 2012. Mr. Rosén does not hold, and has not previously held, any directorships in any reporting companies.

Alison D. Silva. Ms. Silva, 47, who has been a member of our Board of Directors since 2018, has now expanded her role to include President and Chief Business Officer since September 1, 2021. Previously, Ms. Silva was the Chief Executive Officer of Cotinga Pharmaceuticals, formerly Critical Outcome Technologies, from December 2016 through August 2021, and served as president from June 2016 to December 2026. She has served on the Board of Directors of Cotinga Pharmaceuticals since 2015, and management consultant to several organizations, including EMA Wellness and The Orphan Group. Before joining Cotinga, Alison co-founded The Microbiome Company in 2013, later rebranded to Synlogic Therapeutics, where she served as Executive Vice President and Chief Operating Officer until June 2016. Other relevant positions include co-founder and Vice President, Development at Marina Biotech; co-founder and Director at The Orphan Group; Director, Drug Development at Cequent Pharmaceuticals; COO at SLA Pharma; and various other positions in biotech and pharma. Ms. Silva obtained her undergraduate degree in Biology from Clark University in 2001 and her graduate degree from Clark University, through a direct study program with the University of Massachusetts Medical School in 2002.

Independent Directors

Allison W. Brady. Ms. Brady, 55, has served as an independent director at Jupiter Neurosciences, Inc. since September 8, 2021. She is co-founder of Gene Spotlight, Inc., a non-profit dedicated to raising money to sponsor medical research for rare diseases, and she has served on its board since January 2012. Since January 2024, Ms. Brady has served on the Board of Advisors at University of Pennsylvania's school of Social Policy & Practice and is currently the Fundraising Chair of its Power of Penn campaign. Ms. Brady received a BAS from University of Pennsylvania in 1993. She also received a PR Strategy Certificate in 2021 from Cornell University. Ms. Brady does not hold, and has not previously held, any directorships in any reporting companies. Gene Spotlight is presently the largest outside investor in the Company We believe Ms. Brady is qualified to serve on our Board of Directors due to her board experience.

Nicholas H. Hemmerly. Mr. Hemmerly, 43, has served as an independent director at Jupiter Neurosciences, Inc. since September 8, 2021. Mr. Hemmerly has been Managing Director and Co- Head of Investment Banking for Clear Street LLC since June 2023. Mr. Hemmerly has over 18 years of investment banking experience with broad transactional experience having completed approximately $25 billion of debt and equity transactions. Prior to joining Clear Street Mr. Hemmerly was Head of Investment Banking at Bridgeway Capital Partners, a merchant banking firm, from January 2020 to June 2023 From March 2016 to February 2020 Mr. Hemmerly was the Director, Head of Life Sciences at PricewaterhouseCoopers LLC where he led U.S. M&A and capital raising in the life sciences space with a focus on specialty and generic pharmaceuticals as well as healthcare consumer products and contract manufacturing. From June 2014 to March 2016, Mr. Hemmerly was a Vice President at Jefferies LLC with a focus on executing M&A and financing transactions within the pharmaceutical and life sciences sectors. Prior experience includes investment banking roles in JPMorgan Chase & Co.'s Healthcare Group as well as JMP Securities LLC's Healthcare Group. Mr. Hemmerly began his investment banking career as an analyst with Wachovia Securities. Mr. Hemmerly has also served as an independent director for Liberty Star Uranium & Metals Corp since September 2022. We believe Mr. Hemmerly is qualified to serve on our Board of Directors due to his extensive experience in the investment banking, life sciences and pharmaceutical sectors.

Julie Kampf. Ms. Kampf, 64, has served as an independent director at Jupiter Neurosciences, Inc. since September 2021. Ms. Kampf is the founder and chief executive officer of JBK Associates International Inc., an executive search firm focused on the life science industry, which she founded in 2003. Ms. Kampf has served as a director of EOM Pharmaceuticals since April 2022, where she chairs its compensation committee. Ms. Kampf also served as a director of Marizyme, Inc., a Florida-based biotechnology company, from February 2021 to May 2024. Ms. Kampf has received numerous awards, including having been recognized as one of New Jersey's Best 50 Women in Business, an Enterprising Woman of The Year, an Ernst & Young Entrepreneurial Winning Woman and a Brava Smart CEO Winner. In 2013 and 2009, Julie was recognized as one of the PharmaVoice 100 'most inspiring people in the Life Science Industry'. Ms. Kampf received a B.A. in Political Science from the University of Rhode Island in 1983. Ms. Kampf does not hold, and has not previously held, any directorships in any reporting companies. We believe Ms. Kampf is qualified to serve on our Board of Directors due to her experience as a director in the pharmaceutical and biotechnology industries, as well as her extensive business experience.

Holger Weis. Mr. Weis, 63, has served as an independent director at Jupiter Neurosciences, Inc. since September 8, 2021. From December 2020 through June 2025, he served as an independent director of Alaunos Therapeutics, Inc. where he served as Chair of the Audit Committee and as a member of the Compensation Committee. He was appointed as chairman of the board of directors in September 2023, and was subsequently appointed Chief Executive Officer of Alaunos Therapeutics, Inc. in July 2025 and relinquished his duties on the Audit and Compensation Committees. He is the principal of Weis Advisors, Inc., a company that provides consulting services to life science companies, since founding the company in April 2018. Between December 2011 and April 2018, Mr. Weis served many roles at DemeRx, Inc. including COO, CFO, President as well as a Consultant. From August 2010 to November 2011 Mr. Weis served as CFO for EnSA Holdings, LLC. Prior to his time at EnSA Holdings, LLC. Mr. Weis served as Vice President & CFO, Secretary and Treasurer at NovaVision, Inc. from January 2006 to August 2010. Prior to that, he served as the Chief Financial Officer & Treasurer of GMP Companies, Inc., a company that develops and commercializes pharmaceutical, medical device and diagnostic technologies, from 2000 to 2005. Earlier in his career, Mr. Weis served as a Senior Manager at Ernst & Young, a multinational professional services company, from 1986 to 2000. Mr. Weis received a Bachelor of Business Administration in Accounting from the University of Georgia in 1985 and is a Certified Public Accountant. We believe Mr. Weis is qualified to serve on our Board of Directors due to his experience in the life science industry and extensive financial background.

Family Relationships

There are no family relationships among any of our directors or executive officers, except that Christer Rosén, our Chief Executive Officer, is the father of Alexander Rosén, our Chief Administrative Officer.

Involvement in Certain Legal Proceedings

No executive officer, member of the board of directors or control person of our Company has been involved in any legal proceeding listed in Item 401(f) of Regulation S-K in the past 10 years.

Board Leadership Structure and Board's Role in Risk Oversight

We have not separated the positions of Chairman of the Board and Chief Executive Officer. Christer Rosén has served as our Chairman of the Board of Directors and Chief Executive Officer since January 1, 2016. We believe that combining the positions of Chairman and Chief Executive Officer allows for focused leadership of our organization which benefits us in our relationships with investors, customers, suppliers, employees and other constituencies. We believe that consolidating the leadership of the Company under Mr. Rosén is the appropriate leadership structure for our Company and that any risks inherent in that structure are balanced by the oversight of our other independent directors on our Board. However, no single leadership model is right for all companies and at all times. The Board recognizes that depending on the circumstances, other leadership models, such as the appointment of a lead independent director, might be appropriate. Accordingly, the Board may periodically review its leadership structure. In addition, the Board holds executive sessions in which only independent directors are present.

Our Board is generally responsible for the oversight of corporate risk in its review and deliberations relating to our activities. Our principal source of risk falls into two categories, financial and product commercialization. The audit committee oversees management of financial risks; our Board regularly reviews information regarding our cash position, liquidity and operations, as well as the risks associated with each. The Board regularly reviews plans, results and potential risks related to our business. The Board is also expected to oversee risk management as it relates to our compensation plans, policies and practices for all employees including executives and directors, particularly whether our compensation programs may create incentives for our employees to take excessive or inappropriate risks which could have a material adverse effect on the Company.

Director Independence

As required under the Nasdaq Marketplace Rules, a majority of the members of a listed company's board of directors must qualify as "independent," as affirmatively determined by the board of directors. Our Board of Directors considered certain relationships between our directors and us when determining each director's status as an "independent director" under Rule 5605(a)(2) of the Nasdaq Marketplace Rules. Based upon such definition and SEC regulations, the Company's Board of Directors has affirmatively determined that currently three of its seven directors (Christer Rosén, Marshall Hayward, Ph.D., and Alison D. Silva) are non-independent directors of the Company and four of its seven directors (Nicholas H. Hemmerly, Julie Kampf, Allison W. Brady, and Holger Weis) are "independent" directors under Nasdaq listing standards. Therefore, the Board of Directors has determined that a majority of the members of our Board of Directors are "independent".

Committees of the Board of Directors

Audit Committee

We have established an audit committee ("Audit Committee"), which consists of three independent directors: Holger Weis, Allison W. Brady and Nicholas Hemmerly. Mr. Weis is the chair of the Audit Committee. Mr. Weis qualifies as an audit committee financial expert under SEC rules and as a financially sophisticated audit committee member under the Nasdaq Capital Market rules. Our Audit Committee operates under a written charter that is reviewed annually. A copy of the charter is posted on the Corporate Governance section of our website, at *www.jupiterneurosciences.com*.

Our Audit Committee is authorized to:

- approve and retain the independent auditors to conduct the annual audit of our financial statements;
- review the proposed scope and results of the audit;
- review and pre-approve audit and non-audit fees and services;
- review accounting and financial controls with the independent auditors and our financial and accounting staff;
- review and approve transactions between us and our directors, officers and affiliates;
- recognize and prevent prohibited non-audit services;
- establish procedures for complaints received by us regarding accounting matters; and
- oversee internal audit functions, if any.

Compensation Committee

We have established a compensation committee ("Compensation Committee"), which consists of three independent directors: Nicholas H. Hemmerly, Julie Kampf and Allison Brady. Mr. Hemmerly is the chair of the Compensation Committee. Our Compensation Committee operates under a written charter that is reviewed annually.[7] A copy of the charter is posted on the Corporate Governance section of our website, at *www.jupiterneurosciences.com*.

The Compensation Committee is authorized to:

- review and determine the compensation arrangements for management;
- establish and review general compensation policies with the objective to attract and retain superior talent, to reward individual performance and to achieve our financial goals;
- administer our incentive compensation and benefit plans and purchase plans;
- oversee the evaluation of the Board of Directors and management; and
- review the independence of any compensation advisers.

Nominating and Corporate Governance Committee

We have established a nominating and corporate governance committee ("Nominating and Corporate Governance Committee"), which consists of three independent directors: Julie Kampf, Holger Weis and Nicholas H. Hemmerly. Ms. Kampf is the chair of the Nominating and Corporate Governance Committee. Our Nominating and Corporate Governance Committee operates under a written charter, a copy of which is posted on the Corporate Governance section of our website, at *www.jupiterneurosciences.com*.

The functions of the Nominating and Corporate Governance Committee, among other things, include:

- identifying individuals qualified to become board members and recommending director;
- nominees and board members for committee membership;
- developing and recommending to our board corporate governance guidelines;
- review and determine the compensation arrangements for directors; and
- overseeing the evaluation of our board of directors and its committees and management.

Director Nominations

Our full Board of Directors recommends candidates for nomination for election at the annual meeting of the stockholders. We have not formally established any specific, minimum qualifications that must be met or skills that are necessary for directors to possess. In general, in identifying and evaluating nominees for director, the Board of Directors considers educational background, diversity of professional experience, knowledge of our business, integrity, professional reputation, independence, wisdom, and the ability to represent the best interests of our stockholders.

Board and Committee Meetings and Director Attendance

During the year ended December 31, 2025, the Board held six meetings, the Audit Committee held four meetings, the Compensation Committee held one meeting, and the Nominating and Governance Committee held no meetings. During 2025, each director attended more than 75% of the combined meetings of the Board and each committee on which he or she served.

Compensation Committee Interlocks and Insider Participation

None of our executive officers currently serves, or in the past year has served, as a member of the Board of Directors or compensation committee of any entity that has one or more executive officers on our Board of Directors or Compensation Committee. For a description of transactions between us and members of our Compensation Committee and affiliates of such members, please see "Certain Relationships and Related Party Transactions".

Code of Ethics

The Company has adopted a Code of Ethics and Business Conduct that applies to all of its directors, officers (including our principal executive officer, principal financial officer, principal accounting officer or controller, and any person performing similar functions) and employees. The Code of Ethics and Business Conduct is available on our website at *www.jupiterneurosciences.com*.

Compensation Recovery Policy

On March 26, 2025, the Board of Directors approved a new compensation recovery policy (the "Clawback Policy") in compliance with SEC and Nasdaq rules and regulations. The Clawback Policy provides that in the event we are required to prepare an "Accounting Restatement" (as defined in the Clawback Policy), we shall, subject to certain limited exceptions as described in the Clawback Policy, recover certain incentive-based compensation from executive officers who are or have been designated as an "officer" by the Board of Directors in accordance with Exchange Act Rule 16a-1(f). Compensation that shall be recovered under the Clawback Policy generally includes "Incentive-Based Compensation" (as defined in the Clawback Policy) received during the three-year period prior to the "Accounting Restatement Determination Date" (as defined in the Clawback Policy) that exceeds the amount that otherwise would have been received by the "officer" had such compensation been determined based on the restated amounts in the financial restatement. Under the Clawback Policy, "Incentive-Based Compensation" includes any compensation that is granted, earned, or vested based, in whole or in part, upon the attainment of a Financial Reporting Measure (as defined in the Clawback Policy).

Policy Prohibiting Insider Trading and Related Procedures.

The Company adopted an insider trading policy governing the purchase, sale, and other dispositions of the Company's securities by directors, senior management, and employees. A copy of the insider trading policy is filed as an exhibit to this Annual Report on Form 10-K.

Communications with the Board

Stockholders and other interested parties can send communications to one or more members of the Board by writing to the Board or specific directors or group of directors at the following address: Jupiter Neurosciences, Inc. Board of Directors, c/o Corporate Secretary, 1001 North US Hwy 1, Suite 504, Jupiter, FL 33477. Any communication will be promptly distributed by our Corporate Secretary to the individual director or directors named in the communication or to all directors if addressed to the entire Board.

Indemnification and Limitation on Liability of Officers and Directors

Our certificate of incorporation provides that our officers and directors will be indemnified by us to the fullest extent authorized by Delaware law, as it now exists or may in the future be amended. In addition, our certificate of incorporation provides that our directors will not be personally liable for monetary damages to us for breaches of their fiduciary duty as directors, except to the extent such exemption from liability or limitation thereof is not permitted by the Delaware General Corporation Law ("DGCL").

Our certificate of incorporation also permits us to maintain insurance on behalf of any officer, director or employee for any liability arising out of his or her actions, regardless of whether Delaware law would permit such indemnification. We have purchased a policy of directors' and officers' liability insurance that insures our officers and directors against the cost of defense, settlement or payment of a judgment in some circumstances and insures us against our obligations to indemnify our officers and directors.

These provisions may discourage stockholders from bringing a lawsuit against our directors for breach of their fiduciary duty. These provisions also may have the effect of reducing the likelihood of derivative litigation against officers and directors, even though such an action, if successful, might otherwise benefit us and our stockholders. Furthermore, a stockholder's investment may be adversely affected to the extent we pay the costs of settlement and damage awards against officers and directors pursuant to these indemnification provisions.

We believe that these provisions and the insurance are necessary to attract and retain talented and experienced officers and directors.

ITEM 11. EXECUTIVE COMPENSATION

2025 Summary Compensation Table

The following summary compensation table provides information regarding the compensation earned during our fiscal years ended December 31, 2025 and 2024 to certain of our executive officers, who we collectively refer to as our "named executive officers" or "NEOs".

Name and Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards ($)	Option Awards ($)(1)	Non-Equity Incentive Plan Compensation ($)	Non-qualified Deferred Compensation Earnings ($)	All Other Compensation ($)	Total ($)
Christer Rosén	2025	441,000	210,000	-	-	-	-	20,407[2]	$ 671,407
Chief Executive Officer	2024	134,750	-	-	-	-	-	19,326[2]	$ 154,076
Saleem Elmasri	2025	240,000	72,000	-	102,128[3]	-	-	-	$ 414,128
Chief Financial Officer	2024	127,006	-	-	-	-	-	-	$ 127,006
Marshall Hayward	2025	176,400	50,000	-	-	-	-	16,145[4]	$ 242,445
Chief Scientific Officer	2024	107,800	-	-	-	-	-	-	$ 107,800
Alexander Rosén	2025	252,000	72,000	-	-	-	-	15,665[4]	$ 339,665
Chief Administration Officer	2024	77,000	-	-	-	-	-	26,655[4]	$ 103,655
Alison Silva	2025	315,000	45,000	-	255,320[3]	-	-	16,779[5]	$ 632,099
Chief Business Officer and President	2024	96,250	-	-	-	-	-	42,294[5]	$ 138,544

(1) Amounts reflect the aggregate grant-date fair value of stock awards computed in accordance with the Financial Accounting Standards Board's Accounting Standards Codification Topic 718. See Note 6 – Stockholders' Equity (Deficit) – Stock Options.

(2) Includes healthcare benefits and 401(k) contribution of $20,407 and $19,326, respectively, for the fiscal years ended December 31, 2025 and 2024.

(3) On July 2, 2025, the Compensation Committee of the board of directors (the "Compensation Committee") of Jupiter Neurosciences, Inc. (the "Company"), after review of the Company's Final 2025 Budget, approved equity incentives to compensate certain officers of the Company for their role in the success of the Company's initial public offering completed in December 2024 and their willingness to forgo additional compensation and forgive debts owed to them by the Company. The equity incentives approved by the Compensation Committee consisted of stock options granted to the following individuals pursuant to the Company's 2023 Equity Incentive Plan: Alison Silva, Chief Business Officer, received a grant of 255,320 options and Saleem Elmasri, Chief Financial Officer, received a grant of 102,128 options. The stock options have an exercise price of $1.19 per share, representing the closing price of the Company's common stock on the Nasdaq Stock Market on the date of grant. The stock options have a ten (10) year term and vest in equal installments over a three (3) year period beginning on the grant date of July 2, 2025, subject to the officers' continued employment at the time of vesting.

(4) Includes healthcare benefits and 401(k) contribution of $15,665 and $26,655, respectively, for the fiscal years ended December 31, 2025 and 2024.

(5) Includes healthcare benefits and 401(k) contribution of $16,779 and $42,294 respectively, for the fiscal years ended December 31, 2025 and 2024.

Executive Compensation Philosophy

Our Board of Directors determines the compensation given to our executive officers in their sole determination. Our Board of Directors reserves the right to pay our executives or any future executives a salary, and/or issue them shares of common stock issued in consideration for services rendered and/or to award incentive bonuses which are linked to our performance, as well as to the individual executive officer's performance. This package may also include long-term stock-based compensation to certain executives, which is intended to align the performance of our executives with our long-term business strategies. Additionally, while our Board of Directors has not granted any performance-based stock options to date , the Board of Directors reserves the right to grant such options in the future, if the Board in its sole determination believes such grants would be in the best interests of the Company.

Incentive Bonus

The Board of Directors may grant incentive bonuses to our executive officers in its sole discretion, if the Board of Directors believes such bonuses are in the Company's best interest, after analyzing our current business objectives and growth, if any, and the amount of revenue we are able to generate each month, which revenue is a direct result of the actions and ability of such executives.

Long-Term, Stock-Based Compensation

In order to attract, retain and motivate executive talent necessary to support the Company's long-term business strategy we may award our executives and any future executives with long-term, stock-based compensation in the future, at the sole discretion of our Board of Directors.

NEO Employment Agreements

Employment Agreement with Christer Rosén, dated as of September 1, 2021

Mr. Rosén's agreement provides that he will serve as the Chief Executive Officer of the Company and provides that he will be paid an annual base salary of $420,000. Mr. C. Rosén is eligible to receive an annual cash bonus, with the target amount of the bonus equal to 50% of the base salary in the year to which the bonus relates, and the actual amount of the bonus may be greater or less than the target amount, and will ultimately be determined by the Board.

Amended Employment Agreement with Christer Rosén, dated as of September 2, 2021

Mr. Rosen's employment agreement was amended to update the term of his employment to expire on the earlier of the third anniversary of the date of signing and the termination of his employment in accordance with the terms of the agreement. The amendment also clarifies that the executive's statements and assurances apply not only to shares of common stock issued to Mr. Rosen but also to stock options granted to him.

Amended Employment Agreement with Christer Rosén, dated as of December 18, 2023

Mr. Rosén's employment agreement was amended on December 18, 2023. The amendment reduces Mr. C. Rosén's annual base salary from $420,000 to $84,000, effective retrospectively to October 1, 2023, until the time that the Company has raised additional capital from the sale of its securities in the amount of $1,500,000 (the "Reduction Period"). Upon the expiration of the Reduction Period, the base salary shall be adjusted to be 105% the original base salary. The remainder of the original agreement shall remain in full force. Upon the expiration of the Reduction Period, which occurred on December 4, 2024, the base salary was adjusted to be 105% the original base.

Employment Agreement with Marshall Hayward, dated as of September 1, 2021

Dr. Hayward's agreement provides that he will serve as the Chief Scientific Officer of the Company and that he will be paid an annual base salary of $336,000. Dr. Hayward is eligible to receive an annual cash bonus, with the target amount of the bonus equal to 30% of the base salary in the year to which the bonus relates, and the actual amount of the bonus may be greater or less than such target amount, and will ultimately be determined by the Board.

Amended Employment Agreement with Marshall Hayward, dated as of September 29, 2021

Dr. Hayward's employment agreement was amended to update the term of his employment to expire on the earlier of the third anniversary of the date of signing and the termination of his employment in accordance with the terms of the agreement. The amendment also clarifies that the executive's statements and assurances apply not only to shares of common stock issued to Dr. Hayward but also to stock options granted to him.

Amended Employment Agreement with Marshall Hayward, dated as of December 18, 2023

Dr. Hayward's employment agreement was amended on December 18, 2023. The amendment reduces Dr. Hayward's annual base salary from $336,000 to $67,200, effective retrospectively to October 1, 2023, until the time that the Company has raised additional capital from the sale of its securities in the amount of $1,500,000 (the "Reduction Period"). Upon the expiration of the Reduction Period, the base salary shall be adjusted to be 105% the original base salary. The remainder of the original agreement shall remain in full force.

Amended Employment Agreement with Marshall Hayward, dated as of February 1, 2025

Dr. Hayward's employment agreement was amended on February 1, 2025. The amendment increased Dr. Hayward's annual base salary from $67,200 to $176,400. The previously planned increase to $352,800 never went into effect.

Employment Agreement with Alexander Rosen, dated as of June 1, 2021

Mr. Rosen's agreement provides that he will serve as the Chief Administrative Officer of the Company and that he will be paid an annual base salary of $240,000. Mr. Rosen is eligible to receive an annual cash bonus, with the target amount of the bonus equal to 30% of the base salary in the year to which the bonus relates, and the actual amount of the bonus may be greater or less than such target amount, and will ultimately be determined by the Board.

Amended Employment Agreement with Alexander Rosen, dated as of September 29, 2021

Mr. Rosen's employment agreement was amended to update the term of his employment to expire on the earlier of the third anniversary of the date of signing and the termination of his employment in accordance with the terms of the agreement. The amendment also clarifies that the executive's statements and assurances apply not only to shares of common stock issued to Mr. Rosen but also to stock options granted to him.

Amended Employment Agreement with Alexander Rosen, dated as of December 18, 2023

Mr. Rosen's employment agreement was amended on December 18, 2023. The amendment reduces Mr. Rosen's annual base salary from $240,000 to $48,000 effective retrospectively to October 1, 2023, until the time that the Company has raised additional capital from the sale of its securities in the amount of $1,500,000 (the "Reduction Period"). Upon the expiration of the Reduction Period, the base salary shall be adjusted to be 105% the original base salary. The remainder of the original agreement shall remain in full force. Upon the expiration of the Reduction Period, which occurred on December 4, 2024, the base salary was adjusted to be 105% the original base.

Employment Agreement with Alison Silva, dated as of September 1, 2021

Ms. Silva's agreement provides that she will serve as the President and Chief Business Officer of the Company and that she will be paid an annual base salary of $300,000. Ms. Silva is eligible to receive an annual cash bonus, with the target amount of the bonus equal to 30% of the base salary in the year to which the bonus relates, and the actual amount of the bonus may be greater or less than such target amount, and will ultimately be determined by the Board.

Amended Employment Agreement with Alison Silva, dated as of September 29, 2021

Ms. Silva's employment agreement was amended to update the term of her employment to expire on the earlier of the third anniversary of the date of signing and the termination of her employment in accordance with the terms of the agreement. The amendment also clarifies that the executive's statements and assurances apply not only to shares of common stock issued to Ms. Silva but also to stock options granted to her.

Amended Employment Agreement with Alison Silva, dated as of December 18, 2023

Ms. Silva's employment agreement was amended on December 18, 2023. The amendment reduces Ms. Silva's annual base salary from $300,000 to $60,000, effective retrospectively to October 1, 2023, until the time that the Company has raised additional capital from the sale of its securities in the amount of $1,500,000 (the "Reduction Period"). Upon the expiration of the Reduction Period, the base salary shall be adjusted to be 105% the original base salary. The remainder of the original agreement shall remain in full force. Upon the expiration of the Reduction Period, which occurred on December 4, 2024, the base salary was adjusted to be 105% the original base.

Provisions Applicable to All NEO Employment Agreements

Each of the employment agreements described above has a term of three years, which will be automatically extended for one or more additional terms of one year each unless either party provides notice to the other party of their desire to not so renew the term at least 30 days prior to the expiration of the then-current term. Each of the agreements is "at will," meaning that either party may terminate the employment at any time and for any reason, subject to the provisions of the applicable agreement.

Each executive is entitled to fringe benefits consistent with the practices of the Company, and to the extent the Company provides similar benefits to the Company's executive officers, and is entitled to be reimbursed for all reasonable and necessary out-of-pocket business, entertainment and travel expenses incurred in connection with the performance of their duties.

Each agreement may be terminated by the Company at any time, either with or without "Cause", and by the applicable executive any time, either with or without "Good Reason". "Cause" is defined as (i) violation of any material written rule or policy of the Company for which violation any employee may be terminated pursuant to the written policies of the Company reasonably applicable to an executive employee; (ii) misconduct by the applicable executive to the material detriment of the Company; (iii) the applicable executive conviction (by a court of competent jurisdiction, not subject to further appeal) of, or pleading guilty to, a felony; (iv) the applicable executive's gross negligence in the performance of their duties and responsibilities to the Company as described in the agreement; or the applicable executive's material failure to perform their duties and responsibilities to the Company as described in the agreement (other than any such failure resulting from their incapacity due to physical or mental illness or any such failure subsequent to the applicable executive delivered a notice of termination without Cause by the Company or delivering a notice of termination for Good Reason to the Company), in either case after written notice from the Board to the applicable executive of the specific nature of such material failure and such executive's failure to cure such material failure within 10 days following receipt of such notice.

"Good Reason" is defined as (i) at any time following a Change of Control (as defined below), a material diminution by the Company of compensation and benefits (taken as a whole) provided to the applicable executive immediately prior to a Change of Control; (ii) reduction in base salary or target or maximum bonus, other than as part of an across-the-board reduction in salaries of management personnel; (iii) the relocation of the applicable executive's principal executive office to a location more than 50 miles further from their principal executive office immediately prior to such relocation; or (iv) a material breach by the Company of any of the terms and conditions of the agreement which the Company fails to correct within 10 days after the Company receives written notice from the applicable executive of such violation.

A "Change of Control" will be deemed to have occurred if, after the effective date of the applicable agreement, (i) the beneficial ownership (as defined in Rule 13d-3 under the Exchange Act) of securities representing more than 50% of the combined voting power of the Company is acquired by any "person" as defined in sections 13(d) and 14(d) of the Exchange Act (other than the Company, any subsidiary of the Company, or any trustee or other fiduciary holding securities under an employee benefit plan of the Company), (ii) the merger or consolidation of the Company with or into another corporation where the stockholders of the Company, immediately prior to the consolidation or merger, would not, immediately after the consolidation or merger, beneficially own (as such term is defined in Rule 13d-3 under the Exchange Act), directly or indirectly, shares representing in the aggregate 50% or more of the combined voting power of the securities of the corporation issuing cash or securities in the consolidation or merger (or of its ultimate parent corporation, if any) in substantially the same proportion as their ownership of the Company immediately prior to such merger or consolidation, or (iii) the sale or other disposition of all or substantially all of the Company's assets to an entity, other than a sale or disposition by the Company of all or substantially all of the Company's assets to an entity, at least 50% of the combined voting power of the voting securities of which are owned directly or indirectly by stockholders of the Company, immediately prior to the sale or disposition, in substantially the same proportion as their ownership of the Company immediately prior to such sale or disposition.

If the Company terminates any executive's employment for "Cause", or the applicable executive terminates their employment without "Good Reason", then the Company will pay to the applicable executive any unpaid base salary and benefits then owed or accrued, and any unreimbursed expenses, any unvested portion of any equity granted to the applicable executive under the agreement or any other agreements with the Company will immediately be forfeited as of the termination date without any further action of the parties; and all of the parties' rights and obligations under the applicable agreement cease, other than such rights or obligations which arose prior to the termination date or in connection with such termination, and subject to those provisions which survive the termination.

If the Company terminates the applicable executive's employment without "Cause", or the applicable executive terminates their employment with "Good Reason", the Company will pay to the applicable executive any base salary and benefits then owed or accrued and any unreimbursed expenses; the Company will pay to the applicable executive an amount in cash equal to the target annual performance bonus for which they would have been eligible with respect to the year in which termination of their employment occurs multiplied by a portion of the year for which the agreement was in place; the Company will continue to pay to the applicable executive the base salary that would have been paid to them for the following 12 month period, assuming that the agreement and the term had remained in effect; any equity grant already made to the applicable executive will, to the extent not already vested, be deemed automatically vested; and all of the parties' rights and obligations under the agreement cease, other than such rights or obligations which arose prior to the termination date or in connection with such termination, and subject to those provisions which survive the termination.

Each of the agreements also provides for certain "gross-up payments" being payable to the applicable executive if it is determined that any payment or benefit provided to the executive under the agreement or otherwise, whether or not in connection with a Change of Control would constitute an "excess parachute payment" within the meaning of section 280G of the Internal Revenue Code of 1986, as amended (the "Code"), such that the payment would be subject to an excise tax under section 4999 of the Code.

Each of the agreements contains customary confidentiality provisions, and customary provisions relating to intellectual property created by the executive (i.e., a "work-made-for-hire" provision).

Each of the agreements also contains a customary non-solicitation provision, wherein the executive agrees that they shall not, directly or indirectly solicit or discuss with any employee of Company the employment of such Company employee by any other commercial enterprise other than Company, nor recruit, attempt to recruit, hire or attempt to hire any such Company employee on behalf of any commercial enterprise other than Company, provided that this provision does not prohibit the executive from undertaking a general recruitment advertisement provided that the foregoing is not targeted towards any person identified above, or from hiring, employing or engaging any such person who responds to such general recruitment advertisement. This provision applies for three years.

Each of the agreements also contains a customary non-compete provision, wherein the executive agrees that they will not, directly or indirectly: (i) engage in any other business, association or relationship of any kind with any business which provides, in whole or in part, the same or similar services and/or products offered by Company as part of its existing or developing businesses which directly or indirectly competes with Company; nor (ii) solicit or accept, or induce any person to reduce goods or services to Company, or in any manner assist others in the solicitation, acceptance, or inducement of, any business transactions with Company's existing and prospective clients, accounts, suppliers and/or other persons or entities with whom Company has had business relationships (or whom Company had specifically identified for a prospective business relationship). This provision applies for nine months.

Each of the agreements contains a "Blue Pencil" provision, wherein if a court of competent jurisdiction determines that any of the non-solicit or non-compete provisions are unenforceable, the court may substitute an enforceable restriction in place of any restriction deemed unenforceable.

Each of the agreements is governed by Florida law, and contains customary representations and warranties and other miscellaneous provisions.

Elements of Compensation

Our NEOs were provided with the following primary elements of compensation in 2025 and 2024:

Base Salary

Christer Rosén and Marshall Hayward received a fixed base salary in an amount determined by the Board of Directors based on a number of factors, including:

- The nature, responsibilities and duties of the officer's position;
- The officer's expertise, demonstrated leadership ability and prior performance;
- The officer's salary history and total compensation, including annual cash bonuses and long-term incentive compensation; and
- The competitiveness of the market for the officer's services.

See "—2025 Summary Compensation Table."

Stock Option Grants

On July 2, 2025, the Company granted non-qualified stock options to purchase 102,128 of common stock to Saleem Elmasri, CPA at an exercise price of $1.19 per share.

On July 2, 2025, the Company granted non-qualified stock options to purchase 255,320 of common stock to Alison Silva at an exercise price of $1.19 per share.

Other Benefits

In 2025 and 2024 our NEOs were reimbursed for healthcare expenses. The amounts paid to our NEOs in respect of these benefits is reflected above in "—2025 Summary Compensation Table."

2023 Equity Incentive Plan

Overview

The Board of Directors and stockholders holding a majority of the Company's voting capital approved and adopted the 2023 Equity Incentive Plan (the "2023 Plan") on October 4, 2023, respectively. The 2023 Plan authorizes the issuance of up to an aggregate maximum of 4,012,785 shares of the common stock, subject to adjustment as described in the 2023 Plan. The 2023 Plan shall be administered by the Board or one or more committees appointed by the Board or another committee ("Administrator"). The Administrator, in its discretion, selects the individuals to whom awards may be granted, the time or times at which such awards are granted, and the terms of such awards. The 2023 Plan authorizes the Company to grant stock options, stock appreciation rights, restricted shares, restricted share unit, cash awards, other awards, and performance-based awards. Awards may be granted to the Company's officers, employees, directors and consultants.

The purpose of 2023 Plan is to promote the success of the Company and to increase stockholder value by providing an additional means through the grant of awards to attract, motivate, retain and reward selected employees and other eligible persons. The Board may, at any time, terminate or, from time to time, amend, modify or suspend this 2023 Plan, in whole or in part. To the extent then required by applicable law or any applicable stock exchange or required under the Internal Revenue Code to preserve the intended tax consequences of the 2023 Plan, or deemed necessary or advisable by the Board, the 2023 Plan and any amendment to the 2023 Plan shall be subject to stockholder approval. Unless earlier terminated by the Board, the 2023 Plan will terminate 10 years from the date of adoption.

Authorized Shares

A total of 4,012,785 shares of the Company's common stock are authorized for issuance pursuant to the 2023 Plan. Subject to adjustment as provided in the 2023 Plan, the maximum aggregate number of shares that may be issued under the 2023 Plan will be cumulatively increased on January 1, 2024 and on each subsequent January 1, by a number of shares equal to the smaller of (i) 3% of the number of shares of common stock issued and outstanding on the immediately preceding December 31, or (ii) an amount determined by the Board.

Additionally, if any award issued pursuant to the 2023 Plan expires or becomes exercisable without having been exercised in full, is surrendered pursuant to an exchange program, as provided in the 2023 Plan, or, with respect to restricted stock, restricted stock units ("RSUs"), performance units or performance shares, is forfeited to or repurchased by the Company due to the failure to vest, the unpurchased shares (or for awards other than stock options or stock appreciation rights the forfeited or repurchased shares) which were subject thereto will become available for future grant or sale under the 2023 Plan (unless the 2023 Plan has terminated). With respect to stock appreciation rights, only shares actually issued pursuant to a stock appreciation right will cease to be available under the 2023 Plan; all remaining shares under stock appreciation rights will remain available for future grant or sale under the 2023 Plan (unless the 2023 Plan has terminated). Shares that have actually been issued under the 2023 Plan under any award will not be returned to the 2023 Plan and will not become available for future distribution under the 2023 Plan; provided, however, that if shares issued pursuant to awards of restricted stock, restricted stock units, performance shares or performance units are repurchased by the Company or are forfeited to the Company due to the failure to vest, such shares will become available for future grant under the 2023 Plan. Shares used to pay the exercise price of an award or to satisfy the tax withholdings related to an award will become available for future grant or sale under the 2023 Plan. To the extent an award under the 2023 Plan is paid out in cash rather than shares, such cash payment will not result in reducing the number of shares available for issuance under the 2023 Plan.

Notwithstanding the foregoing and, subject to adjustment as provided in the 2023 Plan, the maximum number of shares that may be issued upon the exercise of incentive stock options will equal the aggregate share number stated above, plus, to the extent allowable under Section 422 of the Internal Revenue Code of 1986, as amended, and regulations promulgated thereunder, any shares that become available for issuance under the 2023 Plan in accordance with the foregoing.

Plan Administration

The Board or one or more committees appointed by the Board will administer the 2023 Plan. In addition, if the Company determines it is desirable to qualify transactions under the 2023 Plan as exempt under Rule 16b-3 of the Securities Exchange Act of 1934, as amended, such transactions will be structured with the intent that they satisfy the requirements for exemption under Rule 16b-3. Subject to the provisions of the 2023 Plan, the administrator has the power to administer the 2023 Plan and make all determinations deemed necessary or advisable for administering the 2023 Plan, including the power to determine the fair market value of the Company's common stock, select the service providers to whom awards may be granted, determine the number of shares covered by each award, approve forms of award agreements for use under the 2023 Plan, determine the terms and conditions of awards (including the exercise price, the time or times at which the awards may be exercised, any vesting acceleration or waiver or forfeiture restrictions and any restriction or limitation regarding any award or the shares relating thereto), construe and interpret the terms of the 2023 Plan and awards granted under it, prescribe, amend and rescind rules relating to the 2023 Plan, including creating sub-plans and modify or amend each award, including the discretionary authority to extend the post-termination exercisability period of awards (provided that no option or stock appreciation right will be extended past its original maximum term), and to allow a participant to defer the receipt of payment of cash or the delivery of shares that would otherwise be due to such participant under an award. The administrator also has the authority to allow participants the opportunity to transfer outstanding awards to a financial institution or other person or entity selected by the administrator and to institute an exchange program by which outstanding awards may be surrendered or cancelled in exchange for awards of the same type which may have a higher or lower exercise price or different terms, awards of a different type or cash, or by which the exercise price of an outstanding award is increased or reduced. The administrator's decisions, interpretations and other actions are final and binding on all participants.

Eligibility

Awards under the 2023 Plan, other than incentive stock options, may be granted to employees (including officers) of the Company or a subsidiary, members of the Company's Board, or consultants engaged to render bona fide services to the Company or a subsidiary. Incentive stock options may be granted only to employees of the Company or a subsidiary.

Stock Options

Stock options may be granted under the 2023 Plan. The exercise price of options granted under the 2023 Plan generally must at least be equal to the fair market value of the Company's common stock on the date of grant. The term of each option will be as stated in the applicable award agreement; provided, however, that the term may be no more than 10 years from the date of grant. The administrator will determine the methods of payment of the exercise price of an option, which may include cash, shares or other property acceptable to the administrator, as well as other types of consideration permitted by applicable law. After the termination of service of an employee, director or consultant, they may exercise their option for the period of time stated in their option agreement. In the absence of a specified time in an award agreement, if termination is due to death or disability, the option will remain exercisable for 12 months. In all other cases, in the absence of a specified time in an award agreement, the option will remain exercisable for three months following the termination of service. An option may not be exercised later than the expiration of its term. Subject to the provisions of the 2023 Plan, the administrator determines the other terms of options.

Stock Appreciation Rights

Stock appreciation rights may be granted under the 2023 Plan. Stock appreciation rights allow the recipient to receive the appreciation in the fair market value of the Company's common stock between the exercise date and the date of grant. Stock appreciation rights may not have a term exceeding 10 years. After the termination of service of an employee, director or consultant, they may exercise their stock appreciation right for the period of time stated in their stock appreciation right agreement. In the absence of a specified time in an award agreement, if termination is due to death or disability, the stock appreciation rights will remain exercisable for 12 months. In all other cases, in the absence of a specified time in an award agreement, the stock appreciation rights will remain exercisable for three months following the termination of service. However, in no event may a stock appreciation right be exercised later than the expiration of its term. Subject to the provisions of the 2023 Plan, the administrator determines the other terms of stock appreciation rights, including when such rights become exercisable and whether to pay any increased appreciation in cash or with shares of the Company's common stock, or a combination thereof, except that the per share exercise price for the shares to be issued pursuant to the exercise of a stock appreciation right will be no less than 100% of the fair market value per share on the date of grant.

Restricted Stock

Restricted stock may be granted under the 2023 Plan. Restricted stock awards are grants of shares of the Company's common stock that vest in accordance with terms and conditions established by the administrator. The administrator will determine the number of shares of restricted stock granted to any employee, director or consultant and, subject to the provisions of the 2023 Plan, will determine the terms and conditions of such awards. The administrator may impose whatever conditions to vesting it determines to be appropriate (for example, the administrator may set restrictions based on the achievement of specific performance goals or continued service to the Company); provided, however, that the administrator, in its sole discretion, may accelerate the time at which any restrictions will lapse or be removed. Recipients of restricted stock awards generally will have voting and dividend rights with respect to such shares upon grant without regard to vesting, unless the administrator provides otherwise. Shares of restricted stock that do not vest are subject to the Company's right of repurchase or forfeiture.

Restricted Stock Units

RSUs may be granted under the 2023 Plan. RSUs are bookkeeping entries representing an amount equal to the fair market value of one share of the Company's common stock. Subject to the provisions of the 2023 Plan, the administrator determines the terms and conditions of RSUs, including the vesting criteria and the form and timing of payment. The administrator may set vesting criteria based upon the achievement of Company-wide, divisional, business unit or individual goals (including continued employment or service), applicable federal or state securities laws or any other basis determined by the administrator in its discretion. The administrator, in its sole discretion, may pay earned RSUs in the form of cash, in shares of the Company's common stock or in some combination thereof. Notwithstanding the foregoing, the administrator, in its sole discretion, may accelerate the time at which any vesting requirements will be deemed satisfied.

Performance Units and Performance Shares

Performance units and performance shares may be granted under the 2023 Plan. Performance units and performance shares are awards that will result in a payment to a participant only if performance goals established by the administrator are achieved or the awards otherwise vest. The administrator will establish performance objectives or other vesting criteria in its discretion, which, depending on the extent to which they are met, will determine the number or the value of performance units and performance shares to be paid out to participants. The administrator may set performance objectives based on the achievement of Company-wide, divisional, business unit or individual goals (including continued employment or service), applicable federal or state securities laws or any other basis determined by the administrator in its discretion. After the grant of a performance unit or performance share, the administrator, in its sole discretion, may reduce or waive any performance criteria or other vesting provisions for such performance units or performance shares. Performance units shall have an initial dollar value established by the administrator on or prior to the grant date. Performance shares shall have an initial value equal to the fair market value of the Company's common stock on the grant date. The administrator, in its sole discretion, may pay earned performance units or performance shares in the form of cash, in shares or in some combination thereof.

Non-Employee Directors

The 2023 Plan provides that all non-employee directors will be eligible to receive all types of awards (except for incentive stock options) under the 2023 Plan. The 2023 Plan includes a maximum limit of $750,000 of equity awards that may be granted to a non-employee director in any fiscal year, increased to $1,500,000 in connection with his or her initial service. For purposes of this limitation, the value of equity awards is based on the grant date fair value (determined in accordance with accounting principles generally accepted in the United States). Any equity awards granted to a person for their services as an employee, or for their services as a consultant (other than as a non-employee director), will not count for purposes of the limitation. The maximum limit does not reflect the intended size of any potential compensation or equity awards to the Company's non-employee directors.

Non-transferability of Awards

Unless the administrator provides otherwise, the 2023 Plan generally does not allow for the transfer of awards and only the recipient of an award may exercise an award during their lifetime. If the administrator makes an award transferrable, such award will contain such additional terms and conditions as the administrator deems appropriate.

Certain Adjustments

In the event of certain changes in the Company's capitalization, to prevent diminution or enlargement of the benefits or potential benefits available under the 2023 Plan, the administrator will adjust the number and class of shares that may be delivered under the 2023 Plan or the number, and price of shares covered by each outstanding award and the numerical share limits set forth in the 2023 Plan.

Dissolution or Liquidation

In the event of the Company's proposed liquidation or dissolution, the administrator will notify participants as soon as practicable and all awards will terminate immediately prior to the consummation of such proposed transaction.

Merger or Change in Control

The 2023 Plan provides that in the event of the Company's merger with or into another corporation or entity or a "change in control" (as defined in the 2023 Plan), each outstanding award will be treated as the administrator determines, including, without limitation, that (i) awards will be assumed, or substantially equivalent awards will be substituted, by the acquiring or succeeding corporation (or an affiliate thereof) with appropriate adjustments as to the number and kind of shares and prices; (ii) upon written notice to a participant, that the participant's awards will terminate upon or immediately prior to the consummation of such merger or change in control; (iii) outstanding awards will vest and become exercisable, realizable or payable, or restrictions applicable to an award will lapse, in whole or in part, prior to or upon consummation of such merger or change in control and, to the extent the administrator determines, terminate upon or immediately prior to the effectiveness of such merger or change in control; (iv) (A) the termination of an award in exchange for an amount of cash or property, if any, equal to the amount that would have been attained upon the exercise of such award or realization of the participant's rights as of the date of the occurrence of the transaction (and, for the avoidance of doubt, if as of the date of the occurrence of the transaction the administrator determines in good faith that no amount would have been attained upon the exercise of such award or realization of the participant's rights, then such award may be terminated by the Company without payment) or (B) the replacement of such award with other rights or property selected by the administrator in its sole discretion; or (v) any combination of the foregoing. The administrator will not be obligated to treat all awards, all awards a participant holds, or all awards of the same type, similarly. In the event that awards (or portion thereof) are not assumed or substituted for in the event of a merger or change in control, the participant will fully vest in and have the right to exercise all of their outstanding options and stock appreciation rights, including shares as to which such awards would not otherwise be vested or exercisable, all restrictions on restricted stock and RSUs will lapse and, with respect to awards with performance-based vesting, all performance goals or other vesting criteria will be deemed achieved at 100% of target levels and all other terms and conditions met, in all cases, unless specifically provided otherwise under the applicable award agreement or other written agreement between the participant and the Company or any of the Company's subsidiaries or parents, as applicable. If an option or stock appreciation right is not assumed or substituted in the event of a merger or change in control, the administrator will notify the participant in writing or electronically that the option or stock appreciation right will be exercisable for a period of time determined by the administrator in its sole discretion and the vested option or stock appreciation right will terminate upon the expiration of such period.

For awards granted to an outside director, the outside director will fully vest in and have the right to exercise all of their outstanding options and stock appreciation rights, all restrictions on restricted stock and RSUs will lapse and, for awards with performance-based vesting, unless specifically provided for in the award agreement, all performance goals or other vesting criteria will be deemed achieved at 100% of target levels and all other terms and conditions met.

Clawback

Awards will be subject to any Company clawback policy that the Company is required to adopt pursuant to the listing standards of any national securities exchange or association on which the Company's securities are listed or as is otherwise required by the Dodd-Frank Wall Street Reform and Consumer Protection Act or other applicable laws. The administrator also may specify in an award agreement that the participant's rights, payments or benefits with respect to an award will be subject to reduction, cancellation, forfeiture or recoupment upon the occurrence of certain specified events. The Board may require a participant to forfeit, return or reimburse the Company all or a portion of the award or shares issued under the award, any amounts paid under the award and any payments or proceeds paid or provided upon disposition of the shares issued under the award in order to comply with such clawback policy or applicable laws.

Amendment and Termination

The administrator has the authority to amend, suspend or terminate the 2023 Plan provided such action does not impair the existing rights of any participant. The 2023 Plan automatically will terminate on October 4, 2033, unless it is terminated sooner.

Outstanding Equity Awards as of December 31, 2025

The following table sets forth information concerning outstanding equity awards held by each of our named executive officers as of December 31, 2025:

	Option awards				Stock Awards			
Name	Number of securities underlying unexercised options exercisable (#)	Number of securities underlying unexercised options unexercisable (#)	Option exercise price ($/ share)	Option expiration date	Number of shares or units of stock that have not vested (#)	Market value of shares or units that have not vested ($)	Equity incentive plan awards: Number of unearned shares, units or other rights that have not vested (#)	Equity incentive plan awards: Market or payout value of unearned shares, units or other rights that have not vested ($)
Christer Rosén	2,003,678	-	$ 1.00	2029-2033		497,392		
Saleem Elmasri	666,420	102,128	$ 1.31	2032-2035		66.292		
Marshall Hayward	1,245,098		$ 0.93	2026-2033		389,793		
Alexander Rosén	1,171,688		$ .97	2029-2033		164,553		
Alison Silva	870,871	255,320	$ 1.20	2028-2035		110,227		

Director Compensation

Prior to our 2024 initial public offering, we did not have a formal policy to compensate our non-employee directors. Following our initial public offering, our non-employee directors are eligible to receive the following cash retainers and equity awards. The retainers will be payable in four equal installments in each calendar quarter and will be payable within five business days of the end of each calendar quarter, and with such amount for any partial calendar quarter being appropriately prorated.

Annual Retainer for Board Membership	
Annual service on the board of directors	$ 30,000
Additional Annual Retainer for Committee Membership	
Annual service as member of the audit committee (other than chair)	$ 5,000
Annual service as chair of the audit committee	$ 10,000
Annual service as member of the compensation committee (other than chair)	$ 5,000
Annual service as chair of the compensation committee	$ 10,000
Annual service as member of the nominating and corporate governance committee (other than chair)	$ 4,000
Annual service as chair of the nominating and corporate governance committee	$ 7,500

Upon initial election to our board of directors, each non-employee director will be granted an option to acquire up to 18,000 shares of the common stock at an exercise price of $5.00 per share (subject to customary adjustments), which options shall vest ratably over 36 months, subject to the director continuing to serve as a director of the Company during such period, pursuant to the Option Award Agreement. During the term of the independent director agreements, the Company will reimburse each director for all reasonable out-of-pocket expenses incurred by the director in attending any in-person meetings, provided that the director complies with the generally applicable policies, practices and procedures of the Company for submission of expense reports, receipts or similar documentation of such expenses. Any reimbursements for allocated expenses (as compared to out-of-pocket expenses of the director in excess of $500) must be approved in advance by the Company.

Other than as set forth in the table below and as described more fully below, we did not pay any compensation or make any equity awards or non-equity awards to any of our non-employee directors during 2025. Directors may be reimbursed for travel and other expenses directly related to their activities as directors. Directors who also serve as employees receive no additional compensation for their service as directors. During 2025, each of Christer Rosén, our Chief Executive Officer, Marshall Hayward, our Chief Scientific Officer, and Alison Silva, our President and Chief Business Officer, was a member of our board of directors, as well as an employee, and therefore, received no additional compensation for their services as a director. See "—2025 Summary Compensation Table" for more information about compensation to our NEOs for 2025 and 2024. The following table presents the total compensation for each person who served as a non-employee director during 2025 and 2024.

2025 and 2024 Director Compensation Table

Name	Year	Fees Earned or Paid in Cash ($)	Stock Awards ($)	Option Awards ($)	Total ($)
Nicholas H. Hemmerly	2025	$ 49,000	$ -	$ -	$ 49,000
	2024	$ 49,000	$ -	$ -	$ 49,000
Julie Kampf	2025	$ 42,500	$ -	$ -	$ 42,500
	2024	$ 42,500	$ -	$ -	$ 42,500
Holger Weis	2025	$ 44,000	$ -	$ -	$ 44,000
	2024	$ 44,000	$ -	$ -	$ 44,000
Allison W. Brady	2025	$ 40,000	$ -	$ -	$ 40,000
	2024	$ 40,000	$ -	$ -	$ 40,000

Director Agreements

On September 8, 2021, the Company entered into Independent Director Agreements with each of Allison Brady, Holger Weis, Julie Kampf and Nick Hemmerly (each, a "Director") relating to their service as independent directors of the Company.

Pursuant to each of the agreements, the Director agreed to serve as an independent director of the Company and to perform the duties consistent with such position. In addition, pursuant to their respective agreements, Ms. Brady agreed to serve as a member of the Compensation Committee and Audit Committee; Mr. Weis agreed to serve as a member of the Nomination Committee and the Chairman of the Audit Committee; Ms. Kampf agreed to serve as a member of the Compensation Committee and as Chairman of the Nomination Committee of the Board; and Mr. Hemmerly agreed to serve as Chairman of the Compensation Committee as well as a member of the Audit Committee and Nominating Committee.

Each of the Directors confirmed that the Director is independent (as such term has been construed under Delaware law with respect to directors of Delaware corporations and the OTC Markets, the NASDAQ Stock Exchange and the New York Stock Exchange). Each Director also confirmed that, to their knowledge, (a) that Director does not possess material business, close personal relationships or other affiliations, or any history of any such material business, close personal relationships or other affiliations, with the Company's significant equity or debt holders or any of their respective corporate affiliates that would cause that Director to be unable to (i) exercise independent judgment based on the best interests of the Company or (ii) make decisions and carry out that Director's responsibilities as a director of the Company, in each case in accordance with the terms of the Company's governing documents and applicable law, and (b) that they have no existing relationship or affiliation of any kind with any entity that the applicable Director knows to be a competitor of the Company.

Each of the agreements continues until the earliest of (a) such time as the Director resigns or is removed in accordance with the Company's governing documents, and (b) the death of the Director.

The Directors are compensated as follows under their respective agreements:

Each of the Directors will be paid $30,000 annually for their service as directors, to be paid $7,500 each calendar quarter, with the amount for any partial calendar quarter being appropriately prorated. In addition, the Company agreed that, on October 1, 2021, the Company will issue to each Director an option to acquire up to 67,500 shares of the common stock at an exercise price of $1.33 per share, which options will vest ratably over 36 months subject to the applicable Director continuing to serve as a director of the Company during such period. The option grants were made pursuant to an Option Award Agreement as attached to each of their respective agreements.

In addition, the applicable agreements provide that the Directors will be compensated as follows in connection with their service on Committees of the Board.

- Ms. Brady: For as long as Ms. Brady serves as a member of the Compensation Committee, Ms. Brady will be paid $5,000 annually to be paid $1,250 each calendar quarter, with the amount for any partial calendar quarter being appropriately prorated.
- For as long as Ms. Brady serves as a member of the Audit Committee, Ms. Brady will be paid $5,000 annually to be paid $1,250 each calendar quarter, with the amount for any partial calendar quarter being appropriately prorated.
- Mr. Weis:
    - For as long as Mr. Weis serves as Chairman of the Audit Committee, Mr. Weis will be paid $10,000 annually to be paid $2,500 each calendar quarter, with the amount for any partial calendar quarter being appropriately prorated.
    - For as long as Mr. Weis serves as a member of the Nominating Committee, Mr. Weis will be paid $4,000 annually to be paid $1,000 each calendar quarter, with the amount for any partial calendar quarter being appropriately prorated.

- Ms. Kampf:
    - For as long as Ms. Kampf serves as a member of the Compensation Committee, Ms. Kampf will be paid $5,000 annually to be paid $1,250 each calendar quarter, with the amount for any partial calendar quarter being appropriately prorated.
    - For as long as Ms. Kampf serves as Chairman of the Nominating Committee, Ms. Kampf will be paid $7,500 annually and $1,875 each calendar quarter, with the amount for any partial calendar quarter being appropriately prorated.
- Mr. Hemmerly:
    - For as long as Mr. Hemmerly serves as a member of the Audit Committee, Mr. Hemmerly will be paid $5,000 annually to be paid $1,250 each calendar quarter, with the amount for any partial calendar quarter being appropriately prorated.
    - For as long as Mr. Hemmerly serves as Chairman of the Compensation Committee, Mr. Hemmerly will be $10,000 annually to be paid $2,500 each calendar quarter, with the amount for any partial calendar quarter being appropriately prorated.
    - For as long as Mr. Hemmerly serves as a member of the Nominating Committee, Mr. Hemmerly will be paid $4,000 annually to be paid $1,000 each calendar quarter, with the amount for any partial calendar quarter being appropriately prorated.

Each of the agreements contains customary confidentiality provisions, and customary provisions relating to intellectual property created by the executive (i.e., a "work-made-for-hire" provision. Each of the agreements is governed by Delaware law and contains customary representations and warranties and other miscellaneous provisions.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The following table sets forth information regarding the beneficial ownership of our common stock as of March 31, 2026 by:

- each person known by us to be the beneficial owner of more than 5% of our outstanding shares of common stock;
- each of our executive officers and directors that beneficially owns shares of our common stock; and
- all our executive officers and directors as a group.

In the table below, percentage ownership is based on 36,281,252 shares of our common stock issued and outstanding as of March 31, 2026. Unless otherwise noted below, the address for each beneficial owner listed on the table is c/o Jupiter Neurosciences, Inc., 1001 North US Hwy 1, Suite 504, Jupiter, FL 33477. We have determined beneficial ownership in accordance with the rules of the SEC. We believe, based on the information furnished to us, that the persons and entities named in the tables below have sole voting and investment power with respect to all shares of common stock that they beneficially own, subject to applicable community property laws.

Name and Address of Beneficial Owner	Amount and Nature of Shares Beneficial Ownership (1)	Percentage of Class
Executive Officers and Directors:		
Christer Rosén	13,080,566(2)	33.7%
Marshall Hayward, Ph.D.	4,015,175(3)	10.7
Saleem Elmasri	732,712(4)	2.0
Alison D. Silva	983,648(5)	2.6
Alexander Rosén	1,789,099(6)	4.8
Nicholas H. Hemmerly	289,287(7)	*
Julie Kampf	259,868(8)	*
Allison W. Brady	270,409(9)	*
Holger Weis	277,436(10)	*
All executive officers and directors as a group (9 persons)	21,698,200(11)	49.0%
Other 5% Stockholders:		
Claes Wahlestedt, M.D., Ph.D.	3,120,885(12)	8.5%
Shaun Brothers	1,939,736(13)	5.6%

* less than 1%.

(1) The percentages in the table have been calculated based on 36,281,252 shares of our common stock outstanding on March 31, 2026. To calculate a stockholder's percentage of beneficial ownership, we include in the numerator and denominator the common stock outstanding and all shares of our common stock issuable to that person in the event of the exercise of outstanding options and other derivative securities owned by that person which are exercisable within 60 days of March 31, 2026. Common stock options and derivative securities held by other stockholders are disregarded in this calculation. Therefore, the denominator used in calculating beneficial ownership among our stockholders may differ. Unless we have indicated otherwise, each person named in the table has sole voting power and sole investment power for the shares listed opposite such person's name.

(2) Includes 2,003,678 shares of common stock that may be acquired within 60 days of March 31, 2026 upon exercise of vested options.

(3) Includes 1,020,098 shares of common stock that may be acquired within 60 days of March 31, 2026 upon exercise of vested options.

(4) Includes 666,420 shares of common stock that may be acquired within 60 days of March 31, 2026 upon exercise of vested options.

(5) Includes 870,871 shares of common stock that may be acquired within 60 days of March 31, 2026 upon exercise of vested options.

(6) Includes 1,171,688 shares of common stock that may be acquired within 60 days of March 31, 2026 upon exercise of vested options.

(7) Includes 193,737 shares of common stock that may be acquired within 60 days of March 31, 2026 upon exercise of vested options.

(8) Includes 176,993shares of common stock that may be acquired within 60 days of March 31, 2026 upon exercise of vested options.

(9) Includes 170,659 shares of common stock that may be acquired within 60 days of March 31, 2026 upon exercise of vested options.

(10) Includes 180,855 shares of common stock that may be acquired within 60 days of March 31, 2026 upon exercise of vested options.

(11) Represents shares of common stock beneficially owned by Christer Rosén, Marshall Hayward, Ph.D., Saleem Elmasri, Alison D. Silva, Alexander Rosén, Nicholas H. Hemmerly, Julie Kampf, Allison W. Brady, and Holger Weis, as shown in the table above and in the footnotes to such table.

(12) Includes 289,609 shares of common stock that may be acquired within 60 days of March 31, 2026 upon exercise of vested options.

(13) Includes 326,319 shares of common stock that may be acquired within 60 days of March 31, 2026 upon exercise of vested options.

Securities Authorized for Issuance under Equity Compensation Plans

The following table provides information as of December 31, 2025, regarding our compensation plans under which equity securities are authorized for issuance:

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
	(a)	(b)	(c)
Equity compensation plans approved by security holders	8,254,974	$ 0.94	9,893,319
Equity compensation plans not approved by security holders	3,948,928	1.20	-
Total	12,203,902	$ 1.02	9,893,319

The Company's stockholders approved the 2016 Equity Incentive Plan ("2016 Plan") on January 4, 2016. Under the 2016 Plan, as modified, 8,437,500 shares of common stock are authorized for issuance to employees, officers, directors, consultants. The 2016 Plan authorizes the grant of nonqualified stock options and incentive stock options, restricted stock awards, restricted stock units, stock appreciation rights, under the 2016 Plan. The Company does not intend to make any additional grants under the 2016 Plan. As of March 31, 2026, there were 2,156,184 shares available for issuance under the 2016 Plan.

The Board of Directors and stockholders of the Company approved the 2021 Equity Incentive Plan (the "2021 Plan") on September 17, 2021. Under the 2021 Plan, 1,125,000 shares of common stock were initially authorized for issuance to employees, directors and independent contractors (except those performing services in connection with the offer or sale of the Company's securities in a capital raising transaction, or promoting or maintaining a market for the Company's securities) of the Company or its subsidiaries. The 2021 Plan authorizes equity-based and cash-based incentives for participants. On July 22, 2022, the Board of Directors increased the shares authorized for issuance pursuant to the 2021 Plan to 1,710,000. The Company does not intend to make any grants under the 2021 Plan. As of March 31, 2026, there were 1,440,000 shares available for issuance under the 2021 Plan.

The Board of Directors and stockholders of the Company approved the 2023 Plan on October 4, 2023. Under the 2023 Plan, 4,012,785 shares of common stock were authorized for issuance to employees, directors and independent contractors (except those performing services in connection with the offer or sale of the Company's securities in a capital raising transaction, or promoting or maintaining a market for the Company's securities) of the Company or its subsidiaries. As of March 31, 2026, there were 1,047,135 shares available for issuance under the 2023 Plan.

The Board of Directors and stockholders of the Company approved the 2025 Equity Incentive Plan (the "2025 Plan") on December 19, 2025. Under the 2025 Plan, 5,250,000 shares of common stock are authorized for issuance to employees, directors and independent contractors (except those performing services in connection with the offer or sale of the Company's securities in a capital raising transaction, or promoting or maintaining a market for the Company's securities) of the Company or its subsidiaries. As of March 31, 2026, there were 5,250,000 shares available for issuance under the 2025 Plan.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Policies and Procedures for Related Party Transactions

Under Item 404 of SEC Regulation S-K, a related person transaction is any actual or proposed transaction, arrangement or relationship or series of similar transactions, arrangements or relationships, including those involving indebtedness not in the ordinary course of business, to which we or our subsidiaries were or are a party, or in which we or our subsidiaries were or are a participant, in which the amount involved exceeded or exceeds the lesser of $120,000 or 1% of the average of our total assets at year-end for the last two completed fiscal years and in which any of our directors, nominees for director, executive officers, beneficial owners of more than 5% of any class of our voting securities, or any member of the immediate family of any of the foregoing persons, had or will have a direct or indirect material interest.

We recognize that transactions between us and any of our directors or executives or with a third party in which one of our officers, directors or significant shareholders has an interest can present potential or actual conflicts of interest and create the appearance that our decisions are based on considerations other than the best interests of our Company and stockholders.

The Audit Committee of the Board of Directors is charged with responsibility for reviewing, approving and overseeing any transaction between the Company and any related person (as defined in Item 404 of Regulation S-K), including the propriety and ethical implications of any such transactions, as reported or disclosed to the Audit Committee by the independent auditors, employees, officers, members of the Board of Directors or otherwise, and to determine whether the terms of the transaction are not less favorable to us than could be obtained from an unaffiliated party

From time to time, we engage in transactions with related parties. The following is a summary of the related party transactions for the fiscal years ended December 31, 2025 and 2024 requiring disclosure pursuant to Item 404 of Regulation S-K.

Notes Payable, related party

The Company's Chief Executive Officer (CEO) has loaned the Company working capital since inception. The balance of the loans to the CEO as of December 31, 2024 was $146,432. The loan was due on demand and accrues interest at 3% per year. Accrued interest relating to the loan was $1,064 as of December 31, 2024, and is included in accrued interest on the accompanying 2024 balance sheets. The Company fully settled the debt in 2025 by repaying a total of $150,782, $146,432 in principal and $4,350 in accrued interest. The Company repaid a total of $100,000 during the year ended December 31, 2024, $83,880 in principal and $16,120 in accrued interest.

On April 29, 2024, the Company, the Holder of the Note II and the CEO entered into an amendment in which the CEO agreed to exchange 685,869 shares issued to the Holder in exchange for his related party notes that accrued interest at 3% that are due from the Company in an aggregate principal amount of $266,667 and the Holder agreed to forfeit all rights to all additional future shares from the Company that would have become due upon a qualified offering and the conversion feature of the note. In addition, the Holder agreed to extend the note maturity date to August 11, 2024. The note shall be designated as a 10% original issue discount secured note ("Senior Secured Note") moving forward. The note and interest will become due and payable upon the earliest of the maturity date or upon the occurrence of a qualified event.

Other Related Party Transactions

Accrued compensation includes partially accrued salaries to executives since inception. Since inception, executive salaries have been paid in cash when the Company's cash flow has permitted such payment.

On March 15, 2024, a former executive agreed to forgive $100,000 of accrued compensation in exchange for 49,605 options to purchase common stock and 7,500 restricted stock units, The options to purchase common stock have a strike price of $1.33. The option had a grant date fair value of $50,000. The Company recorded a gain on the forgiveness of accrued compensation in the amount of $40,000.

As of December 31, 2025 and 2024, $64,105 was due to a Company wholly owned by the Company's Chief Financial Officer, who also is an option holder, respectively. The amount is included in accrued compensation on the Company's balance sheets.

Titan Consulting Agreement

On December 31, 2022, the Company entered into a Master Services Agreement with Titan Advisory Services LLC ("Titan"), which is wholly-owned by Mr. Elmasri and his wife, pursuant to which Titan will provide certain services to the Company (the "MSA"). The MSA provides that the specific services (the "Services") will be described in separate Scopes of Work ("SOW") which will constitute a part of the MSA. The term of the MSA continues until 30 days after either party notifies the others that it desires to terminate the MSA.

The Services, which commenced on January 1, 2023, are to be provided by Saleem Elmasri, and include Mr. Elmasri serving as the Chief Financial Officer of the Company, and having the following responsibilities: (i) overall financial strategy implementation and execution; (ii) overseeing forecasts and budgeting; (iii) overseeing the Company's finance/accounting department; (iv) financial reporting; and (v) overseeing tax compliance. Separately, Mr. Elmasri has also been named as the Secretary of the Company.

The MSA agreement provides that the Company shall pay Titan a monthly fee in the amount of $25,000 (annual fee in aggregate of $300,000 per year) and that Mr. Elmasri will be issued an option to acquire 562,500 shares of common stock, pursuant to a separate option agreement. 25% of the options are vested upon issuance, with the balance to vest in equal quarterly installments over the following 24 months, and the option has a 10-year term. The exercise price for the shares of common stock will be $1.33. The options will accelerate and vest immediately upon a merger, acquisition or other transaction that will be deemed a change of control of the Company. Titan and Mr. Elmasri will be eligible to participate in additional incentive equity or cash compensation alongside the Company's other executives, at the sole discretion of the Company. Any additional resources used by Titan to provide the Services, subject to prior approval by the Company, will be billed to the Company at between $150 and $250 per hour, and the Company has also agreed to reimburse Titan for all reasonable out-of-pocket expenses that Titan incurs in providing the Services.

The MSA includes a customary confidentiality provision for the benefit of the Company, and also includes a non-solicitation provision pursuant to which each party agrees that during the term of the MSA and for a period of one year thereafter, neither party will, without the prior written consent of the other, engage in any way, employ, hire, or otherwise do business with any employee or former employee of the other party.

The MSA provides that the Company will be solely responsible for the contents of the information it provides to Titan in connection with the MSA, and the Company makes customary representations and warranties regarding such information. The Company also agreed in the MSA to indemnify Titan, its principals, employees and representatives, from and against any claims, losses, damages or any other liability arising from or as a result of (i) Titan performing the Services or any other services requested by the Company, (ii) any claim by the Company or any third party of any misrepresentation or reliance on any information resulting from the Services; (iii) any claim by the Company or any third party or governmental agency brought under the federal securities laws or other statutes, state statute, or common law, or otherwise, or (iv) any claim by the Company or any third party in connection with the sale or issuance of any shares of the Company's stock, or other equity or debt of the Company. The maximum liability of Titan that may arise out of the Services is limited to the total fees paid to Titan for a particular SOW, unless Titan is found to be grossly negligent in its duties or acts with willful misconduct.

The MSA contains customary miscellaneous provisions, including a no-assignment provision, and an agreement to submit any disputes to mediation, or thereafter to arbitration if the mediation is not successful.

On January 31, 2023, Titan agreed to reduce the monthly fee to $20,000 per month until the time that the Company has raised additional capital from the sale of its securities in the amount of $1,500,000.

On December 18, 2023, Titan agreed to reduce the monthly fee to $5,000 per month, effective retrospectively to October 1, 2023, until the time that the Company has raised additional capital from the sale of its securities in the amount of $1,500,000 (the "Reduction Period"). Upon the expiration of the Reduction Period, the base salary shall be adjusted to be 105% the original base salary. Such adjustment did not go into effect.

On December 17, 2024, the parties agreed that the Company would pay to Titan a monthly fee in the amount of $20,000 (amounting to an aggregate annual fee of $240,000). Titan is not owed any additional fees upon a termination or change in control. In addition, Titan is eligible for cash bonuses and additional equity compensation, at the Company's discretion.

Director Independence

Our common stock is listed on the Nasdaq Capital Market. Under applicable rules of the Nasdaq Capital Market, a director will only qualify as an "independent director" if, in the opinion of the listed company's board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. In order to be considered independent for purposes of Rule 10A-3, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors, or any other board committee, accept, directly or indirectly, any consulting, advisory, or other compensatory fee from the listed company or any of its subsidiaries or otherwise be an affiliated person of the listed company or any of its subsidiaries.

The Company's Board of Directors has affirmatively determined that currently three of its seven directors (Christer Rosén, Marshall Hayward, Ph.D., and Alison D. Silva) are non-independent directors of the Company and four of its seven directors (Nicholas H. Hemmerly, Julie Kampf, Allison W. Brady, and Holger Weis) are independent directors of the Company as defined in the Nasdaq standards. Therefore, a majority of the members of our Board of Directors are independent.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Our Audit Committee has appointed Cherry Bekaert LLP as the Company's independent registered public accounting firm for the fiscal year ended December 31, 2025 and Assurance Dimensions, LLC as the Company's independent registered public accounting firm for the fiscal year ended December 31, 2024. The following is a summary of fees paid or to be paid to Cherry Bekaert and Assurance Dimensions for the fiscal years ended December 31, 2025 and 2024.

	Year Ended December 31,	
	2025	2024
Audit Fees	$ 112,000	$ 84,000
Audit-Related Fees	-	14,300
Tax Fees	-	-
All Other Fees	-	-
Total	$ 112,000	$ 98,300

Audit Fees. Audit fees consist of fees billed for professional services rendered for the audit of our year-end financial statements and services that are normally provided by our independent registered public accounting firm in connection with regulatory filings. The above amounts include interim procedures and audit fees, as well as attendance at Audit Committee meetings.

Audit-Related Fees. Audit-related services consist of fees billed for assurance and related services that are reasonably related to performance of the audit or review of our financial statements and are not reported under "Audit Fees." These services include attest services that are not required by statute or regulation and consultations concerning financial accounting and reporting standards.

Tax Fees. Tax fees consist of fees billed for tax planning services and tax advice. The board of directors must specifically approve all other tax services.

All Other Fees. Other services are services provided by the independent registered public accounting firm that do not fall within the established audit, audit-related, and tax services categories. The board of directors preapproves specified other services that do not fall within any of the specified prohibited categories of services.

Pre-Approval Policy

Since formation of our Audit Committee, all of the foregoing services were pre-approved by our Audit Committee. Our Audit Committee will pre-approve all auditing services and permitted non-audit services to be performed for us by our auditors, including the fees and terms thereof (subject to the de minimis exceptions for non-audit services described in the Exchange Act which are approved by the Audit Committee prior to the completion of the audit).

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

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

(1) Financial Statements

(2) Financial Statements Schedules

All financial statements schedules are omitted because they are not applicable or the amounts are immaterial and not required, or the required information is presented in the financial statements and notes thereto beginning on page F-1 of this Annual Report on Form 10-K.

(3) Exhibits

We hereby file as part of this Annual Report on Form 10-K the exhibits listed in the Exhibit Index below. Exhibits which are incorporated herein by reference can be inspected and copied at the public reference facilities maintained by the SEC, 100 F Street, N.E., Room 1580, Washington, D.C. 20549. Copies of such material can also be obtained from the Public Reference Section of the SEC, 100 F Street, N.E., Washington, D.C. 20549, at prescribed rates or on the SEC website at www.sec.gov.

EXHIBIT INDEX

Exhibit No.	Exhibit
3.1	Certificate of Incorporation of the Company dated December 30, 2015 (incorporated by reference to Exhibit 3.1 of the Company's Registration Statement on Form S-1 filed with the SEC on October 12, 2021)
3.2	Certificate of Amendment to Certificate of Incorporation of Jupiter Neurosciences, Inc. (incorporated by reference to Exhibit 3.1 of the Company's Current Report on 8-K filed with the SEC on December 22, 2025).
3.3	Certificate of Validation of the Company dated July 9, 2021 (including Certificate of Amendment to Certificate of Incorporation of the Company) (incorporated by reference to Exhibit 3.2 of the Company's Registration Statement on Form S-1 filed with the SEC on October 12, 2021)
3.4	Certificate of Amendment to Certificate of Incorporation of the Company dated August 30, 2021 (incorporated by reference to Exhibit 3.3 of the Company's Registration Statement on Form S-1 filed with the SEC on October 12, 2021)
3.5	Certificate of Amendment to Certificate of Incorporation of the Company dated November 19, 2021 (incorporated by reference to Exhibit 3.4 of the Company's Registration Statement on Form S-1/A filed with the SEC on December 17, 2021)
3.6	Certificate of Amendment to Certificate of Incorporation of the Company dated January 25, 2022 (incorporated by reference to Exhibit 3.5 of the Company's Registration Statement on Form S-1/A filed with the SEC on January 26, 2022)
3.7	Certificate of Amendment to Certificate of Incorporation of the Company dated June 14, 2024 (incorporated by reference to Exhibit 3.6 of the Company's Registration Statement on Form S-1/A filed with the SEC on July 12, 2024)
3.8	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.4 of the Company's Registration Statement on Form S-1 filed with the SEC on October 12, 2021)
4.1*	Description of Capital Stock.
4.2	Form of Convertible Promissory Note issued to YA II PN, Ltd. (incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K filed with the SEC on October 27, 2025)+#
4.3	Form of Amended and Restated Convertible Promissory Note issued to YA II PN, Ltd. (incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K filed with the SEC on November 19, 2025).+#
4.4	Omnibus Amendment to the Convertible Promissory Notes issued to YA II PN, Ltd., dated February 20, 2026, between Jupiter Neurosciences, Inc. and YA II PN, Ltd. (incorporated by reference to Exhibit 4.3 of the Company's Current Report on Form 8-K filed with the SEC on February 20, 2026). #
10.1	Jupiter Orphan Therapeutics, Inc. 2021 Equity Incentive Plan† (incorporated by reference to Exhibit 10.1 of the Company's Registration Statement on Form S-1 filed with the SEC on October 12, 2021)
10.2	Employment Agreement, dated as of September 1, 2021, between the Company and Christer Rosén (incorporated by reference to Exhibit 10.2 of the Company's Registration Statement on Form S-1 filed with the SEC on October 12, 2021)†
10.3	Amendment No. 1 to Executive Employment Agreement, dated as of September 29, 2021, between the Company and Christer Rosén (incorporated by reference to Exhibit 10.3 of the Company's Registration Statement on Form S-1 filed with the SEC on October 12, 2021)†
10.4*	Amendment No. 2 to Executive Employment Agreement, dated as of December 18, 2023, between the Company and Christer Rosén†
10.5	Employment Agreement, dated as of September 1, 2021, between the Company and Marshall Hayward, Ph.D. (incorporated by reference to Exhibit 10.4 of the Company's Registration Statement on Form S-1 filed with the SEC on October 12, 2021)†
10.6	Amendment No. 1 to Executive Employment Agreement, dated as of September 29, 2021, between the Company and Marshall Hayward, Ph.D. (incorporated by reference to Exhibit 10.5 of the Company's Registration Statement on Form S-1 filed with the SEC on October 12, 2021)†
10.7*	Amendment No. 2 to Executive Employment Agreement, dated as of December 18, 2023, between the Company and Marshall Hayward, Ph.D.†
10.8	Employment Agreement, dated as of June 6, 2021, between the Company and Alexander Rosén (incorporated by reference to Exhibit 10.6 of the Company's Registration Statement on Form S-1 filed with the SEC on October 12, 2021)†
10.9	Amendment No. 1 to Executive Employment Agreement, dated as of September 29, 2021, between the Company and Alexander Rosén (incorporated by reference to Exhibit 10.7 of the Company's Registration Statement on Form S-1 filed with the SEC on October 12, 2021)†
10.10	Employment Agreement, dated as of September 1, 2021, between the Company and Alison Silva (incorporated by reference to Exhibit 10.8 of the Company's Registration Statement on Form S-1 filed with the SEC on October 12, 2021)†
10.11	Amendment No. 1 to Executive Employment Agreement, dated as of September 29, 2021, between the Company and Alison D. Silva (incorporated by reference to Exhibit 10.9 of the Company's Registration Statement on Form S-1 filed with the SEC on October 12, 2021)†
10.12	Amendment No. 2 to Executive Employment Agreement, dated as of December 18, 2023, between the Company and Alison D. Silva.†
10.13	Employment Agreement, dated as of June 1, 2021, between the Company and Dana Eschenburg Perez (incorporated by reference to Exhibit 10.10 of the Company's Registration Statement on Form S-1 filed with the SEC on October 12, 2021)†
10.14	Amendment No. 1 to Executive Employment Agreement, dated as of September 29, 2021, between the Company and Dana Eschenburg Perez (incorporated by reference to Exhibit 10.11 of the Company's Registration Statement on Form S-1 filed with the SEC on October 12, 2021)†
10.15	Independent Director Agreement, dated as of September 8, 2021, between the Company and Nicholas H. Hemmerly (incorporated by reference to Exhibit 10.12 of the Company's Registration Statement on Form S-1 filed with the SEC on October 12, 2021)†
10.16	Independent Director Agreement, dated as of September 8, 2021, between the Company and Julie Kampf (incorporated by reference to Exhibit 10.13 of the Company's Registration Statement on Form S-1 filed with the SEC on October 12, 2021)†

10.17	Independent Director Agreement, dated as of September 8, 2021 between the Company and Allison W. Brady (incorporated by reference to Exhibit 10.14 of the Company's Registration Statement on Form S-1 filed with the SEC on October 12, 2021)†
10.18	Independent Director Agreement, dated as of September 8, 2021, between the Company and Holger Weis (incorporated by reference to Exhibit 10.16 of the Company's Registration Statement on Form S-1 filed with the SEC on October 12, 2021)†
10.19	License Agreement with Aquanova AG (incorporated by reference to Exhibit 10.16 of the Company's Registration Statement on Form S-1/A filed with the SEC on November 9, 2021)
10.20	Grant Agreement between Company and National Institute on Aging (incorporated by reference to Exhibit 10.17 of the Company's Registration Statement on Form S-1/A filed with the SEC on November 9, 2021)
10.21	Agreement between Company and Murdoch Children's Research Institute (incorporated by reference to Exhibit 10.18 of the Company's Registration Statement on Form S-1/A filed with the SEC on November 9, 2021)
10.22	Manufacturing Agreement between Company and Catalent (incorporated by reference to Exhibit 10.19 of the Company's Registration Statement on Form S-1/A filed with the SEC on November 9, 2021)
10.23	Agreement between the Company and Syneos Health (incorporated by reference to Exhibit 10.20 of the Company's Registration Statement on Form S-1/A filed with the SEC on November 9, 2021)
10.24	Material Transfer Agreement between the Company and University of Miami (incorporated by reference to Exhibit 10.21 of the Company's Registration Statement on Form S-1/A filed with the SEC on November 9, 2021)
10.25	Research Agreement, dated July 1, 2022, between the Company and University of Miami (incorporated by reference to Exhibit 10.30 of the Company's Registration Statement on Form S-1/A filed with the SEC on August 26, 2022)
10.26	Amendment to the Securities Purchase Agreement, dated as of October 10, 2022, between the Company and Puritan Partners LLC (incorporated by reference to Exhibit 10.31 of the Company's Registration Statement on Form S-1/A filed with the SEC on December 2, 2022)
10.27	Second Amendment to the Securities Purchase Agreement, dated as of November 10, 2022, between the Company and Puritan Partners LLC (incorporated by reference to Exhibit 10.32 of the Company's Registration Statement on Form S-1/A filed with the SEC on December 2, 2022)
10.28	Master Services Agreement, dated as of December 27, 2022, between the Company and Titan Advisory Services (incorporated by reference to Exhibit 10.33 of the Company's Registration Statement on Form S-1/A filed with the SEC on January 6, 2023)†
10.29	Third Amendment to the Securities Purchase Agreement, dated as of January 13, 2013, between the Company and Puritan Partners LLC (incorporated by reference to Exhibit 10.35 of the Company's Registration Statement on Form S-1/A filed with the SEC on January 17, 2023)

10.30	CRO Services Agreement, dated June 3, 2024, between the Company and Optimize Wellness Limited (incorporated by reference to Exhibit 10.35 of the Company's Registration Statement on Form S-1/A filed with the SEC on July 12, 2024)
10.31	Regulatory Services Agreement, dated June 3, 2024, between the Company and Regis Healthcare Group Limited (incorporated by reference to Exhibit 10.36 of the Company's Registration Statement on Form S-1/A filed with the SEC on July 12, 2024)
10.32	Product Services Agreement, dated June 3, 2024, between the Company and Longevity Technology Group Limited (incorporated by reference to Exhibit 10.37 of the Company's Registration Statement on Form S-1/A filed with the SEC on July 12, 2024)
10.33	Jupiter Neurosciences, Inc. 2023 Equity Incentive Plan (incorporated by reference to Exhibit 10.40 of the Company's Registration Statement on Form S-1/A filed with the SEC on July 12, 2024)†
10.34	Tenth Amendment, dated as of November 15, 2024, between Puritan Partners LLC and the Company (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on November 19, 2024)
10.35	Underwriting Agreement, dated as of December 2, 2024, between the Company and the certain underwriter set forth in the signature page thereto (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on December 4, 2024)
10.36	Strategic Services Agreement, dated December 15, 2024, by and between the Company and Dominant Treasure Health Company Limited (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on December 19, 2024)
10.37	Scope of Work, dated December 17, 2024, by and between Jupiter Neurosciences, Inc. and Titan Advisory Services LLC (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on December 20, 2024)
10.38	Standby Equity Purchase Agreement, as of October 24, 2025, between Jupiter Neurosciences, Inc. and YA II PN, Ltd. (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on October 27, 2025). +#
10.39	Amendment No. 1 to the Standby Equity Purchase Agreement, as of November 19, 2025, between Jupiter Neurosciences, Inc. and YA II PN, Ltd. (incorporated by reference to Exhibit 10.3 of the Company's Current Report on Form 8-K filed with the SEC on November 19, 2025) +#
10.40	Registration Rights Agreement, as of October 24, 2025, between Jupiter Neurosciences, Inc. and YA II PN, Ltd. (incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K filed with the SEC on October 27, 2025) +
10.41	Jupiter Neurosciences, Inc. 2025 Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on December 22, 2025).
14.1*	Code of Ethics and Business Conduct (incorporated by reference to Exhibit 14.1 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2024, filed with the SEC on March 28, 2025)
19.1*	Policy on Insider Trading (incorporated by reference to Exhibit 19.1 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2024, filed with the SEC on March 28, 2025)
23.1*	Consent of Cherry Bekaert LLP
23.2*	Consent of Assurance Dimensions, LLC
24.1*	Power of Attorney (included on the signature page)
31.1*	Rule 13a-14(a) Certification of Principal Executive Officer
31.2*	Rule 13a-14(a) Certification of Principal Financial Officer
32.1**	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, of Principal Executive Officer and Principal Financial Officer
97.1*	Compensation Recovery Policy.
101.INS*	Inline XBRL Instance Document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase
101.LAB*	Inline XBRL Taxonomy Extension Labels Linkbase
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase
104*	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.
** Furnished herewith.
† Management contracts, compensation plans and arrangements.
+ Certain portions of this exhibit (indicated by "[***]") have been redacted pursuant to Regulation S-K Item 601(a)(6).
# Schedules and exhibits have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The registrant undertakes to furnish supplemental copies of any of the omitted schedules upon request by the SEC.

ITEM 16. FORM 10-K SUMMARY

Not applicable.

JUPITER NEUROSCIENCES, INC.
Index to Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders
Jupiter Neurosciences, Inc.
Jupiter, Florida

Opinion on the Financial Statements

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

Substantial Doubt about the Company's Ability to Continue as a Going Concern

The accompanying financial statements have been prepared assuming the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has recurring losses and negative cash flows from operations that raise substantial doubt about its ability to continue as a going concern. Management's evaluations of the events and conditions and management's plans regarding those matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

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

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

/s/ Cherry Bekaert LLP

We have served as the Company's auditor since 2025.

Tampa, Florida
April 1, 2026

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of Directors of
Jupiter Neurosciences, Inc

Opinion on the Financial Statements

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

Explanatory Paragraph – Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company had a net loss of approximately $2,440,000 and cash used in operating activities of approximately $3,911,000 for the year ended December 31, 2024 as well as an accumulated deficit of approximately $26,022,000 as of December 31, 2024. These factors raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

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

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

Assurance Dimensions

Coral Springs, Florida
March 28, 2025

ASSURANCE DIMENSIONS, LLC
also d/b/a McNAMARA and ASSOCIATES, LLC
TAMPA BAY: 4920 W Cypress Street, Suite 102 | Tampa, FL 33607 | Office: 813.443.5048 | Fax: 813.443.5053
JACKSONVILLE: 7800 Belfort Parkway, Suite 290 | Jacksonville, FL 32256 | Office: 888.410.2323 | Fax: 813.443.5053
ORLANDO: 1800 Pembrook Drive, Suite 300 | Orlando, FL 32810 | Office: 888.410.2323 | Fax: 813.443.5053
SOUTH FLORIDA: 3111 N. University Drive, Suite 621 | Coral Springs, FL 33065 | Office: 754.800.3400 | Fax: 813.443.5053
www.assurancedimensions.com

JUPITER NEUROSCIENCES, INC.
BALANCE SHEETS

	December 31, 2025	December 31, 2024
Assets		
Current Assets:		
Cash	$ 3,789,342	$ 3,769,510
Account receivable	2,637	-
Prepaid contracts	766,667	766,667
Inventory, net	159,790	-
Other current assets	106,542	114,086
Total current assets	4,824,978	4,650,263
Operating lease right of use asset, net	23,214	69,642
Prepaid contracts, noncurrent	712,055	1,478,721
Other assets	3,783	3,783
Total assets	$ 5,564,030	$ 6,202,409
Liabilities and Stockholders' Deficit		
Current Liabilities:		
Accounts payable and accrued expenses	$ 638,646	$ 396,483
Accrued compensation	1,397,357	1,415,093
Accrued interest	39,829	1,064
Deferred revenue	735	-
Current portion of operating lease liability	21,247	50,082
Note payable, related party	-	146,432
Convertible notes payable, fair value	5,298,068	-
Other liability	-	-
Total current liabilities	7,395,882	2,009,154
Operating lease liability, net of current portion	-	21,247
Total liabilities	7,395,882	2,030,401
Commitments and Contingencies (Note 8)		
Stockholders' Deficit:		
Series A preferred stock, par value $0.0001; 5,000,000 shares authorized, nil shares issued and outstanding	-	-
Common stock, par value $0.0001; 500,000,000 and 125,000,000 shares authorized, respectively; 34,446,455 and 33,103,860 issued and outstanding, respectively	3,444	3,310
Additional paid in capital	32,831,730	30,190,827
Accumulated deficit	(34,667,026)	(26,022,129)
Total stockholders' deficit	(1,831,852)	4,172,008
Total liabilities and stockholders' deficit	$ 5,564,030	$ 6,202,409

The accompanying notes are an integral part of these audited financial statements

JUPITER NEUROSCIENCES, INC.
STATEMENTS OF OPERATIONS

	For the Year Ended 31-Dec-25	For the Year Ended 31-Dec-24
Product Revenues, net	$ 21,796	$ -
Cost of goods sold	4,231	-
Gross Profit	$ 17,565	$ -
Expenses:		
Research and development	2,086,574	492,660
General and administrative	6,839,712	2,598,622
Total operating expenses	8,926,286	3,091,282
Operating loss	(8,908,721)	(3,091,282)
Other Income (Expenses):		
Interest income	-	5,557
Loss on change in fair value of derivative liability	-	(53,257)
Gain on change in fair value of convertible notes	281,932	-
Interest expense	(66,020)	(248,366)
Gain on extinguishment of debt	-	857,723
Other income	47,912	90,000
Total other expenses, net	263,824	651,657
Net income (loss)	$ (8,644,897)	$ (2,439,625)
Net loss per common share:		
Basic	$ (0.25)	$ (0.08)
Diluted	$ (0.25)	$ (0.08)
Weighted average number of common shares outstanding:		
Basic	34,628,588	28,783,045
Diluted	34,628,588	28,783,045

The accompanying notes are an integral part of these audited financial statements

JUPITER NEUROSCIENCES, INC.
STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)

	Common Stock		Additional Paid	Accumulated	Total Stockholders'
	Shares	Amount	in Capital	Deficit	Deficit
December 31, 2023	**26,526,405**	**$ 2,652**	**$ 17,778,498**	**$ (23,582,504)**	**$ (5,801,354)**
Stock-based compensation	-	-	1,840,908	-	1,840,908
Issuance of restricted stock units for forgiveness of accrued salary	-	-	10,000	-	10,000
Issuance of stock options for forgiveness of accrued salary	-	-	50,000	-	50,000
Restricted stock issued for consulting agreements	3,487,500	349	(349)		-
Sale of common stock	112,500	11	149,989		150,000
Stock issued in connection with automatic conversion of convertible notes	227,447	23	636,843		636,866
Stock sold in offering, net of offering costs	2,750,000	275	9,724,938		9,725,213
Reconciling shares due to forward stock split	8	-	-		-
Net operating loss	-	-	-	(2,439,625)	(2,439,625)
December 31, 2024	**33,103,860**	**$ 3,310**	**$ 30,190,827**	**$ (26,022,129)**	**$ 4,172,008**

	Common Stock		Additional Paid	Receivables for Sale of Common	Accumulated	Total Stockholders'
	Shares	Amount	in Capital	Stock	Deficit	Deficit
December 31, 2024	**33,103,860**	**$ 3,310**	**$ 30,190,827**	**$ -**	**$ (26,022,129)**	**$ 4,172,008**
Stock-based compensation	-	-	2,139,908	-	-	2,139,908
Shares issued for services rendered	103,186	10	65,990	-	-	66,000
Shares issued for warrant exercises	943,846	94	(94)	-	-	-
Shares issued in connection with warrant amendments	143,654	15	212,593	-	-	212,608
Issuance of common stock for payment of interest	20,000	2	22,519	-	-	22,521
Commitment shares issued in connection with SEPA	131,909	13	199,987	-	-	200,000
Net operating loss	-	-	-	-	(8,644,897)	(8,644,897)
December 31, 2025	**34,446,455**	**$ 3,444**	**$ 32,831,730**	**$ -**	**$ (34,667,026)**	**$ (1,831,852)**

The accompanying notes are an integral part of these financial statements

JUPITER NEUROSCIENCES, INC.
STATEMENTS OF CASH FLOWS

	2025	2024
Cash Flows from Operating Activities:		
Net Loss	$ (8,644,897)	$ (2,439,625)
Adjustments to reconcile net loss to net cash used in operating activities:		
Loss on change in fair value of derivative liability	-	53,257
Gain on change in fair value of convertible notes	(281,932)	-
Amortization of debt discounts	-	43,288
Loss (Gain) on extinguishment of debt	-	(857,723)
Gain on forgiveness of accrued compensation	-	(40,000)
Amortization of prepaid contracts	766,666	54,612
Non-cash financing cost	200,000	-
Interest expense paid through sale of common stock	22,521	-
Stock-based compensation	2,418,516	1,840,908
Changes in operating assets and liabilities:		
Increase in accounts receivable	(2,637)	-
Decrease (increase) in prepaid contracts	-	(2,300,000)
Increase in prepaid and other current assets	-	(113,826)
Increase in inventory	(159,790)	-
Increase in other current assets	7,544	-
Decrease in operating lease right of use asset	(3,654)	(1,785)
Increase in deferred revenue	735	-
Increase in accounts payable and accrued expenses	242,163	(149,530)
Decrease in accrued compensation	(17,736)	(46,948)
Increase in accrued interest	38,765	46,368
Net cash used in operating activities	(5,413,736)	(3,911,004)
Cash Flows from Financing Activities:		
Proceeds from note payable, related parties	-	138,500
Payment on notes payable, related party	(146,432)	(108,880)
Payment on notes payable	-	(2,102,797)
Payment on convertible note payable	-	(150,000)
Proceeds from issuance convertible note payable, net	5,580,000	-
Proceeds from offering, net of offering costs	-	9,725,213
Proceeds from sale of common stock	-	150,000
Net cash provided by financing activities	5,433,568	7,652,036
Net Change in Cash	19,832	3,741,032
Beginning of period	3,769,510	28,478
End of period	$ 3,789,342	$ 3,769,510
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 38,426	$ 147,776
Schedule of Non-Cash Investing and Financing Activities:		
Restricted stock issued for forgiveness of salary	$ -	$ 10,000
Stock options issued for forgiveness of salary	$ -	$ 50,000
Notes payable, related party assign to Note payable	$ -	$ 266,667
Stock issued in connection with convertible promissory notes	$ 200,000	$ 636,866
Stock issued in connection interest payment	$ 22,521	$ -

The accompanying notes are an integral part of these financial statements

Note 1 – Organization and Description of Business

Jupiter Neurosciences, Inc. (the "Company") is a clinical stage research and development pharmaceutical company located in Jupiter, Florida. The Company incorporated in Delaware in January 2016. The Company is advancing a therapeutic pipeline targeting central nervous system ("CNS") disorders and rare diseases, while also expanding into the consumer longevity market with its Nugevia product line. Both efforts are powered by JOTROL™, the Company's proprietary, enhanced resveratrol formulation that has demonstrated potential for significantly improved bioavailability. The Company's prescription pipeline is focused broadly on CNS disorders, presently with a planned Phase IIa clinical study in Parkinson's disease. The Company's Nugevia product line brings clinical-grade science to the supplement space, supporting mental clarity, skin health, and mitochondrial function.

On August 30, 2021, the Company filed a Certificate of Amendment to the Certificate of Incorporation with the State of Delaware to change its name from Jupiter Orphan Therapeutics, Inc. to Jupiter Neurosciences, Inc.

JOTROL™ has the potential to deliver a therapeutically effective dose of resveratrol in the blood stream, using a unique patented micellar formulation, without causing gastrointestinal side effects. We expect JOTROL™, based on the results of our Phase I study, will resolve the major obstacle of resveratrol's poor bioavailability, which has been documented in various scientific articles describing previously conducted human trials with resveratrol as well as preclinical trial results in mice and rats.

On June 14, 2024, the Company increased the number of authorized shares of common stock, $0.0001 par value per share, to 125,000,000 from 45,000,000.

On June 14, 2024, the Company effected a fifteen-for-four (15:4) forward stock split whereby the Company (i) increased the number of issued and outstanding shares of common stock, $0.0001 par value per share, from 8,033,706 to 30,126,413 and (ii) increased by a ratio of fifteen-for-four (15:4) the number of retroactively issued and outstanding shares of common stock. Proportional adjustments for the forward stock split were made to the Company's outstanding stock options, warrants and equity incentive plans. All share and per-share data and amounts have been retroactively adjusted as of the earliest period presented in the financial statements to reflect the forward stock split.

On December 19, 2025, the Company increased the number of authorized shares of common stock, $0.0001 par value per share, to 500,000,000 from 125,000,000.

Initial Public Offering

In December 2024, the Company's sold 2,750,000 shares of Common Stock at a price of $4.00 per share for gross proceeds of $11 million before underwriting discounts and other related expenses in a registered initial public offering (the "IPO"). Net proceeds, after deducting underwriting discounts, commissions, and offering-related expenses, were approximately $9,725,213. In connection with the Public Offering, the Company's Common Stock began trading on The Nasdaq Capital Market under the symbol "JUNS."

Standby Equity Purchase Agreement

On October 24, 2025, the Company entered into a standby equity Purchase Agreement, pursuant to which the Company has the right to sell to an investor up to $20.0 million of its common stock, par value $0.0001 per share, subject to certain limitations and conditions. See *Note 5 – Convertible Debt and Derivative Liability* for further details.

Nasdaq Minimum Bid Price Compliance

On March 21, 2025, the Company received a notification letter from Nasdaq indicating that the Company was not in compliance with the minimum bid price requirement under Nasdaq Listing Rule 5550(a)(2), which requires listed securities to maintain a minimum closing bid price of $1.00 per share for at least 30 consecutive business days. Based on the 30 consecutive business days from February 6, 2025 through March 20, 2025, the Company's Common Stock failed to meet this requirement.

Pursuant to Nasdaq Listing Rule 5810(c)(3)(A), the Company was provided 180 calendar days, or until September 17, 2025, to regain compliance by maintaining a minimum closing bid price of at least $1.00 per share for a minimum of 10 consecutive business days. On July 9, 2025, the Company received a written notice from the Nasdaq stating that the Company has since regained compliance with Listing Rule 5550(a)(2) because the closing bid price of the Company's Common Stock has been $1.00 USD per share or greater for a period of thirteen (13) days (June 18, 2025 to July 8, 2025).

On February 26, 2026, the Company received two written notices from the Listing Qualifications Department of Nasdaq notifying the Company that (i) the listing of the Company's Common Stock was not in compliance with the minimum bid price requirement as set forth under Nasdaq Listing Rule 5550(a)(2) for continued listing of its Common Stock on The Nasdaq Capital Market, as the closing bid price of the Common Stock was less than $1.00 per share for the previous 30 consecutive business days, and (ii) for the 30 consecutive business days ended February 26, 2026, the Company's market value of listed securities closed below the $35 million threshold required for continued listing on The Nasdaq Capital Market under Nasdaq Listing Rule 5550(b)(2).

Pursuant to Nasdaq Listing Rule 5810(c)(3)(A), the Company was provided 180 calendar days, or until August 25, 2026, to regain compliance by maintaining a minimum closing bid price of at least $1.00 per share for a minimum of 10 consecutive business days.

Note 2 – Significant Accounting Policies

Going Concern

The financial statements of the Company have been prepared in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP"). U.S GAAP contemplates continuation of the Company as a going concern. For the year ended December 31, 2025 and 2024, the Company had net revenues from product sales of $21,796 and $0, respectively and incurred a net loss of $8,644,897 and $2,439,625, respectively. Net cash used in operations for the years ended December 31, 2025 and 2024 was $5,413,736 and $3,911,004, respectively. As of December 31, 2025 and 2024, the Company had an accumulated deficit of $34,667,026 and $26,022,129, respectively.

There is substantial doubt regarding our ability to continue as a going concern as a result of our historical recurring losses and negative cash flows from operations as well as our dependence on private equity and financings. The Company plans to finance future operations with proceeds from equity securities, grant awards and strategic collaborations. However, there is no assurance the Company will be successful. These conditions raise substantial doubt about the Company's ability to continue as a going concern for a period of at least twelve months from the date of this report.

Basis of Presentation

The financial statements of the Company have been prepared in accordance with generally accepted accounting principles in the United States of America ("US GAAP").

Business Segment

The Company uses the "management approach" to identify its reportable segments in accordance with ASC 280, Segment Reporting. The management approach requires companies to report segment financial information consistent with the information regularly reviewed by the Chief Operating Decision Maker ("CODM") for purposes of making operating decisions and assessing performance.

The Company's Chief Executive Officer serves as the CODM. The CODM evaluates financial performance and allocates resources based on the operating results of the Company's reportable segments. Effective October 1, 2025, the Company operates through two reportable segments: (i) its premium nutritional supplements, and (ii) pharmaceutical operations focused on drug candidates for CNS and rare orphan diseases.

The CODM assesses segment performance primarily based on segment net loss (income). Selling, general and administrative expenses are directly attributable to segments or allocated based on reasonable and consistently applied methodologies. Corporate and other expenses that are not allocated to reportable segments consist primarily of public company costs, certain executive compensation, certain stock-based compensation, interest income (expense), other income (expense), and income taxes.

The identification of two reportable segments reflects the manner in which the CODM reviews financial information and allocates resources. Prior-period information has been recast to conform to the current presentation.

Use of Estimates

Preparing financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and revenues and expenses during the reported period. Actual results could differ from those estimates, and those estimates may be material.

Changes in estimates are recorded in the period in which they become known. The Company bases its estimates on historical experience and other assumptions, which include both quantitative and qualitative assessments that it believes to be reasonable under the circumstances.

Significant estimates during the years ended December 31, 2025 and 2024, respectively, include valuation of stock-based compensation, uncertain tax positions, the valuation of debt instruments, and the valuation allowance on deferred tax assets.

Cash

The Company considers all highly liquid investments that have maturities of three months or less when acquired to be cash equivalents. Cash and cash equivalents consist primarily of cash on deposit with financial institutions and amounts held in high-yield savings accounts. The Company maintains its cash balances with high-credit-quality financial institutions. At times, such balances may exceed federally insured limits provided by the Federal Deposit Insurance Corporation ("FDIC"). In 2025, the Company has implemented a deposit insurance program in the Company's primary account, whereby funds in excess of FDIC insurance limits are insured.

As of December 31, 2025 and 2024, the cash balances not subject to insurance or that exceed the FDIC limit of $250,000 were $0 and $3,519,510, respectively.

Inventory

Inventory is stated at the lower of cost or net realizable value, with cost determined using the first-in, first-out ("FIFO") method. Inventory consists primarily of raw materials, work-in-process, and finished goods.

The Company periodically reviews inventory quantities on hand and records reserves for excess, obsolete, or slow-moving inventory based on its assessment of forecasted demand, product shelf life, market conditions, and other factors. Inventory reserves are recorded as a reduction of inventory and are based on management's estimates regarding the recoverability of inventory balances. If actual demand or market conditions differ from those projected by management, additional inventory write-downs may be required.

Revenue Recognition

Revenue is recognized when control of promised goods or services is transferred to customers, in an amount that reflects the consideration the Company expects to be entitled to in exchange for those goods or services.

The Company determines revenue recognition through the following five-step model: (i) identification of the contract with a customer; (ii) identification of the performance obligations in the contract; (iii) determination of the transaction price; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when, or as, the Company satisfies a performance obligation.

Note 2 – Significant Accounting Policies, continued

Product Revenue

The Company generates revenue from the sale of its products. Product revenue is recognized when control of the product is transferred to the customer, which generally occurs upon shipment or delivery, depending on the terms of the arrangement.

Revenue is recorded net of variable consideration, including estimates for product returns, rebates, chargebacks, discounts, and other allowances. The Company estimates variable consideration at the time of sale based on historical experience, current market conditions, and contractual terms, and includes such estimates in the transaction price only to the extent that it is probable that a significant reversal of revenue will not occur in future periods.

The Company evaluates whether it is the principal or agent in its arrangements and records revenue on a gross or net basis accordingly. Shipping and handling activities are considered fulfillment activities, and the related costs are recorded in cost of goods sold.

Prepaid Contracts

Prepaid contracts generally represent service agreements which the Company would receive services over a period of time and are expensed as the services are received. The Company's prepaid contracts are related to service agreements that span over three years, therefore the expense will be recognized over the three year term.

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets generally represent payments made for goods or services to be received within one year and are expensed as the related benefit is received.

Research and Development

Research and development costs are expensed as incurred. Costs for certain development activities, such as clinical trials, are recognized based on an evaluation of the progress to completion of specific tasks using data such as subject enrollment, monitoring visits, clinical site activations, or information provided to us by our vendors with respect to their actual costs incurred. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the financial statements as prepaid or accrued research and development expense, as the case may be. Total research and development costs for the years ended December 31, 2025 and 2024 were $2,086,574 and $492,660, respectively.

Income Taxes

The Company recognizes deferred tax assets and liabilities for temporary differences between the financial reporting basis and the tax basis of our assets and liabilities and the expected benefits of net operating loss carryforwards. The impact of changes in tax rates and laws on deferred taxes, if any, applied during the years in which temporary differences are expected to be settled, is reflected in the financial statements in the period of enactment. The measurement of deferred tax assets is reduced, if necessary, if, based on weight of the evidence, it is more likely than not that some, or all, of the deferred tax assets will not be realized. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in the period that such tax rate changes are enacted. As of December 31, 2025 and 2024, the Company concluded that a full valuation allowance is necessary for the net deferred tax assets. The Company had no material amounts recorded for uncertain tax positions, interest or penalties in the accompanying financial statements. The Company is subject to taxation in the U.S. Our tax years for 2021 and forward are subject to examination by tax authorities. The Company is not currently under examination by any tax authority.

Loss Per Share of Common Stock

Basic loss per share is computed by dividing net loss applicable to common stockholders by the weighted average number of shares of common stock outstanding during each period. Diluted loss per share includes the effect, if any, from the potential exercise or conversion of securities, such as convertible preferred stock, convertible notes payable, warrants, stock options, and unvested restricted stock, which would result in the issuance of incremental shares of common stock, as calculated using the treasury method. In computing the basic and diluted net loss per share applicable to common stockholders, the weighted average number of shares remains the same for both calculations due to the fact that when a net loss exists, dilutive shares are not included in the calculation.

As of December 31, 2025, there were no warrants outstanding, 1,626,037 restricted stock units and 11,726,093 stock options. These securities are considered dilutive securities which were excluded from the computation since the effect is anti-dilutive.

As of December 31, 2024, there were 1,359,375 warrants outstanding, 1,626,037 restricted stock units and 10,633,988 stock options. These securities are considered dilutive securities which were excluded from the computation since the effect is anti-dilutive.

Stock-Based Compensation

The Company records stock-based compensation equal to the grant date fair value of the stock awards issued. For stock options issued to employees, non-employees and members of our board of directors, the Company estimates the grant-date fair value of options using the Black-Scholes option pricing model. The use of the Black-Scholes option pricing model requires management to make assumptions with respect to the expected term of the option, the expected volatility of the common stock consistent with the expected life of the option, risk-free interest rates, and, for grants prior to our initial public offering, the value of the common stock. For awards subject to time-based vesting, the Company recognized stock-based compensation expense, on a straight-line basis over the requisite service period, which is generally the vesting term of the award.

Note 2 – Significant Accounting Policies, continued

Clinical Trial Expenses

As part of the process of preparing our financial statements, the Company is required to estimate expenses resulting from obligations under contracts with vendors, clinical research organizations and consultants and under clinical site agreements in connection with conducting clinical trials. The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided under such contracts. The Company's objective is to reflect the appropriate trial expenses in the financial statements by matching those expenses with the period in which services are performed and efforts are expended. The Company accounts for these expenses according to the progress of the trial as measured by patient progression and the timing of various aspects of the trial. The Company determines accrual estimates based on estimates of services received and efforts expended that take into account discussion with applicable personnel and outside service providers as to the progress or state of consummation of trials. During the course of a clinical trial, the Company adjusts the clinical expense recognition if actual results differ from its estimates. The Company makes estimates of the accrued expenses as of each balance sheet date based on the facts and circumstances known at that time. The clinical trial accruals are dependent upon the timely and accurate reporting of contract research organizations and other third-party vendors. Although the Company does not expect the estimates to be materially different from amounts actually incurred, understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low for any particular period.

Fair Value of Financial Instruments and Fair Value Measurements

The Company measures its financial assets and liabilities in accordance with US GAAP. For certain financial instruments, including cash and cash equivalents, accounts receivable, accounts payable and accrued liabilities, the carrying amounts approximate fair value due to their short maturities. Amounts recorded for notes payable, net of discount, and loans payable also approximate fair value because current interest rates available for debt with similar terms and maturities are substantially the same.

The Company follows accounting guidance for financial assets and liabilities. This standard defines fair value, provides guidance for measuring fair value and requires certain disclosures. This standard does not require any new fair value measurements, but rather applies to all other accounting pronouncements that require or permit fair value measurements. This guidance does not apply to measurements related to share-based payments. This guidance discusses valuation techniques, such as the market approach (comparable market prices), the income approach (present value of future income or cash flow), and the cost approach (cost to replace the service capacity of an asset or replacement cost).

The guidance utilizes a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value into six broad levels. The following is a brief description of those three levels:

Level 1: Observable inputs such as quoted prices (unadjusted) in active markets for identical assets or liabilities.

Level 2: Inputs, other than quoted prices that are observable, either directly or indirectly. These include quoted prices for similar assets or liabilities in active markets and quoted prices for identical or similar assets or liabilities in markets that are not active.

Level 3: Unobservable inputs in which little or no market data exists, therefore developed using estimates and assumptions developed by us, which reflect those that a market participant would use.

Note 2 – Significant Accounting Policies, continued

Fair Value of Financial Instruments and Fair Value Measurements, continued

Also see Note 5 - Convertible Debt and Derivative Liability.

Derivative Instruments

ASC Topic 815, Derivatives and Hedging ("ASC Topic 815"), establishes accounting and reporting standards for derivative instruments and for hedging activities by requiring that all derivatives be recognized in the balance sheet and measured at fair value. Gains or losses resulting from changes in the fair value of derivatives are recognized in earnings. On the date of conversion or payoff of debt, the Company records the fair value of the conversion shares, removes the fair value of the related derivative liability, removes any discounts and records a net gain or loss on debt extinguishment. On January 1, 2020, the Company adopted ASU 2017-11 under which down-round Features in Financial Instruments will no longer cause derivative treatment. The Company applies the modified prospective method of adoption. There were no cumulative effects on adoption.

Convertible Notes with Embedded Derivative Liabilities

The Company has entered into convertible notes, some of which contain variable conversion options, whereby the outstanding principal and accrued interest may be converted, by the holder, into shares of common stock at a fixed discount to the price of the common stock at or around the time of conversion upon certain trigger events. The Company evaluates all its financial instruments to determine if those contracts or any potential embedded components of those contracts qualify as derivatives. This accounting treatment requires that the carrying amount of any derivatives be recorded at fair value at issuance and marked-to-market at each balance sheet date. In the event that the fair value is recorded as a liability, as is the case with the Company, the change in the fair value during the period is recorded as either other income or expense. Upon conversion, exercise or repayment, the respective derivative liability is marked to fair value at the conversion, repayment, or exercise date and then the related fair value amount is reclassified to other income or expense as part of gain or loss on debt extinguishment.

Note 2 – Significant Accounting Policies, continued

Leases

Operating lease ROU assets represent the right to use the leased asset for the lease term and operating lease liabilities are recognized based on the present value of future minimum lease payments over the lease term at commencement date. As most leases do not provide an implicit rate, the Company use an incremental borrowing rate based on the information available at the adoption date in determining the present value of future payments. Lease expense for minimum lease payments is amortized on a straight-line basis over the lease term and is included in general and administrative expenses in the statements of operations.

Recent Accounting Pronouncements

The Company has reviewed the FASB issued ASU accounting pronouncements and interpretations thereof that have effectiveness dates during the periods reported and in future periods. The Company has carefully considered the new pronouncements that alter previous generally accepted accounting principles and do not believe that any new or modified principles will have a material impact on the Company's reported financial position or operations in the near term. The applicability of any standard is subject to the formal review of the Company's financial management.

The Company's Chief Executive Officer serves as the CODM.

In December 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*. ASU 2023-09 enhances income tax disclosures by adding more granular, jurisdiction-specific information, especially for investors and analysts. The amendments in ASU 2023-09 are effective for public business entities for annual periods beginning after December 15, 2024. The Company adopted ASU 2023-09 effective January 1, 2025 on a prospective basis. The Company plans to adopt this update during the year ended December 31, 2026. Beyond the expanded, required disclosures, management does not believe that this will have a material impact on the Company's financial statements.

All other newly issued accounting pronouncements that are not yet effective have been deemed immaterial or nonapplicable.

Note 3 – Related Party Transactions

The Company's Chief Executive Officer (CEO) has loaned the Company working capital since inception. The balance of the loans to the CEO as of December 31, 2024 was $146,432. The loan was due on demand and accrues interest at 3% per year. Accrued interest relating to the loan was $1,064 as of December 31, 2024, and is included in accrued interest on the accompanying 2024 balance sheets. The Company fully settled the debt in 2025 by repaying a total of $150,782, $146,432 in principal and $4,350 in accrued interest. The Company repaid a total of $100,000 during the year ended December 31, 2024, $83,880 in principal and $16,120 in accrued interest.

On March 15, 2024, a former executive agreed to forgive $100,000 of accrued compensation in exchange for 49,605 options to purchase common stock and 7,500 restricted stock units, The options to purchase common stock have a strike price of $1.33. The option had a grant date fair value of $50,000. The Company recorded a gain on the forgiveness of accrued compensation in the amount of $40,000.

On April 29, 2024, the Company, the Holder of the Note II (See Note 5 – Convertible Debt and Derivative Liability) and the CEO entered into an amendment in which the CEO agreed to exchange 685,867 shares issued to the Holder in exchange for his related party notes that accrued interest at 3% that are due from the Company in an aggregate principal amount of $266,667 and the Holder agreed to forfeit all rights to all additional future shares from the Company that would of become due upon a qualified offering as well as the conversion option. Therefore, the principal amount of the note was increased to $1,377,778 and the exchange debt follows the requirements of Note II. See Note 5 – Convertible Debt and Derivative liability – Senior Secured Note – Formerly known as the Convertible Debt I for more details.

Note 4 – Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consisted of the following:

	December 31, 2025	December 31, 2024
Accounts payable	$ 131,130	$ 278,676
Professional fees	467,167	40,271
License fee	-	75,000
Credit cards	40,349	2,536
Total accounts payable and accrued expenses	$ 638,646	$ 396,483

As of December 31, 2025 and 2024, $64,105 was due to a Company wholly owned by the Company's Chief Financial Officer, who also is an option holder, respectively. The amount is included in accrued compensation on the Company's balance sheets.

Accrued compensation of $1,397,357 and $1,415,093 as of December 31, 2025 and 2024, respectively, includes accrued salaries and health benefits to executives since inception and board fees. Since inception, executive salaries have been paid in cash when the Company's cash flow has permitted such payment. By November 2022 the Company stopped paying salaries, although they continued to accrue, in an effort to conserve cash and starting in the fourth quarter of 2023, the Company's executives agreed to reduce their salaries by 80% until an initial public offering to limit the Company's compensation expenses. During December 2024, the Company returned to paying salaries due to the completion of the initial public offering. See Note 3 – Related Party Transactions for details related to forgiveness of accrued compensation.

Note 5 – Convertible Debt and Derivative Liability

Standby Equity Purchase Agreement and 2025 Convertible Promissory Notes

On October 24, 2025, the Company entered into a Standby Equity Purchase Agreement ("SEPA") and related Registration Rights Agreement with YA II PN, Ltd. ("Yorkville"), providing the Company the right, but not the obligation, to sell up to $20.0 million of common stock from time to time, subject to customary conditions, including an effective resale registration statement.

In connection with the SEPA, Yorkville agreed to provide up to $6.0 million of pre-paid advances via convertible promissory notes (the "2025 Notes"). On October 27, 2025, the Company received $3,720,000 and issued a $4.0 million note (7% original issue discount, "OID"). A second $1,860,000 tranche was received in December 2025, upon registration effectiveness and receipt of stockholder approval, against a $2.0 million note (7% OID). The notes bear interest at 8% (increasing to 18% upon default), mature on October 24, 2026, and are convertible at $1.50 per share, subject to proportional anti-dilution and price-protection adjustments (not below a contractual floor). Beginning January 7, 2026, and monthly thereafter, the Company must repay one-tenth (1/10) of the then-outstanding principal plus accrued interest (a 5% premium applies to cash repayments). Installments may be satisfied via SEPA advances without the premium, and SEPA proceeds must be applied first to repay the notes until they are repaid in full.

As consideration for Yorkville's commitment to purchase common stock at the Company's direction pursuant the SEPA, the Company (i) paid to Yorkville a cash "structuring fee" in the amount of $25,000 and (ii) upon execution of the SEPA, issued to Yorkville 131,909 Commitment Shares, which have a total aggregate dollar value equal to $200,000, or 1.0% of Yorkville's $20.0 million aggregate purchase commitment under the SEPA (each Commitment Share valued at approximately $1.5162 per share, representing the VWAP on October 23, 2025, the trading day immediately prior to the date of execution of the SEPA, rounded to the nearest whole share).

On February 20, 2026, the Company and Yorkville entered into an Omnibus Amendment (the "Amendment"). Among other changes, the Amendment revises the terms of the convertible promissory notes to defer the commencement of monthly installment payments to April 1, 2026, effectively providing an extension of approximately three months.

The Convertible Notes include features that allow for settlement through either (i) cash repayment or (ii) issuance of common stock at variable or fixed conversion prices, subject to certain contractual terms, including a floor price and installment-based repayment structure.

The Convertible Notes are classified as a Level III liability within the fair value hierarchy, as their valuation is based on significant unobservable inputs and assumptions.

The Company elected the fair value option for the Convertible Notes upon issuance. As such, the Convertible Notes are measured at fair value at inception and remeasured at each reporting date, with changes in fair value recognized in earnings. The fair value of the Convertible Notes was determined using a Monte Carlo simulation model.

This valuation approach incorporates multiple potential stock price paths over the contractual term, the Company's ability to settle in shares or cash, the note holder's ability to convert at a fixed price, variable conversion features tied to market prices, and contractual floors and share caps.

The model simulates a large number of potential outcomes and calculates the expected fair value based on probability-weighted results.

The convertible notes accounted for under the fair value election are each debt host financial instruments containing embedded features wherein the entire financial instrument is initially measured at its issue-date estimated fair value and then subsequently remeasured at estimated fair value on a recurring basis at each reporting period date. Changes in the estimated fair value of the 2025 Notes are recorded as a component of Other (expense) income in the consolidated statements of operations, except that the change in estimated fair value attributable to a change in the instrument-specific credit risks is recognized as a component of other comprehensive income. The instrument specific credit risk associated with the 2025 Notes was de minimis. As a result of electing the fair value method, issuance costs related to the 2025 Notes, including the structuring fee and the commitment fee were expensed as incurred.

The following key assumptions were used in the valuation at each measurement date:

Assumption	Issuance (Oct 24, 2025)	December 24, 2025	December 31, 2025
Stock Price (VWAP)	$1.50	$1.09	$0.99
Volatility	~65%	~65%	~65%
Risk-Free Rates	3.4% – 4.5%	3.5% – 4.6%	3.4% – 4.7%
Valuation Technique	Monte Carlo Simulation	Monte Carlo Simulation	Monte Carlo Simulation

Volatility was estimated using a combination of the Company's historical volatility and that of comparable publicly traded companies.

At issuance, the initial convertible promissory note was measured at a fair value of $3,914,515. As of December 24, 2025, concurrent with the second tranche, the fair value of the 2025 Notes was remeasured to $5,225,670. As of December 31, 2025, the fair value of the 2025 Notes was $5,298,068. Changes in fair value during the period were recognized in the Statements of Operations as Gain on change in fair value of convertible notes. The original issue discounts totaling $420,000 were incorporated into the initial and subsequent fair value measurements of the 2025 Notes. As of December 31, 2025, the outstanding principal balance on the 2025 Notes is $6,000,000.

For the year ended December 31, 2025, the Company recognized a net gain on change in fair value of convertible notes of $281,932.

As of December 31, 2025, the Company incurred $61,723 of interest expense and paid $22,251 through the sale of 20,000 shares of common stock at an average price of approximately $1.11 through the SEPA. As of December 31, 2025, $39,829 is accrued in Accrued interest on the Company's balance sheets.

Note 5 – Convertible Debt and Derivative Liability, continued

Convertible Debt I

Between August and December 2021, the Company issued convertible notes (collectively, "Notes I") totaling $527,650, originally maturing on July 31, 2022, with an interest rate of 1%. Notes I featured an automatic conversion feature upon an IPO into Common Stock at 70% of the IPO price. Various amendments extended the maturity, ultimately to December 31, 2024, and increased the interest rate to 10%. In December 2024, following a successful IPO, the then outstanding principal and accrued interest totaling $636,852 Notes I converted into 227,447 shares of Common Stock at $2.80 per share.

Convertible Debt II

On April 11, 2022, the Company issued a senior secured convertible note ("Note II") and 514,403 shares of Common Stock for net proceeds of $977,333 ($1,000,000 less origination costs and an embedded discount). Note II had an original principal of $1,111,111. The original terms of Note II included, among other provisions, penalties and stock conversions at substantial discounts upon default or qualified offerings. Various amendments were executed which extended principal repayment dates and increased repayment premiums resulting in losses on debt extinguishment totaling $887,946 in 2023. On April 24, 2024, Note II was further modified, removing the conversion feature, increasing principal to $1,377,778, and extending the maturity, resulting in a gain on modification of $951,868 and an increase to derivative liability of $407,494. Note II was fully repaid in December 2024 for $2,102,797, which included all outstanding principal and accrued interest.

Convertible Debt III

On March 1, 2023, the Company issued a convertible note ("Note III") with a principal amount of $150,000 in connection with an investor relations settlement, maturing February 28, 2026 and a compounding 5% annual interest rate. In December 2024, the then outstanding balance of Note III totaling $178,386 was fully repaid, which included all then outstanding principal and accrued interest.

Interest

During the year ended December 31, 2024, $147,705, was included in interest expense for the combined convertible Notes I, II and III on the accompanying 2024 statements of operations. These notes were paid in full in December 2024.

Note 5 – Convertible Debt and Derivative Liability, continued

Derivative Liability Pursuant to Convertible Debt

In connection with the issuance of the Notes, the Company determined that the terms of Notes contain an embedded conversion option to be accounted for as a derivative liability due to the Holder having the potential to gain value upon IPO. Accordingly, the embedded conversion option contained in Notes was accounted for as derivative liability and debt discount at the date of issuance and has been adjusted to fair value through earnings at each reporting date. The fair value of the embedded conversion option was determined using the Monte Carlo valuation model.

During the year ended December 31, 2024, the derivative liabilities were revalued, and a $857,723 adjustment was recorded as a gain on extinguishment of debt to other expenses reflected in the accompanying statements of operations.

The Company also recorded $53,257 as a loss on the change in the fair value of the derivative liability for the year ended December 31, 2024.

The fair value of the derivative liability of Notes I, Note II and Note III was estimated using the Monte Carlo Valuation model at issuance and each reporting period with the following assumptions:

	December 31, 2024
Dividend Rate	-
Term	0.13
Volatility	90%
Risk-free rate	5.00%

Note 5 – Convertible Debt and Derivative Liability, continued

Derivative Liability Pursuant to Convertible Debt, continued

A summary of activity of the derivative liabilities and the 2025 Notes, which represent the Level III fair value measurements, is presented below:

	Derivative Liability	2025 Notes
Balance at December 31, 2023	$ 1,505,398	$ -
Fair value change	53,257	-
Extinguishment of derivative liability - Note II	(1,359,362)	-
Fair value at issuance on April 29, 2024 - Senior Secured Note	407,494	-
Repayment of derivative liability	(606,787)	-
Balance at December 31, 2024	$ -	$ -
Issuance of the 2025 Notes	-	5,580,000
Fair value change	-	(281,932)
Balance at December 31, 2025	$ -	$ 5,298,068

Note 6 – Stockholders' Equity (Deficit)

Common Stock

The Company is authorized to issue 500,000,000 shares of common stock and 5,000,000 shares of preferred stock. The Company had 34,446,455 shares of common stock issued and outstanding as of December 31, 2025. There was no preferred stock issued and outstanding as of December 31, 2025.

On October 24, 2025, As consideration for Yorkville's commitment to purchase common stock at the Company's direction pursuant the SEPA, the Company, upon execution of the SEPA, issued to Yorkville 131,909 Commitment Shares, which have a total aggregate dollar value equal to $200,000, or 1.0% of Yorkville's $20.0 million aggregate purchase commitment under the SEPA (each Commitment Share valued at approximately $1.5162 per share, representing the VWAP on October 23, 2025, the trading day immediately prior to the date of execution of the SEPA, rounded to the nearest whole share).

On April 23, 2025, the Company issued 103,186 shares of common stock, with an aggregate fair value of $66,000, as consideration for services rendered related to media and investor relations activities, strategic communications support, enhancement to the Company's market visibility and shareholder engagement. The fair value of the shares issued was determined based on the market price of the Company's common stock at the date of issuance and is included general and administrative expenses in the accompanying 2024 condensed consolidated statement of operations.

On June 3, 2024, the Company entered into a three 36-month service agreement with three different entities. The Company issued an aggregate of 3,487,500 restricted shares of common stock, 1,162,500 restricted shares of common stock to each entity. The shares were registered upon the Company's offering that closed in December 2024. In addition, each of the entities purchased 37,500 shares each of the Company's common stock at a price of $1.33 per share prior to the occurrence of the Company's offering. As of December, 31, 2024, the Company issued 112,500 common stock and the Company received an aggregate of $150,000 for the sale of the Company's common stock from the three entities. These shares were also registered upon the closing of the Company's offering. The aggregate value of $4,638,375 related to the 3,487,500 restricted shares will be recognize as compensation expense from the date the obligations are met with the remaining expense being amortized over the remaining term of the 36-months per the services agreements. As of December 31, 2025 and 2024, the Company recorded compensation expense for services provided of $ 1,546,117 and $893,781, respectively related to the restricted shares issued.

See Note 5 – Convertible Debt and Derivative Liability for shares issued upon the conversion of the convertible notes.

See Note 8 – Commitment and Contingencies – Service agreements for details related to sale of common stock per the service agreements.

Note 6 – Stockholders' Equity (Deficit), continued

Closing of Offering

On December 2, 2024, the Company priced its initial public offering of 2,750,000 shares of common stock at a price of $4.00 per share. The offering closed on December 4, 2024, and the Company started trading on the Nasdaq Capital Market under the ticker symbol "JUNS". The Company sold 2,750,000 shares of its Common Stock to the underwriters and yielded proceeds of $9,725,213, net of underwriters and other fees of $1,274,787.

Stock Options

The Company grants stock awards to officers, employees, directors, and other key persons pursuant to its 2021 Equity Incentive Plan ("the Plan").

During the year ended December 31, 2025 and 2024, the Company recognized stock-based compensation of $2,418,516 and $947,124, respectively, related to vested stock options. There was $697,835 unvested stock options expense as of December 31, 2025.

On January 24, 2024, the Company granted 180,000 stock options to a consultant with an exercise price of $1.33 per share. The option had a grant date fair value of $190,560.

On April 17, 2024, the Company granted 67,500 stock options to a consultant with an exercise price of $1.33 per share. The option had a grant date fair value of $73,459.

On June 10, 2025, the Company granted 250,000 stock options to a consultant with an exercise price of $0.97 per share and a grant date fair value of $191,168, and a 10-year term. The 25% of the stock options vest immediately on the grant date, with the remaining 187,500 options vesting in equal monthly installments ratably beginning in July 2025 through May 2027.

On July 2, 2025, the Compensation Committee approved the grant of an aggregate of 357,448 stock options issued to certain executives. The stock options have an exercise price of $1.19 per share, representing the closing price of the Company's Common Stock on Nasdaq on the date of grant. The stock options have a 10-year term and vest in equal installments over a three (3) year period beginning on the grant date of July 2, 2025, subject to the officers' continued employment at the time of vesting.

On September 5, 2025, the Company granted an aggregate of 374,755 stock options to two consultants with an exercise price of $1.23 per share and a grant date fair value of $340,900. The stock options have a 10 year term and 25% of the stock options vest immediately on the grant date, with 281,066 options vesting in equal monthly installments until September 5, 2027. The Company also granted 109,902 stock options to one of the consultants with an exercise price of $1.23 per share and a grant date fair value of $100,000, and a 10 year term that vest solely upon achievement of performance conditions as follows: (a) 15% per Ambassador (maximum of three) referred by consultant and subsequently engaged by the Company, (b) 20% if consultant is instrumental in arranging a distribution arrangement not previously pursued by the Company, on terms acceptable to the Company, (c) 20% when such Distribution Contract achieves $1 million in annual sales and (d) 15% when the consultant arranges the first Celebrity Golf Tournament featuring Nugevia on terms and conditions acceptable to the Company.

On October 24, 2025, in connection with the SEPA and 2025 Convertible Promissory Notes, the Company issued 131,909 commitment shares with an aggregate value of $200,000 to the Investor, Yorkville, representing 1.0% of Yorkville's $20.0 million aggregate purchase commitment under the SEPA, valued at approximately $1.5162 per share, representing the VWAP on October 23, 2025, the trading day immediately prior to the date of execution of the SEPA, rounded to the nearest whole share.

See Note 3 – Related Party Transactions above for details related to options issued for forgiveness of accrued salaries.

A summary of activity for the year ended December 31, 2025 and 2024 is presented below:

	Number of Options	Weighted Average Exercise Price	Weighted Average Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2023	10,336,883	$ 1.00	6.9	$ 3,316,119
Granted	297,105	1.33		
Exercised	-	-		
Forfeited	-	-		
Outstanding as of December 31, 2024	10,633,988	$ 1.02	6.3	$ 102,921,147
Granted	1,092,105	1.16		
Exercised	-	-		
Forfeited	-	-		
Outstanding as of December 31, 2025	11,726,093	$ 1.02	5.4	$ 1,772,167
Exercisable as of December 31, 2025	10,874,222	$ 1.03	5.1	$ 1,765,237
Exercisable as of December 31, 2024	10,297,412	$ 1.01	6.18	$ 99,768,543

The following table summarized information about employee stock options outstanding as of December 31, 2025 and 2024:

	Outstanding Options		Vested Options	
Exercise Price	Number Outstanding at December 31, 2025	Weighted Average Remaining Life	Number Exercisable at December 31, 2025	Weighted Average Remaining Life
$ 0.01	675,000	0.25	675,000	0.25
$ 0.74	1,657,560	3.07	1,657,560	3.07
$ 0.80	2,783,243	3.29	2,783,243	3.29
$ 0.97	250,000	9.42	111,412	9.42
$ 1.19	357,448	9.51	-	-
$ 1.23	484,657	9.68	128,822	9.68
$ 1.33	5,461,935	7.08	5,461,935	7.08
$ 2.16	56,250	5.46	56,250	5.06
	11,726,093	5.43	10,874,222	5.10

	Outstanding Options		Vested Options	
Exercise Price	Number Outstanding at December 31, 2024	Weighted Average Remaining Life	Number Exercisable at December 31, 2024	Weighted Average Remaining Life
$ 0.01	675,000	1.25	675,000	1.25
$ 0.74	1,657,560	4.32	1,657,562	4.32
$ 0.8	2,783,243	4.54	2,783,238	4.54
$ 1.33	5,461,935	8.33	5,125,362	8.31
$ 2.16	56,250	6.71	56,250	6.71
	10,633,988	6.25	10,297,412	6.15

Warrants

The following is a summary of the Company's warrant activity for the year ended December 31, 2025 and 2024:

	Number of Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Life (Years)
Outstanding as of December 31, 2024	1,359,375	0.80	0.93
Granted	-	-	-
Exercised	(1,359,375)	0.80	-
Forfeited	-	-	-
Outstanding as of December 31, 2025	-	$ -	-

Effective June 22, 2025, the Company entered into an amendment with a warrant holder for a warrant to purchase 109,376 shares of Common Stock. The amendment extended the warrant's exercise period through August 31, 2025, and clarified the exercise mechanism applicable to the warrant. The effects of the warrant modification were de minimis.

On July 16, 2025 the Company entered into an amendment with a warrant holder who holds 1,249,999 warrants that clarified the exercise mechanisms. Concurrently with the amendment, the warrant holder exercised the warrants via a cashless exercise and received 913,299 shares of Common Stock. Pursuant to the amendment, the Company agreed to issue the warrant holder 86,700 shares of Common Stock.

On August 12, 2025, the Company received an exercise notice from a warrant holder who holds 109,376 warrants. The warrant was exercised via a cashless exercise, and the warrant holder received 30,547 shares of Common Stock. Pursuant to the amended warrant agreement, the Company agreed to issue the warrant holder 56,954 shares of Common Stock.

Note 6 – Stockholders' Equity (Deficit), continued

Restricted Stock Units

On March 15, 2024, the Company issued 7,500 restricted stock units with a grant date value of $1.33 per unit in exchange for the forgiveness of accrued compensation. The restricted stock units shall vest on the earlier event of either the expiration of the lock-up period by the underwriters after the initial public offering or in the event of change of control of the Company.

As of both December 31, 2025 and December 31, 2024, the Company had an aggregate of 1,626,037 restricted stock units outstanding with an aggregate fair value of $2,195,550.

Note 7 – Income Taxes

A reconciliation of income taxes at the U.S. federal statutory rate to the benefit for income taxes is as follows:

	2025	2024
Federal	21.00%	21.00%
State	4.19%	2.07%
Nondeductible expenses	14.66%	-2.33%
Change in valuation allowance	-39.84%	-20.74%
Effective tax rate	**-**	**-**

Note 7 – Income Taxes, continued

A summary of the Company's deferred tax assets is as follows:

	2025	2024
U.S Federal and State net operating loss	$ 5,473,294	$ 3,083,545
Stock-based compensation	1,423,288	1,272,925
Accrued salaries	348,012	382,288
Orphan drug credit	1,682,207	1,060,118
Derivative liability	-	-
Other	119,699	260,481
Total net deferred tax assets	9,046,500	6,059,357
Valuation allowance	(9,046,500)	(6,059,357)
Total Deferred Tax Asset	**$ -**	**$ -**

As of December 31, 2025, the Company had federal and state (post-apportioned basis) net operating losses ("NOLs") of $43.14 million, as well as federal orphan drug credit and research and development tax credit carryforwards of approximately $1.72 million. Approximately $22.3 million of the foregoing federal and state NOLs will expire at various dates from 2036 through 2045, if not limited by triggering events prior to such time. Under the provisions of the Internal Revenue Code, changes in ownership of the Company, in certain circumstances, would limit the amount of federal NOLs that can be utilized annually in the future to offset taxable income. In particular, Section 382 of the Internal Revenue Code ("Section 382") imposes limitations on an entity's ability to use NOLs upon certain changes in ownership. If the Company is limited in its ability to use its NOLs in future years in which it has taxable income, then the Company will pay more taxes than if it were otherwise able to fully utilize its NOLs. The Company may experience ownership changes in the future as a result of subsequent shifts in ownership of the Company's capital stock that the Company cannot predict or control that could result in further limitations being placed on the Company's ability to utilize its federal NOLs.

A valuation allowance, if needed, reduces deferred tax assets to the amount expected to be realized. When determining the amount of net deferred tax assets that are more likely than not to be realized, the Company assesses all available positive and negative evidence. This evidence includes, but is not limited to, prior earnings history, expected future earnings, carry-back and carry-forward periods and the feasibility of ongoing tax strategies that could potentially enhance the likelihood of the realization of a deferred tax asset. The weight given to the positive and negative evidence is commensurate with the extent the evidence may be objectively verified. As such, it is generally difficult for positive evidence regarding projected future taxable income, exclusive of reversing taxable temporary differences, to outweigh objective negative evidence of recent financial reporting losses. Based on these criteria and the relative weighting of both the positive and negative evidence available, management continues to maintain a full valuation allowance against its net deferred tax assets.

Note 8 – Commitments and Contingencies

Legal Matters

From time to time, claims are made against the Company in the ordinary course of business, which could result in litigation. Claims and associated litigation are subject to inherent uncertainties and unfavorable outcomes could occur, such as monetary damages, fines, penalties or injunctions prohibiting the Company from selling one or more products or engaging in other activities. The occurrence of an unfavorable outcome in any specific period could have a material adverse effect on the Company's results of operations for that period or future periods.

On July 19, 2022, Tiberend Strategic Advisors ("Tiberend"), an entity that the Company had previously engaged as a communications and investor relations firm, filed a summons for civil action in the District Court of Southern Florida against the Company alleging non-payment by the Company under a services agreement (the "Services Agreement") with Tiberend in the amount of $130,400. The Company and Tiberend entered into a full settlement and release agreement in exchange for a $150,000 convertible promissory note in March 2023. As of December 31, 2024, the note was fully repaid. See Note 5 – Convertible Debt and Derivative Liability – Convertible Debt III for details associated with the note issuance.

Office Lease

On May 1, 2021, the Company entered into a 61-month operating lease for office space for a base rent of $3,783 subject to a 3% yearly escalation.

As of December 31, 2025 and 2024, the Company's operating lease right-of-use asset, net (ROU) is $23,214 and $69,642, respectively, and the total lease liability is $21,247 and $71,329, respectively, based on an incremental borrowing rate of 0.81% at lease inception.

	December 31, 2025	December 31, 2024
Operating lease right-of-use asset ("ROU") is summarized below:		
Office lease ROU	$ 236,009	$ 236,009
Less accumulated reduction	(212,795)	(166,367)
Balance of ROU, net	$ 23,214	$ 69,642
Operating lease liability related to the ROU asset is summarized below:		
Office lease liability	$ 236,009	$ 236,009
Reduction of lease liability	(214,762)	(164,680)
Total	$ 21,247	$ 71,329

Future minimum lease liability payments under non-cancelable operating lease at December 31, 2025 are as follows:

2025	-	50,476
2026	21,290	21,290
	21,290	71,766
Less: imputed interest	(43)	(437)
Total lease liabilities	$ 21,247	$ 71,329
Current operating lease liabilities	21,247	50,082
Non-current operating lease liabilities	-	21,247
Total lease liabilities	$ 21,247	$ 71,329

Note 8 – Commitments and Contingencies, continued

Office Lease, continued

On October 1, 2021, the Company entered into a month-to-month lease for office space in Charlestown, MA.

Rental expenses of $16,972 and $17,740 for the years ended December 31, 2025 and 2024, respectively, are included in general and administrative expenses on the accompanying statement of operations.

Consulting Agreements

The Company utilizes various consultants and advisors for clinical research, scientific advisory services and business strategies. Each consultant has an executed agreement in place defining term, compensation, duties, confidentiality, intellectual property. The majority of the agreements have a 2-year term. Agreements are evaluated for renewal upon expiration. Bonus provisions are at the discretion of the Company's Board of Directors and are granted on an individual agreement basis.

On December 15, 2024, the Company entered into a Strategic Services Agreement (the "Dominant Treasure Agreement") with Dominant Treasure Health Company Limited ("Dominant Treasure"). Pursuant to the terms of the Dominant Treasure Agreement, Dominant Treasure agreed to provide certain services to the Company to assist the Company in accelerating the Company's desire to get its products developed and distributed in the Southeast Asian market. In exchange for Dominant Treasure's services pursuant to the Dominant Treasure Agreement, the Company agreed to pay Dominant Treasure a one-time payment of $2,300,000. In addition, if Dominant Treasure is involved in generating negotiations and conclusion of a distribution agreement for the Company in the countries of China (including Hong Kong), Singapore and Malaysia, the Company will pay Dominant Treasure a success fee of 5% of any upfront and/or milestone payments to be received by the Company. If such an agreement will include a royalty payment to the Company, Dominant Treasure will receive 5% of such royalty payment. The Dominant Treasure Agreement has a term of 36 months and may be terminated at any time upon mutual agreement of the parties. The one-time payment of $2,300,000 was accounted for as a prepaid contract and will be expensed over a three-year period. For the years ended December 31, 2025 and December 31, 2024, the Company recorded prepaid contract expense of $766,667 and $54,612, respectively.

Executive Employment Agreements

The Company's standard executive employment agreements have a stated term of six years. Per the agreements, employees are eligible for a discretionary annual performance bonus, determined by the Board of Directors. If the Company terminates an employee without cause, the employee is entitled to a pro-rated pay out of the annual performance bonus based on days worked in the fiscal year, severance of twelve months of the base salary, and automatic vesting of unvested equity grants. If the employee terminates with good reason, as defined in the employment contract, the employee is entitled to automatic vesting of unvested equity grants.

During 2020, the Company began consistently paying salaries at 50% of the salaries reflected in the respective employment agreements. As of September 2021, the Company began paying full salaries. Throughout 2022, the Company returned to paying partial salaries and by October 2023 the company stopped paying 100% in an effort to conserve cash. See Note 3 – Related Party Transactions for details related to forgiveness of accrued compensation during the year ended December 31, 2023.

On December 18, 2023, various employees agreed to reduce their annual base salary to 20% of their original base salary effective October 1, 2023 until the time the Company raises additional capital from securities in the amount of $1,500,000 (the "Reduction Period"). Upon the expiration of the Reduction Period, the bases salaries shall adjust to be 105% of their original base salary as set forth in their original agreements.

As of December 4, 2024, the base salaries was adjusted to 105% of the original base salaries and the Company started paying a 100% of the salaries.

Note 8 – Commitments and Contingencies, continued

***Licensing and Royalty Agreements* - Aquanova AG**

On September 13, 2016, the Company entered into a Development, Collaboration and License Agreement ("License Agreement") with Aquanova AG, a German company in the field of development, manufacturing and selling of colloidal formulas. The License Agreement resulted in the creation of the pharmaceutic product, JOTROL™. The Chief Scientific Officer of the Company and Aquanova's founder, former CEO, and lead scientist, Darius Benham, are the joint inventors of JOTROL™. Aquanova is assignee on the patents in the United States, the European Union, China and Japan whereas the Company is obligated to maintain the patents. The agreement grants ownership to the Company for regulatory approvals and the sole and exclusive worldwide right to develop, manufacture and commercialize all products, including JOTROL™. Aquanova is granted the exclusive license to conduct formulation development and manufacturing. The agreement also defines fees owed to Aquanova for product and formulation development and licensing of the products. The Company is required to pay Aquanova an annual license fee of $75,000 upon acceptance of the product formulation by both parties, with the license fee requirement ending in the year of marketing authorization approval ("MMA") in a single territory. MMA has not yet been received as of the period ended December 31, 2025.

As of December 31, 2025 and 2024, $0 and $75,000 of accrued license fees are included in accounts payable and accrued expenses on the balance sheet, respectively. Upon receipt of approval of the MMA in each territory (e.g., United States, European Union, China, Japan), the Company will pay $200,000 to Aquanova per territory an MMA approval is received, up to a max of $600,000. The Company shall pay Aquanova a royalty of 5% of net sales in each territory through the later of ten years after the first commercial sale, the first date there is no valid claim within the Aquanova patent rights, or the date of expiration of the MMA in each territory.

On December 1, 2021, the Company and Aquanova entered into a Debt Forgiveness and Exchange Agreement, pursuant to which $225,000 of accrued and outstanding obligations owed to Aquanova under the License Agreement were forgiven in exchange for $125,000 in cash, a $100,000 promissory note, and the issuance of stock options to Aquanova. As of December 31, 2025, $0 in accrued license fees are recorded in accounts payable.

There is an option (exercisable by either party) to require the Company to pay a one-time royalty of $3,000,000 within 180 days of United States marketing approval, with subsequent royalty payments reduced to 1.25%, in accordance with the terms set forth above.

Murdoch Children's Research Institute

On September 1, 2015, the Company entered into a Global Development and License Agreement ("License Agreement II") with Murdoch Children's Research Institute ("MCRI"), an Australian Institute at the Royal Children's Hospital in Australia, with the know-how in the process of using pharmaceutical grade Resveratrol for the treatment of Friedreich's ataxia. The License Agreement II is for both parties to work jointly to develop an appropriate delivery system and conduct clinical trials for the purpose of product approval in the treatment of Friedreich's ataxia and worldwide commercialization by the Company. The License Agreement II grants an exclusive worldwide license to the Company to use the MCRI know-how for developing, manufacturing and commercializing the product for proposed treatment for Friedreich's ataxia. MCRI is granted an irrevocable, royalty free, worldwide license to use the product inventions and patent rights for internal research and development. Upon receipt of approval of the MMA in each territory (e.g., United States, European Union, China, Japan), the Company will pay $100,000 to MCRI per each territory up to a maximum of $300,000. MMA has not yet been received as of September 30, 2024. The Company shall pay MCRI a royalty of 1.5% of net sales in each territory until the product is no longer sold in the respective territory. The Company has presently put all R&D efforts associated with the treatment of Friedreich's Ataxia on hold.

Research and Development Service Providers

In addition to the services received under the licensing agreements noted above, a substantial portion of the research and development ("R&D") expense included in the statement of operations is incurred pursuant to short term service and consulting agreements with third party providers for research, development, testing and manufacturing services. The agreements generally provide termination, at any time by either party without cause, upon a 30-day written notice, unless otherwise disclosed below. There are no pending milestone payments due as of December 31, 2025.

Service Agreements

On June 3, 2024, the Company entered into three 36-month service agreements with three different entities. The Company issued an aggregate of 3,487,500 restricted shares of common stock, 1,162,500 restricted shares of common stock to each entity. The shares were to be registered upon an IPO as long as an IPO happens no later than March 31, 2025. Either party is able to terminate the respective agreement with no liability upon the occurrence of i) the Company failing to raise at least $10 million in gross proceeds from an IPO prior to May 31, 2025, ii) if either party is involved in any illegal activity or iii) at any time as long as both parties agree to it. The shares were registered in the IPO.

The Company initially recognized stock-based compensation expense from the effective date of the agreement through the date the obligations were met with the remaining expense being amortized over the remaining term of the 36-months per the services agreements. Upon the occurrence of the initial public offering the Company recorded stock- based compensation expense for services provided of $779,411, and through December 31, 2024 the Company recorded an additional stock-based compensation expense of $114,373 for a total stock-based compensation expense of $893,784. For the year ended December 31, 2025, the Company recorded $1,546,117 stock-based compensation expense and the remaining future stock-based compensation expense as of December 31, 2025 is $2,198,474.

In addition, each of the entities agreed to purchase 37,500 shares each of the Company's common stock at a price of $1.33 per share prior to the occurrence of the IPO and these shares were registered in the IPO.

Note 9 – Segment Report

The Company's Chief Executive Officer serves as the Chief Operating Decision Maker ("CODM"). The CODM evaluates financial performance and makes resource allocation decisions based on the operating results of the Company's reportable segments.

Effective October 1, 2025, the Company operates through two reportable segments under ASC 280, Segment Reporting: (i) its premium nutritional supplements, and (ii) pharmaceutical operations focused on drug candidates for CNS and rare orphan diseases.

Premium Nutritional Supplements

This segment includes all activities related to the commercialization and sale of the Company's Nugevia product line. Activities within this segment primarily consist of marketing, distribution, sales, customer support, and related supply chain management associated with Nugevia products.

Pharmaceutical Operations

This segment includes all activities related to the research, development, and regulatory advancement of JOTROL™, the Company's proprietary resveratrol-based therapeutic candidate, which is being developed to address unmet medical needs and improve patient outcomes. Activities within this segment primarily consist of clinical development, regulatory, manufacturing development, intellectual property protection, and related research and development functions.

The CODM assesses segment performance and allocates resources based on segment net loss (income), which represents the primary measure of profit or loss reviewed. The CODM does not evaluate segments using discrete asset or liability information. Accordingly, total assets are reported on a consolidated basis in the accompanying consolidated balance sheets.

Allocation Methodology

Expenses are attributed to each reportable segment based on the nature of the activity and the function to which the expense relates. Costs that are directly identifiable with a specific segment are recorded to that segment. Selling, general and administrative expenses that benefit both segments are allocated using reasonable and consistently applied methodologies that reflect the estimated level of effort or resources consumed by each segment. These allocation methodologies may include time and effort analyses, headcount, relative revenue, or other activity-based measures, depending on the underlying cost driver.

The allocation methodologies are reviewed periodically and refined as necessary to reflect changes in the business. The Company believes such allocations are reasonable and consistent with the manner in which the CODM evaluates segment performance and makes resource allocation decisions.

Corporate and other expenses consist primarily of public company costs (including board, investor relations, and SEC reporting expenses), certain executive compensation, certain stock-based compensation, interest income (expense), other income (expense), and income taxes. These costs are not allocated to reportable segments because they are not included in the measures reviewed by the CODM for purposes of assessing segment performance.

Segment information for the year ended December 31, 2025 is presented below:

	Pharmaceutical Operations	Premium Nutritional Supplements	Total Reportable Segments	Corporate / Other	Consolidated Total
Revenue	-	21,796	21,796	-	21,796
Cost of goods sold	-	4,231	4,231	-	4,231
Research and development	2,086,574	-	2,086,574	-	2,086,574
Selling, general and administrative	817,554	1,179,492	1,997,046	4,842,666	6,839,712
Segment net loss	(2,904,128)	(1,161,927)	(4,066,055)	(4,842,666)	(8,908,721)
Other interest income (expense), net	-	-	-	263,824	263,824
Net loss	(2,904,128)	(1,161,927)	(4,066,055)	(4,578,842)	(8,644,897)

Note 10 – Subsequent Events

SEPA Activity

Subsequent to year end and through March 31, 2026, we have issued and sold approximately 1.1 million SEPA Shares to Yorkville pursuant to the SEPA, including SEPA Shares issued in connection with the settlement of Prepaid Advances and upon conversion of the Convertible Notes, for aggregate net proceeds to us of approximately $625,748.

Nasdaq Compliance

On February 26, 2026, the Company received two written notices from the Listing Qualifications Department of Nasdaq notifying the Company that (i) the listing of the Company's Common Stock was not in compliance with the minimum bid price requirement as set forth under Nasdaq Listing Rule 5550(a)(2) for continued listing of its Common Stock on The Nasdaq Capital Market, as the closing bid price of the Common Stock was less than $1.00 per share for the previous 30 consecutive business days, and (ii) for the 30 consecutive business days ended February 26, 2026, the Company's market value of listed securities closed below the $35 million threshold required for continued listing on The Nasdaq Capital Market under Nasdaq Listing Rule 5550(b)(2). The Company has 180 calendar days, or until August 25, 2026, to regain compliance with both the minimum bid price requirement and the market value of listed securities requirement. To regain compliance with the minimum bid price requirement, the Company's common stock must have a closing bid price of at least $1.00 per share for a minimum of 10 consecutive business days (or such longer period, up to 20 consecutive business days, as Nasdaq may require). To regain compliance with the market value of listed securities requirement, the Company's market value of listed securities must be at least $35 million for a minimum of 10 consecutive business days.

2025 Notes Amendment

On February 20, 2026, the Company and Yorkville entered into an Omnibus Amendment. Among other changes, the Amendment revises the terms of the 2025 Convertible Promissory Notes to defer the commencement of monthly installment payments to April 1, 2026, effectively providing an extension of approximately three months.

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.

JUPITER NEUROSCIENCES, INC.

Dated: April 1, 2026

By: */s/ Christer Rosén*
Christer Rosén
Chairman of the Board and Chief Executive Officer

POWER OF ATTORNEY

Each person whose signature appears below hereby appoints Christer Rosén as attorney-in-fact with full power of substitution to execute in the name and on behalf of the registrant and each such person, individually and in each capacity stated below, one or more amendments to the Annual Report on Form 10-K, which amendments may make such changes in the report as the attorney-in-fact acting deems appropriate and to file any such amendment to the Annual Report on Form 10-K with the Securities and Exchange Commission. 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.

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.

Signature	Title	Date
/s/ Christer Rosén Christer Rosén	Chairman of the Board and Chief Executive Officer (principal executive officer)	April 1, 2026
/s/ Saleem Elmasri Saleem Elmasri	Chief Financial Officer (principal financial officer and principal accounting officer)	April 1, 2026
/s/ Marshall Hayward, Ph.D. Marshall Hayward, Ph.D.	Director	April 1, 2026
/s/ Alison D. Silva Alison D. Silva	Director	April 1, 2026
/s/ *Nicholas H. Hemmerly* Nicholas H. Hemmerly	Director	April 1, 2026
/s/ Julie Kampf Julie Kampf	Director	April 1, 2026
/s/ Allison W. Brady Allison W. Brady	Director	April 1, 2026
/s/ Holger Weis Holger Weis	Director	April 1, 2026

Exhibit 4.1

DESCRIPTION OF CAPITAL STOCK

The following description of our capital stock is based upon our amended and restated certificate of incorporation, as amended, our amended and restated bylaws, as amended, and applicable provisions of law, in each case as currently in effect. This discussion does not purport to be complete and is qualified in its entirety by reference to our certificate of incorporation, as amended, and our amended and restated bylaws, copies of which are filed with the SEC.

Authorized Capital Stock

As of March 28, 2026, our authorized capital stock consists of (i) 500,000,000 shares of common stock, par value $0.0001 per share ("Common Stock"), and (ii) 5,000,000 shares of preferred stock, par value $0.0001 per share ("Preferred Stock"). At March 31, 2026, we had 36,281,252 shares of Common Stock issued and outstanding and no shares of Preferred Stock issued and outstanding.

As of March 28, 2026, there were 31 holders of record of our Common Stock and no holders of record of our Preferred Stock.

Common Stock

Voting

The holders of our common stock are entitled to one vote for each share held on all matters to be voted on by the Company's stockholders. There shall be no cumulative voting.

Dividends

The holders of shares of our common stock are entitled to dividends when and as declared by the Board from funds legally available therefor if, as and when determined by the Board of Directors of the Company in their sole discretion, subject to provisions of law, and any provision of the Company's Certificate of Incorporation, as amended from time to time. There are no preemptive, conversion or redemption privileges, nor sinking fund provisions with respect to the common stock.

Liquidation

In the event of any voluntary or involuntary liquidation, dissolution or winding up of our affairs, the holders of our common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of or provision for all of our debts and other liabilities.

Fully Paid and Non-assessable

All outstanding shares of common stock are duly authorized, validly issued, fully paid and non-assessable.

Preferred Stock

The board of directors shall have the authority to authorize the issuance of the preferred stock from time to time in one or more classes or series, and to state in the resolution or resolutions from time to time adopted providing for the issuance thereof the following:

The shares of each class or series of the preferred stock may vary from the shares of any other class or series thereof in any respect. The Board of Directors may increase the number of shares of the preferred stock designated for any existing class or series by a resolution adding to such class or series authorized and unissued shares of the preferred stock not designated for any existing class or series of the preferred stock and the shares so subtracted shall become authorized, unissued and undesignated shares of the preferred stock.

Anti-Takeover Effects of Certain Provisions of Our Certificate of Incorporation, as Amended, and Our Amended and Restated Bylaws, as Amended

Provisions of our certificate of incorporation, as amended, and our amended and restated bylaws, as amended ("bylaws"), could make it more difficult to acquire us by means of a merger, tender offer, proxy contest, open market purchases, removal of incumbent directors and otherwise. These provisions, which are summarized below, are expected to discourage types of coercive takeover practices and inadequate takeover bids and to encourage persons seeking to acquire control of us to first negotiate with us. We believe that the benefits of increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging takeover or acquisition proposals because negotiation of these proposals could result in an improvement of their terms.

Removal of Directors. Our amended and restated bylaws provide that directors may be removed prior to the expiration of their terms by the affirmative vote of the holders of not less than two-thirds (2/3) of the voting power of the issued and outstanding stock entitled to vote.

Vacancies. Our amended and restated bylaws provide the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death, or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors

Preferred Stock. Our certificate of incorporation, as amended, authorizes the issuance of up to 5,000,000 shares of preferred stock with such rights and preferences as may be determined from time to time by our board of directors in their sole discretion. Our board of directors may, without stockholder approval, issue series of preferred stock with dividends, liquidation, conversion, voting or other rights that could adversely affect the voting power or other rights of the holders of our common stock.

Amendment of Bylaws. The certificate of incorporation, as amended, and amended and restated bylaws provide that the bylaws may be altered, amended or repealed by the Board of Directors by an affirmative vote of a majority of the Board of Directors at any regular meeting of the Board of Directors.

Limitation of Liability. The certificate of incorporation provides for the limitation of liability of, and providing indemnification to, our directors and officers;

Special Stockholders Meeting. The amended and restated bylaws provide that a special meeting of the stockholders may only be called by a majority of the board of directors.

Nominations of Directors. The amended and restated bylaws provide for advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of the Company.

Exclusive Forum Provision

Section IX of our certificate of incorporation, as amended, and Section 7.4 of our amended and restated bylaws provide that "unless the corporation consents in writing to the selection of an alternative forum, the sole and exclusive forum for (i) any derivative action or proceeding brought on behalf of the Corporation, (ii) any action asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee of the Corporation to the Corporation or the Corporation's stockholders, (iii) any action asserting a claim arising pursuant to any provision of the DGCL, or (iv) any action asserting a claim governed by the internal affairs doctrine shall be a state or federal court located in the county in which the principal office of the corporation in the State of Delaware is established, in all cases subject to the court's having personal jurisdiction over the indispensable parties named as defendants. Notwithstanding the foregoing, the exclusive forum provision will not apply to suits brought to enforce any liability or duty created by the Exchange Act of 1934, as amended, the Securities Act of 1933, as amended, or any claim for which the federal courts have exclusive or concurrent jurisdiction."

This choice of forum provision may limit a bondholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and employees. Alternatively, a court could find these provisions of our certificate of incorporation, as amended, and our amended and restated bylaws to be inapplicable or unenforceable in respect of one or more of the specified types of actions or proceedings, which may require us to incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business and financial condition.

Fee Shifting Provision

Section 7.4 of our amended and restated bylaws provides that "if any action is brought by any party against another party, relating to or arising out of these Bylaws, or the enforcement hereof, the prevailing party shall be entitled to recover from the other party reasonable attorneys' fees, costs and expenses incurred in connection with the prosecution or defense of such action."

Our amended and restated bylaws provide that for this section, the term "attorneys' fees" or "attorneys' fees and costs" means the fees and expenses of counsel to the Company and any other parties asserting a claim subject to Section 7.4 of the amended and restated bylaws, which may include printing, photocopying, duplicating and other expenses, air freight charges, and fees billed for law clerks, paralegals and other persons not admitted to the bar but performing services under the supervision of an attorney, and the costs and fees incurred in connection with the enforcement or collection of any judgment obtained in any such proceeding.

We adopted the fee-shifting provision to eliminate or decrease nuisance and frivolous litigation. We intend to apply the fee-shifting provision broadly to all actions except for claims brought under the Exchange Act and Securities Act.

There is no set level of recovery required to be met by a plaintiff to avoid payment under this provision. Instead, whoever is the prevailing party is entitled to recover the reasonable attorneys' fees, costs and expenses incurred in connection with the prosecution or defense of such action. Any party who brings an action, and the party against whom such action is brought under Section 7.4 of our amended and restated bylaws, which could include, but is not limited to former and current shareholders, Company directors, officers, affiliates, legal counsel, expert witnesses and other parties, are subject to this provision. Additionally, any party who brings an action, and the party against whom such action is brought under Section 7.4 of our amended and restated bylaws, which could include, but is not limited to former and current shareholders, Company directors, officers, affiliates, legal counsel, expert witnesses and other parties, would be able to recover fees under this provision.

In the event you initiate or assert a claims against us, in accordance with the dispute resolution provisions contained in our amended and restated bylaws, and you do not, in a judgment prevail, you will be obligated to reimburse us for all reasonable costs and expenses incurred in connection with such claim, including, but not limited to, reasonable attorney's fees and expenses and costs of appeal, if any. Additionally, this provision in Section 7.4 of our amended and restated bylaws could discourage shareholder lawsuits that might otherwise benefit the Company and its shareholders.

THE FEE SHIFTING PROVISION CONTAINED IN THE AMENDED AND RESTATED BYLAWS IS NOT INTENDED TO BE DEEMED A WAIVER BY ANY HOLDER OF COMMON STOCK OF THE COMPANY'S COMPLIANCE WITH THE U.S. FEDERAL SECURITIES LAWS AND THE RULES AND REGULATIONS PROMULGATED THEREUNDER. THE FEE SHIFTING PROVISION CONTAINED IN THE AMENDED AND RESTATED BYLAWS DO NOT APPLY TO CLAIMS BROUGHT UNDER THE EXCHANGE ACT AND SECURITIES ACT.

Our Transfer Agent

Our transfer agent is Equiniti Trust Company. The transfer agent address is 1110 Centre Pointe Curve, Suite 101, Mendota Heights, Minnesota 55120, and its telephone number is (800) 401-1957.

Exhibit 10.4

Amendment to Executive Employment Agreement

Dated as of December 18, 2023

This Amendment to Executive Employment Agreement (this "Amendment") dated as of the date first set forth above (the "Amendment Date") is entered into by and between Jupiter Neurosciences, Inc., a Delaware corporation (the "Company") and Christer Rosén (the "Executive"). The Company and Executive may collective be referred to as the "Parties" and each individually as a "Party".

WHEREAS, the Parties are the parties to that certain Executive Employment Agreement, dated as of June 1, 2021 (the "Original Agreement"), and now desire to amend the Original Agreement as set forth herein and pursuant to Section 14 of the Original Agreement the Parties may amend the Original Agreement in writing;

NOW, THEREFORE, in consideration of the promises and of the mutual covenants and agreements hereinafter set forth, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties hereby agree as follows:

1. Defined Terms. Defined terms used herein without definition shall have the meanings given in the Original Agreement.

2. Amendment.

   (a) Pursuant to Section 14 of the Original Agreement, the Original Agreement is hereby amended by adding the following to the end of Section 2 of the Original Agreement:

   > Notwithstanding the foregoing, for the period from October 1, 2023, until the time that the Company has raised additional capital from the sale of its securities in the amount of $1,500,000 (the "Reduction Period"), the Base Salary shall be reduced to $84,000 on an annual basis. Upon the expiration of the Reduction Period, the Base Salary shall be adjusted to be 105% the original Base Salary as set forth above.

   (b) Notwithstanding the fact that this Amendment is being executed on the Amendment Date, the Parties acknowledge and agree that the amendment to the Original Agreement as set forth in Section 2(a) shall be operative and effective as of the date of the commencement of the "Reduction Period" as set forth in Section 2(a), and shall operate to reduce the Base Salary from such date and during the remainder of the Reduction Period.

3. Remainder in Force. Other than as amended herein, the Original Agreement shall remain in full force and effect until terminated in accordance with its terms. Any reference in the Original Agreement to the "Agreement" shall now be deemed a reference to the Original Agreement as amended by this Amendment.

4. Miscellaneous.

   (a) The headings in this Amendment are for reference only and shall not affect the interpretation of this Amendment.

   (b) This Amendment and the rights and obligations of the Parties shall be governed by and construed and enforced in accordance with the laws of the State of Florida without giving effect to any choice or conflict of law provision or rule (whether of the State of Florida or any other jurisdiction).

   (c) This Amendment may be executed in counterparts, each of which shall be deemed an original, but all of which together shall be deemed to be one and the same agreement. A signed copy of this Amendment delivered by facsimile, e-mail or other means of electronic transmission shall be deemed to have the same legal effect as delivery of an original signed copy of this Amendment.

[Signatures appear on following page]

IN WITNESS WHEREOF, the Parties hereto have caused this Amendment to be executed as of the Amendment Date.

Jupiter Neurosciences, Inc.

By: */s/ Alison Silva*
Name: Alison Silva
Title: President & Chief Business Officer

Executive: Christer Rosén

By: */s/ Christer Rosén*
Name: Christer Rosén

Exhibit 10.7

Amendment to Executive Employment Agreement

Dated as of December 18, 2023

This Amendment to Executive Employment Agreement (this "Amendment") dated as of the date first set forth above (the "Amendment Date") is entered into by and between Jupiter Neurosciences, Inc., a Delaware corporation (the "Company") and Marshall Hayward (the "Executive"). The Company and Executive may collective be referred to as the "Parties" and each individually as a "Party".

WHEREAS, the Parties are the parties to that certain Executive Employment Agreement, dated as of June 1, 2021 (the "Original Agreement"), and now desire to amend the Original Agreement as set forth herein and pursuant to Section 14 of the Original Agreement the Parties may amend the Original Agreement in writing;

NOW, THEREFORE, in consideration of the promises and of the mutual covenants and agreements hereinafter set forth, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties hereby agree as follows:

1. Defined Terms. Defined terms used herein without definition shall have the meanings given in the Original Agreement.

2. Amendment.

   (a) Pursuant to Section 14 of the Original Agreement, the Original Agreement is hereby amended by adding the following to the end of Section 2 of the Original Agreement:

   > Notwithstanding the foregoing, for the period from October 1, 2023, until the time that the Company has raised additional capital from the sale of its securities in the amount of $1,500,000 (the "Reduction Period"), the Base Salary shall be reduced to $67,200 on an annual basis. Upon the expiration of the Reduction Period, the Base Salary shall be adjusted to be 105% the original Base Salary as set forth above.

   (b) Notwithstanding the fact that this Amendment is being executed on the Amendment Date, the Parties acknowledge and agree that the amendment to the Original Agreement as set forth in Section 2(a) shall be operative and effective as of the date of the commencement of the "Reduction Period" as set forth in Section 2(a), and shall operate to reduce the Base Salary from such date and during the remainder of the Reduction Period.

3. Remainder in Force. Other than as amended herein, the Original Agreement shall remain in full force and effect until terminated in accordance with its terms. Any reference in the Original Agreement to the "Agreement" shall now be deemed a reference to the Original Agreement as amended by this Amendment.

4. Miscellaneous.

   (a) The headings in this Amendment are for reference only and shall not affect the interpretation of this Amendment.

   (b) This Amendment and the rights and obligations of the Parties shall be governed by and construed and enforced in accordance with the laws of the State of Florida without giving effect to any choice or conflict of law provision or rule (whether of the State of Florida or any other jurisdiction).

   (c) This Amendment may be executed in counterparts, each of which shall be deemed an original, but all of which together shall be deemed to be one and the same agreement. A signed copy of this Amendment delivered by facsimile, e-mail or other means of electronic transmission shall be deemed to have the same legal effect as delivery of an original signed copy of this Amendment.

[Signatures appear on following page]

IN WITNESS WHEREOF, the Parties hereto have caused this Amendment to be executed as of the Amendment Date.

Jupiter Neurosciences, Inc.

By: */s/ Christer Rosén*
Name: Christer Rosén
Title: Chief Executive Officer

Executive: Marshall Hayward

By: */s/ Marshall Hayward*
Name: Marshall Hayward

Exhibit 10.12

Amendment to Executive Employment Agreement

Dated as of December 18, 2023

This Amendment to Executive Employment Agreement (this "Amendment") dated as of the date first set forth above (the "Amendment Date") is entered into by and between Jupiter Neurosciences, Inc., a Delaware corporation (the "Company") and Alison Silva (the "Executive"). The Company and Executive may collective be referred to as the "Parties" and each individually as a "Party".

WHEREAS, the Parties are the parties to that certain Executive Employment Agreement, dated as of June 1, 2021 (the "Original Agreement"), and now desire to amend the Original Agreement as set forth herein and pursuant to Section 14 of the Original Agreement the Parties may amend the Original Agreement in writing;

NOW, THEREFORE, in consideration of the promises and of the mutual covenants and agreements hereinafter set forth, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties hereby agree as follows:

1. Defined Terms. Defined terms used herein without definition shall have the meanings given in the Original Agreement.

2. Amendment.

   (a) Pursuant to Section 14 of the Original Agreement, the Original Agreement is hereby amended by adding the following to the end of Section 2 of the Original Agreement:

   > Notwithstanding the foregoing, for the period from October 1, 2023, until the time that the Company has raised additional capital from the sale of its securities in the amount of $1,500,000 (the "Reduction Period"), the Base Salary shall be reduced to $60,000 on an annual basis. Upon the expiration of the Reduction Period, the Base Salary shall be adjusted to be 105% the original Base Salary as set forth above.

   (b) Notwithstanding the fact that this Amendment is being executed on the Amendment Date, the Parties acknowledge and agree that the amendment to the Original Agreement as set forth in Section 2(a) shall be operative and effective as of the date of the commencement of the "Reduction Period" as set forth in Section 2(a), and shall operate to reduce the Base Salary from such date and during the remainder of the Reduction Period.

3. Remainder in Force. Other than as amended herein, the Original Agreement shall remain in full force and effect until terminated in accordance with its terms. Any reference in the Original Agreement to the "Agreement" shall now be deemed a reference to the Original Agreement as amended by this Amendment.

4. Miscellaneous.

   (a) The headings in this Amendment are for reference only and shall not affect the interpretation of this Amendment.

   (b) This Amendment and the rights and obligations of the Parties shall be governed by and construed and enforced in accordance with the laws of the State of Florida without giving effect to any choice or conflict of law provision or rule (whether of the State of Florida or any other jurisdiction).

   (c) This Amendment may be executed in counterparts, each of which shall be deemed an original, but all of which together shall be deemed to be one and the same agreement. A signed copy of this Amendment delivered by facsimile, e-mail or other means of electronic transmission shall be deemed to have the same legal effect as delivery of an original signed copy of this Amendment.

[Signatures appear on following page]

IN WITNESS WHEREOF, the Parties hereto have caused this Amendment to be executed as of the Amendment Date.

Jupiter Neurosciences, Inc.

By: */s/ Christer Rosén*
Name: Christer Rosén
Title: Chief Executive Officer

Executive: Alison Silva

By: */s/ Alison Silva*
Name: Alison Silva

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We hereby consent to the incorporation by reference in the Registration Statements of Jupiter Neurosciences, Inc. on Form S-1 (No. 333-291832) and on Form S-8 (No. 333-293466) of our report, dated April 1, 2026, with respect to our audit of the financial statements as of December 31, 2025 and for the year then ended. Our report includes an explanatory paragraph regarding the existence of substantial doubt concerning the Company's ability to continue as a going concern. We also consent to reference to our firm under the caption "Experts" in such registration statements.

/s/ Cherry Bekaert LLP
Tampa, Florida
April 1, 2026

Exhibit 23.2

CONSENT OF INDEPENDENT ACCOUNTANTS

We hereby consent to the incorporation by reference in this Registration Statement on Form S-8 of Jupiter Neurosciences, Inc. of our report dated March 28, 2025, relating to our audit of the financial statements as of December 31, 2024 and for the year ended December 31, 2024, which appears in the Registration Statement on Form S-1 of Jupiter Neurosciences, Inc. for the year then ended.

We also consent to the reference to our firm under the caption "Experts" in the Prospectus, which is part of this Registration Statement.

Assurance Dimensions
Coral Springs, Florida
April 1, 2026

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Christer Rosén, certify that:

1. I have reviewed this Annual Report on Form 10-K for the fiscal year ended December 31, 2025 of Jupiter Neurosciences, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared; and

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles; and

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: April 1, 2026

/s/ Christer Rosén
Christer Rosén
Chief Executive Officer (principal executive officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Saleem Elmasri, certify that:

1. I have reviewed this Annual Report on Form 10-K for the fiscal year ended December 31, 2025 of Jupiter Neurosciences, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared; and

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles; and

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: April 1, 2026

/s/ Saleem Elmasri
Saleem Elmasri
Chief Financial Officer (principal financial officer and principal accounting officer)

Exhibit 32.1

CERTIFICATION
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Jupiter Neurosciences, Inc. (the "Company") for the fiscal year ended December 31, 2025 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Christer Rosén, Chief Executive Officer of the Company, and I, Saleem Elmasri, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: April 1, 2026

/s/ Christer Rosén
Christer Rosén
Chief Executive Officer (principal executive officer)

Date: April 1, 2026

/s/ Saleem Elmasri
Saleem Elmasri
Chief Financial Officer (principal financial officer and principal accounting officer)

This certification accompanies this Annual Report on Form 10-K pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not, except to the extent required by such Act, be deemed filed by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent that the Company specifically incorporates it by reference.

Exhibit 97.1

JUPITER NEUROSCIENCES, INC.
CLAWBACK POLICY

This Jupiter Neurosciences, Inc. Clawback Policy (this "**Policy**") was approved effective as of March 25, 2025 (the "**Effective Date**") by the Compensation Committee (the "**Committee**") of the Board of Directors (the "**Board**") of Jupiter Neurosciences, Inc. (the "**Company**"). This Policy is adopted pursuant to and intended to comply with Rule 5608 (Recovery of Erroneously Awarded Compensation) of The Nasdaq Stock Market LLC ("**Nasdaq**") so long as the Company's securities are listed on Nasdaq.

Purpose and Policy Statement

The Company is committed to conducting business with integrity in accordance with high ethical standards and in compliance with all applicable laws, rules, and regulations. This includes the Company's commitment to comply with all laws, rules, and regulations applicable to the presentation of the Company's financial information to the public and to the recovery of erroneously awarded incentive-based compensation.

As a result, the Committee has adopted this Policy to provide that, in the event the Company is required to prepare an accounting restatement due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period (each, as applicable, a "**Restatement**"), the Company will recover reasonably promptly the amount of any "erroneously awarded compensation" "received" by an "executive officer," in each case as such terms are defined in this Policy, if and to the extent required by any federal or state law, rule or regulation, or rule, regulation, policy or listing standard of the Securities and Exchange Commission ("**SEC**") or any securities exchange on which the Company's securities are listed, including without limitation, Nasdaq Rule 5608 (Recovery of Erroneously Awarded Compensation).

In the event of any change in any federal or state law, rule or regulation, or rule, regulation, policy or listing standard of the SEC or any securities exchange on which the Company's securities are listed after the Effective Date, which requires the Company to recover compensation from an executive officer, the Company will seek recovery under this Policy to the extent required by such laws, rules, regulations or listing standards.

Administration

The Committee has full power, authority, and sole and exclusive discretion to reasonably construe, interpret, and administer this Policy. The Committee will interpret this Policy consistent with Nasdaq Rule 5608 (Recovery of Erroneously Awarded Compensation) and any guidance issued thereunder, the rules and regulations of the SEC, and any other applicable laws, rules or regulations governing the mandatory recovery of compensation, as such laws, rules or regulations may change, be interpreted, or evolve from time to time. All determinations and decisions made by the Committee will be made in its reasonable discretion and will be final, conclusive, and binding on all affected individuals.

The term "**Committee**" as used in this Policy means the Compensation Committee of the Board, or in the absence of such a committee, a majority of the "independent directors" (as defined under Nasdaq Rule 5605(a)(2)) serving on the Board.

Applicability

This Policy applies to all "incentive-based compensation" "received" by a person, in each case as such terms are defined in this Policy:

- After beginning service as an "executive officer," as such term is defined in this Policy, and who served as an executive officer at any time during the performance period for that incentive-based compensation;
- While the Company has a class of securities listed on Nasdaq or another national securities exchange or a national securities association; and
- During the three completed fiscal years immediately preceding the date that the Company is required to prepare the Restatement, plus any transition period (that results from a change in the Company's fiscal year) within or immediately following those three completed fiscal years; provided, however, that a transition period between the last day of the Company's previous fiscal year-end and the first day of its new fiscal year that comprises a period of nine to 12 months would be deemed a completed fiscal year; and provided, further, that the Company's obligation to recover erroneously awarded compensation is not dependent on if or when the restated financial statements are filed.

For purposes of determining the relevant recovery period, the date that the Company is required to prepare a Restatement is the earlier to occur of (i) the date the Company's Board, a committee of the Board, or the officer or officers of the Company authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare a Restatement; or (ii) the date a court, regulator or other legally authorized body directs the Company to prepare a Restatement.

Executive Officers Covered by Policy

This Policy covers the Company's current and former executive officers who received erroneously awarded compensation regardless of whether the executive officer committed misconduct or contributed to the error.

The term "**executive officer**" as used in this Policy means the Company's:

- president;
- principal financial officer;
- principal accounting officer (or if there is no such accounting officer, the controller);
- any vice-president of the Company in charge of a principal business unit, division, or function (such as sales, administration, or finance);
- any other officer who performs a policy-making function; or
- any other person who performs similar policy-making functions for the Company and executive officers of the Company's parents or subsidiaries if such individuals perform such policy-making functions for the Company.

Policy-making function is not intended to include policy-making functions that are not significant. Identification of an executive officer for purposes of this Policy would include at a minimum executive officers identified by the Company pursuant to Item 401(b) of SEC Regulation S-K.

Authority and Obligation to Recover Erroneously Awarded Compensation; Exceptions

In the event of a Restatement, the Company must reasonably promptly recover any "erroneously awarded compensation," as such term is defined in this Policy, in compliance with this Policy, except to the extent one of the three conditions below is met and the Committee has made a determination that recovery would be impracticable.

1. The direct expense paid to a third party to assist in enforcing this Policy would exceed the amount to be recovered and the Company has made a reasonable attempt to recover any amount of erroneously awarded compensation, has documented such reasonable attempt(s) to recover and provided that documentation to Nasdaq.

2. Recovery would violate home country law where that law was adopted prior to November 28, 2022, and the Company has obtained an opinion of home country counsel, acceptable to Nasdaq, that recovery would result in such a violation and has provided such opinion to Nasdaq.

3. Recovery would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the Company, to fail to meet the requirements of Section 401(a)(13) or 411(a) of the U.S. Internal Revenue Code and regulations thereunder.

Erroneously Awarded Compensation

The term "**erroneously awarded compensation**" as used in this Policy means that amount of "incentive-based compensation" received that exceeds the amount of "incentive-based compensation" that otherwise would have been received had it been determined based on the restated amounts, and must be computed without regard to any taxes paid.

For incentive-based compensation based on stock price or total shareholder return, where the amount of erroneously awarded compensation is not subject to mathematical recalculation directly from the information in a Restatement:

- the amount must be based on a reasonable estimate of the effect of the Restatement on the stock price or total shareholder return upon which the incentive-based compensation was received; and
- the Company must maintain documentation of the determination of that reasonable estimate and provide such documentation to Nasdaq.

The term "**incentive-based compensation**" as used in this Policy means any compensation that is granted, earned, or vested based wholly or in part upon the attainment of a financial reporting measure.

The term "**financial reporting measures**" as used in this Policy means measures that are determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measures that are derived wholly or in part from such measures. Financial reporting measures include, without limitation, stock price and total shareholder return, and may include non-GAAP financial measures. A financial reporting measure need not be presented within the Company's financial statements or included in an SEC filing to constitute a financial reporting measure for this purpose.

Incentive-based compensation is deemed "**received**" as such term is used in this Policy by an executive officer in the Company's fiscal period during which the financial reporting measure specified in the incentive-based compensation award is attained, even if the payment or grant of the incentive-based compensation occurs after the end of that period.

Notwithstanding the generality of the foregoing, "incentive-based compensation" is intended to be interpreted and construed broadly and includes with respect to any plan that takes into account incentive-based compensation (other than a tax-qualified plan) any amount contributed to a notional account based on erroneously awarded compensation and any earnings accrued to date on that notional account. Such plans include without limitation long-term disability plans, life insurance plans, supplemental executive retirement plans and other compensation, if it is based on incentive-based compensation.

For clarity and the avoidance of doubt, "incentive-based compensation" does not include the following:

- base salary (other than any base salary increase earned wholly or in part based on the attainment of a financial reporting measure, which increase is subject to recovery as incentive-based compensation hereunder);
- bonuses paid solely at the discretion of the Committee or Board that are not paid from a "bonus pool" that is determined by satisfying a financial reporting measure performance goal;
- bonuses paid solely upon satisfying one or more subjective standards (e.g. demonstrated leadership) and/or completion of a specified employment period;
- non-equity incentive plan awards earned solely upon satisfying one or more strategic measures (e.g., consummating a merger or divestiture), or operational measures (e.g., completion of a project); and
- equity awards for which the grant is not contingent upon achieving any financial reporting measure performance goal, and vesting is contingent solely upon completion of a specified employment period and/or attaining one or more non-financial reporting measures.

Method of Recovery

The Committee will determine, in its reasonable discretion, the method for recovering incentive-based compensation hereunder, which may include, without limitation, any one or more of the following:

- requiring reimbursement of cash incentive-based compensation previously paid;
- seeking recovery of any gain realized on the vesting, exercise, settlement, sale, transfer, or other disposition of any equity-based awards;
- cancelling or rescinding some or all outstanding vested or unvested equity-based awards;
- adjusting or withholding from unpaid compensation, deferred compensation, or other set-off;
- cancelling or setting-off against planned future grants of equity-based awards; and/or
- any other method required or authorized by applicable law or contract.

Enforceability

In addition to the adoption of this Policy, the Company will take steps to implement an agreement to this Policy by all current and future executive officers. In furtherance of the foregoing, each executive officer subject to this Policy is required to sign and return to the Company the Acknowledgement Form attached hereto as Exhibit A pursuant to which such executive officer will agree to be bound by the terms and comply with this Policy.

Policy Not Exclusive

Any recovery under this Policy is in addition to, and not in lieu of, any other remedies or rights of recovery that may be available to the Company pursuant to the terms of any other clawback or recovery policy or any similar policy in any employment agreement, incentive or equity compensation plan or award or other agreement and any other legal rights or remedies available to the Company.

Notwithstanding the generality of the foregoing, to the extent that the requirements under the provisions of Section 304 of the Sarbanes-Oxley Act of 2002 are broader than the provisions in this Policy, the provisions of such law will apply to the Company's Chief Executive Officer and Chief Financial Officer.

No Indemnification

The Company will not indemnify or agree to indemnify any executive officer or former executive officer against the loss of erroneously awarded compensation nor will the Company pay or agree to pay any insurance premium to cover the loss of erroneously awarded compensation.

Effective Date

This Policy is effective as of the Effective Date and applies to all incentive-based compensation received by the Company's current and former executive officers on or after the Effective Date.

Required Disclosures

The Company will file all disclosures with respect to this Policy in accordance with the requirements of the federal securities laws, including the disclosure required by the applicable SEC filings, and will provide all required SEC and other disclosures regarding this Policy and in the event of a Restatement.

Amendment and Termination

The Committee may amend, modify, or terminate this Policy in whole or in part at any time in its sole discretion and may adopt such rules and procedures that it deems necessary or appropriate to implement this Policy or to comply with Nasdaq Rule 5608 (Recovery of Erroneously Awarded Compensation) and any other applicable laws, rules, and regulations.

Successors

This Policy shall be binding and enforceable against all current and former executive officers of the Company and their respective beneficiaries, heirs, executors, administrators, or other legal representatives.

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Adopted by the Compensation Committee
of the Board of Directors of Jupiter Neurosciences, Inc.
on March 25, 2025

JUPITER NEUROSCIENCES, INC.
CLAWBACK POLICY
ACKNOWLEDGEMENT FORM

By signing below, the undersigned acknowledges and confirms that the undersigned has received and reviewed a copy of the Jupiter Neurosciences, Inc. Clawback Policy (the "**Policy**").

By signing this Acknowledgement Form, the undersigned acknowledges and agrees that the undersigned is and will continue to be subject to the Policy and that the Policy will apply both during and after the undersigned's employment with Jupiter Neurosciences, Inc., and its direct and indirect subsidiaries.

Further, by signing below, the undersigned agrees to abide by the terms of the Policy, including, without limitation, by returning any erroneously awarded compensation (as defined in the Policy) to Jupiter Neurosciences, Inc. and its direct and indirect subsidiaries to the extent required by, and in a manner permitted by the Policy.

Signature: _____

Name: _____

Date: _____