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

FORM 10-K

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

For the fiscal year ended December 31, 2024

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

For the transition period from _____ to _____

Commission File Number 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 ☒

As of March 28, 2025, there were 33,103,860 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:

- the ability of our preclinical studies and planned clinical trials to demonstrate safety and efficacy of our product candidate JOTROL, and other positive results;
- the timing, progress and results of preclinical studies and clinical trials for JOTROL and other product candidates we may develop, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the studies or trials will become available, and our research and development programs;
- the timing, scope and likelihood of regulatory filings and approvals, including timing of INDs and final FDA approval of JOTROL and any other future product candidates;
- the timing, scope or likelihood of foreign regulatory filings and approvals;
- our ability to develop and advance our current product candidate JOTROL and programs into, and successfully complete, clinical studies;
- our manufacturing, commercialization, and marketing capabilities and strategy;
- our plans relating to commercializing our product candidates, if approved, including the geographic areas of focus and sales strategy;
- the need to hire additional personnel and our ability to attract and retain such personnel;
- the size of the market opportunity for our product candidate JOTROL, including our estimates of the number of patients who suffer from the diseases we are targeting;
- our expectations regarding the approval and use of our product candidate JOTROL in combination with other drugs;
- our competitive position and the success of competing therapies that are or may become available;
- our estimates of the number of patients that we will enroll in our clinical trials;
- the beneficial characteristics, and the potential safety, efficacy and therapeutic effects of our product candidate JOTROL;
- our ability to obtain and maintain regulatory approval of our product candidate JOTROL;
- our plans relating to the further development of our product candidate JOTROL, including additional indications we may pursue;
- existing regulations and regulatory developments in the United States, Europe and other jurisdictions;
- our intellectual property position, including the scope of protection we are able to establish and maintain for intellectual property rights covering JOTROL and other product candidates we may develop, including the extensions of existing patent terms where available, the validity of intellectual property rights held by third parties, and our ability not to infringe, misappropriate or otherwise violate any third-party intellectual property rights;
- our continued reliance on third parties to conduct additional preclinical studies and planned clinical trials of our product candidate JOTROL, and for the manufacture of our product candidate JOTROL for preclinical studies and clinical trials;
- our relationships with patient advocacy groups, key opinion leaders, regulators, the research community and payors;

- our ability to obtain, and negotiate favorable terms of, any collaboration, licensing or other arrangements that may be necessary or desirable to develop, manufacture or commercialize our product candidate JOTROL;
- the pricing and reimbursement of JOTROL and other product candidates we may develop, if approved;
- the rate and degree of market acceptance and clinical utility of JOTROL and other product candidates we may develop;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our financial performance;
- the period over which we estimate our existing cash and cash equivalents will be sufficient to fund our future operating expenses and capital expenditure requirements;
- the impact of laws and regulations;
- our expectations regarding the period during which we will qualify as an emerging growth company under The Jumpstart Our Business Startups Act of 2012 and a smaller reporting company under the Securities Exchange Act of 1934, as amended;
- our anticipated use of our existing resources and the proceeds from our initial public offering; and
- the price of our common stock could be subject to rapid and substantial volatility. 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 "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.

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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. We have developed a unique resveratrol platform product primarily targeting treatment of neuro-inflammation. Our platform product, JOTROL, an enhanced oral formulation of resveratrol, has many potential indications of use for rare diseases. In the larger disease areas, we are primarily targeting Parkinson's Disease and Mild Cognitive Impairment/early Alzheimer's disease.

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, par value $0.0001 per share ("common stock") at a price of $4.00 per share for gross proceeds of $11 million before deducing 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

The Company's platform product, JOTROL, is an enhanced orally administered resveratrol formulation designed and intended to deliver therapeutically relevant, safe levels of resveratrol. This platform has many potential indications of use for rare diseases, which include Mucopolysaccharidoses Type 1, Friedreich's ataxia and MELAS. In the larger disease areas, we are primarily targeting Parkinson's Disease and Mild Cognitive Impairment/early Alzheimer's disease.

Currently available resveratrol products are associated with severe gastrointestinal (GI) side effects at the dose levels we believe are needed for therapeutic effect. Our belief, that a high dose of resveratrol is needed for therapeutic effects, is based on available scientific literature, preclinical trial results conducted in mice and rats, and previously conducted human trials with resveratrol. We believe that JOTROL, based on the results from our Phase I clinical trial conducted at the University of Miami and completed in 2021 ("Miami Clinical Trial"), has the potential to deliver a therapeutically effective dose of resveratrol in the blood stream without causing any severe side effects. Based on our own preclinical studies we believe that resveratrol has the ability to cross the blood-brain barrier. In studies conducted in Friedreich's ataxia (FA) and Alzheimer's disease (AD) patients, JOTROL resulted in positive effects on oxidative stress, inflammation, and mitochondrial function.

The present primary target for the Company is treatment of Parkinson's Disease (PD). The Company completed preclinical activities in a validated mouse model of Parkinson's Disease (PD) at the University of Miami in 2021. See our "Clinical Studies". The model of Parkinson's Disease that was used in this clinical trial mimics many aspects of the disease utilizing a unilateral injection of a neurotoxin precursor that elicits nigral cell loss, striatal dopamine loss and behavior deficits similar to physiological characteristics of human disease. We believe that results from this clinical trial indicate that Parkinson's Disease might be the best target for treatment and financial opportunity among the multiple indications where JOTROL might play a role. The Company is now in process to start its first Phase II trial in a patient population. This will be a Phase IIa study conducted with the assistance of Zina Biopharmaceuticals that is led by Dr. Charbel Moussa, MBBS,Ph.D. The study is expected to start in the third quarter of 2025 and have results available approximately 12 months thereafter. The trial design and outcomes are further described in this section, see JNS115.

We are also targeting the treatment of MCI/early Alzheimer's Disease. We received funding of $2.2 million from the National Institute of Aging ("NIA") in in 2020 and 2022 from a grant application for a Phase 1 study for Mild Cognitive Impairment/ Alzheimer'. In the NIA scientific review summary statement of our Phase I study application, it is stated that the NIA is looking forward to a Phase II study with an enhanced resveratrol product, based on the earlier study results from the well published Turner et al. Alzheimer's study. We presently have a pending grant application, $16.5 Million, for a Phase II trial in MCI/early Alzheimer's Disease with the NIA. This is an application for a 3-year Phase II trial that is expected to be completed with approximately 100 patients that have Mild Cognitive Impairment. The award will be decided in May 2025. There is no guarantee that the application will be approved, and the trial will be put on hold if an approval is not rewarded to the Company. A draft of the final study design is not yet determined but a draft synopsis is described in "Item 1. Business - " of this Annual Report on Form 10-K.

We have over the past three years received a strong interest in JOTROL from various Asian organizations. We believe that this interest has been triggered, in part, because resveratrol is becoming commonly used in Asian herbal medicines as a therapeutic strategy as described in available scientific literature published by PubMed Central: PMCID: PMC7498443 (September 2020); (ii) Hong Kong's and China's recent approval of the patent for JOTROL; (iii) China releasing a list of approximately 120 rare disease indications issued jointly by five national bodies, including the National Health Commission, Ministry of Science and Technology, Ministry of Industry and Information Technology, State Drug Administration, and State Administration of Traditional Chinese Medicine (May 2018), that we believe JOTROL can be applicable as a treatment for MPS-1 and MELAS in this population; (iv) recent publications regarding JOTROL in the Journal of Alzheimer's Disease and AAPS Open (Journal of Alzheimer's Disease 86 (2022) 173–190 February 2022; Kemper et al. AAPS Open June 2022); and (v) the projected increase of the TCM market due to several factors which of one is reformulation of existing compounds. We have recently entered into service agreements in the areas of Business Development, CMC (Chemistry, Manufacturing, and Controls), regulatory affairs and clinical trial management. These agreements are with companies that, we believe, have the knowledge and network in the South-East Asian market to accelerate steps that is needed to have a product that can have treatment value in the territory. The agreements are further described in the section "Activities in Asia".

In March 2025, the Company announced that it had entered into a partnership with Aquanova AG to develop a series of nutritional products targeting longevity, aging and Healthspan. The first three products, which will focus on the concept of "Beauty from Within", are slated to hit the market in the third quarter of 2025 through a Direct-to-Consumer model. The Company will form a wholly-owned subsidiary to focus on the consumer market, and will market its products on a to-be-developed website targeting the US market, along with social media marketing. Internationally, the Company is focusing on partners who can market and accelerate sales, with an initial focus on the Asian region.

Resveratrol

Resveratrol 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 14,000 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 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 for the pharmaceutical industry, due to its poor solubility and bioavailability, as well as adverse effects, such as severe gastro-intestinal side effects when taken at effective dose levels (over 2,000 mg daily). Resveratrol has never before been developed with all the necessary steps to achieve an approval as a pharmaceutical product since the existing natural supplements cannot provide high enough levels of resveratrol in blood plasma to be able to provide a therapeutically effective dose without generating severe gastro-intestinal side effects. This means that we need to take JOTROL through the full regulatory NDA (New Drug Application) requirement to obtain a prescription marketing approval in the USA.

JOTROL

JOTROL was developed together with our technology partner Aquanova AG, 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 has been completed at Catalent Pharmaceutical Services, Inc., St Petersburg, Florida. Catalent is also in process to manufacture 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. Summary details of these studies are included in "Item 1. Business" of this Annual Report on Form 10-K. 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 results from this study will be used as a cross-reference for all indications where JOTROL will be used in Phase II and Phase III clinical trials. The Phase I results and the FDA guidance of cross-referencing is further described in "Item 1. Business" of this Annual Report on Form 10-K. The Company has not discussed the use of cross-referencing in this manner with the FDA or other comparable regulatory authorities.

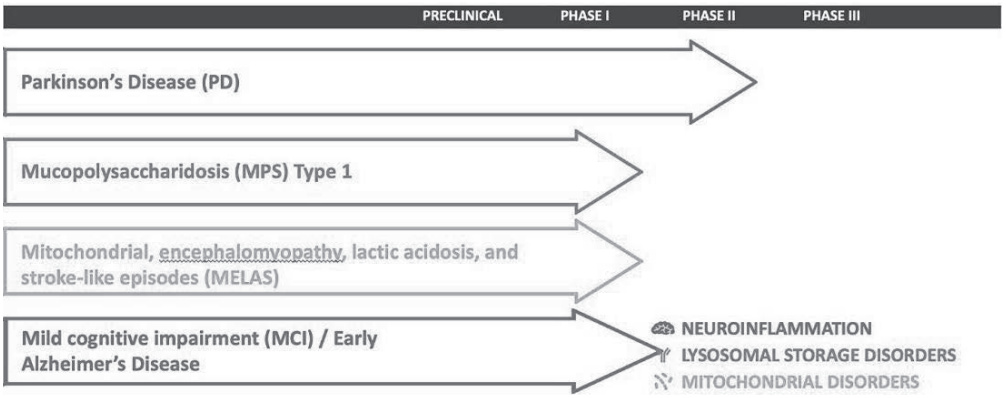
JOTROL Intellectual Property and License Agreement

We hold an exclusive global license from Aquanova AG for micellar technologies to develop, manufacture, and sell JOTROL Our CSO, Marshall Hayward, and Aquanova's lead scientist, Darius Benham, invented JOTROL. The patent is co-owned by Aquanova AG and us, with the application assigned to Aquanova AG. 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 AG is vital, as JOTROL is our primary product. Losing this agreement would delay our plans and force us to seek similar licenses, 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. There is an option to pay $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. As of December 31, 2024, $75,000 in accrued license fees are recorded in accounts payable.

Product Pipeline

The Company's product pipeline is built arounds proprietary platform product, JOTROL an enhanced oral formulation of resveratrol. Resveratrol, a natural compound is optimized in JOTROL to deliver therapeutically effective doses safety, aiming to address 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.



The pipeline chart above shows the indications that we presently are prioritizing. However, JNS101 is an additional indication that we believe will be of interest to perform a clinical trial in at a later stage.

The product pipeline represented above assume 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 partner which are further described in "Item 1. Business" of this Annual Report on Form 10-K. 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 and JNS **1**08 for MCI/early Alzheimer's Disease. We have started the work with the JNS115 Phase IIa trial and estimate that first dosing of a patients will occur in Q3 of 2025. If we receive funding from the NHI, we will start our clinical trial for MCI/Early Alzheimer's Disease later this year.

We have not set any timeline for starting clinical trials for rare diseases. We may work with other strategic partners on these clinical trials.

JNS115 Parkinson's Disease

We will be utilizing JOTROL in our application 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 2a study in Parkinson's Disease patients

The Company has engaged Zina Biopharmaceuticals to assist with study design, FDA communications including IND and manage the execution of the trial. Catalent has been engaged to manufacture the JOTROL clinical trial supplies. The preliminary study design is described below and is subject to final IND approval by the FDA. The Company expects to start the clinical trial in the third quarter of 2025 and have the first study results available within 12 months thereafter.

We are sponsoring a Phase 2a clinical trial to evaluate the safety, tolerability, and pharmacokinetics of Resveratrol (JOTROLTM) in individuals with Parkinson's Disease. This 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 200mg or 400mg 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 consent. Each participant will be involved for 4-5 months, with the entire study lasting two years. First readout of results are expected within 12 months of first dosing.

JNS108 Mild Cognitive Impairment/early Alzheimer's Disease

We will be utilizing JOTROL in our applications for investigating treatment of various segments of Alzheimer's disease of which MCI/early AD is the initial target. If any NIA grant application is successful, we will have the funding to conduct a Phase II trial in MCI/early Alzheimer's Disease. Our failure to obtain such a grant will most likely result in delays of this project and the need to raise additional capital.

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 be 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 will include in our 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. The effect of JOTROL treatment, in the 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 a significant savings to society.

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

National Institute on Aging ("NIA") financed our Phase I study with $1.76 million through grant 1R44AG067907-01A1. Since 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 Mild Cognitive Impairment (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 vs. 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. The NIA scientific review of our Alzheimer's Phase II trial grant application shows a total score of 47 which is our best score so far. A score of 40 or below is necessary for being considered for funding. After discussions with the NIA, we have decided to apply, in September of 2024, for a much smaller grant, $2.5 million, for a Proof of Concept study focusing on JOTROL's effect on validated biomarkers. The final study design is not yet determined but a draft synopsis is described below. There is however no guarantee that we will ever receive NIA grant funding for this project. A delay or rejection of this funding will cause a delay in this program and most likely requiring additional financing.

The proposed Phase II trial is 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. 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. PK 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.

Based on the recent Scientific Review received from NIA. Our team of scientists in the Alzheimer's field, Professors Raymond Turner, MD, Ph.D. and Charbel Moussa, Ph.D. from Georgetown University, Rudolph Tanzi, Ph.D. Harvard and Li-Huei Tsai, Ph.D. MIT are assisting in designing our POC study to address and explore several biomarkers and areas where the trial results can guide us to a follow-on Phase II trial, if approved to do so by the FDA, that might generate meaningful outcomes for MCI/early AD 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 POC study in MCI patients with the FDA.

Proposed JOTROL MCI Phase II Study

STUDY SYNOPSIS Title: A phase II, randomized, double-blind, placebo-controlled study to assess the safety and efficacy of JOTROL (micellar resveratrol solubilisation formulation) in early Alzheimer's Disease (AD) patients Study Description: This study seeks to assess the safety and efficacy of JOTROL (resveratrol) in patients with MCI/early AD. Approximately 105 patients will be enrolled at study centers across the United States. Patients will 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 JOTROL will be safe and tolerable in individuals with MCI/early AD. Objectives: 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.

- Primary Objective:
    - 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

JNS101 Friedreich's ataxia direct to Phase II

JNS101 is a project utilizing JOTROL, specifically designed to treat Friedreich's Ataxia.

Friedreich's Ataxia (FA) is a rare inherited disease that causes damage to the nervous system as well as mobility dysfunctions. FA usually begins in childhood and leads to impaired muscle coordination (ataxia) which worsens over time. It is caused by a defect (mutation) in a gene labeled FXN. Friedreich's ataxia is recessive, meaning it only occurs in someone who inherits two defective copies of the gene, one from each parent. Although rare, FA is the most common form of hereditary ataxia, affecting about 1 in 50,000 people in the United States. EU5 (5 largest European countries) alone has approximately the same amount of FA patients as there are in USA.

In 2014 Murdoch Children's Research Institute (MCRI) conducted a clinical trial in 27 human subjects where 24 completed the study, resulting in that a high daily dose (5 grams) of nutritional grade trans-resveratrol had statistically different positive results, see p-values for 5 g daily dosing in the table below, on established Friedreich's Ataxia measurements. Key markers, such as FARS Score and measurements of hearing and speech parameters were included in these positive results. The results indicate that an effective dose of resveratrol is expected to be a meaningful treatment for patients with Friedreich's Ataxia. The data from the MCRI study was used in pre-IND meetings with the FDA discussing our Phase II study and was also referenced in our application for orphan drug designation (ODD). The ODD, request #17-5978, was granted to us by the FDA on August 16, 2017.

The MCRI study is widely published, Eppie M. Yiu et al., and below is a summary table of the results including the demonstrated issue with gastro-intestinal side effects at a higher dose.

The p-value (or probability value) is used to determine if the outcome of an experiment is statistically significant. A low p-value means that there is a very low likelihood that this outcome was a result of luck or is a random occurrence. A high p-value means that assuming the null hypothesis is true, this outcome was very likely. Generally, a p value less than 0.05 (or 5% odds of the event being random) is regarded as statistically significant. The lower the P value, the less chance that the comparison is a random outcome. The FDA follows these accepted measures of statistical probability in the evaluation of significant results in preclinical experimental outcomes and for clinical trials. In general, if a primary endpoint in a Phase III/Pivotal trial gets a p-value below 0.05 there is a good possibility, unless there are simultaneous safety issues, that a product may receive approval from the FDA.

The below graph representing results of two different doses of resveratrol in the same patient population. Comparisons are made from the patients' baseline and was not placebo controlled. There is a clear difference between the 1gram daily dosing vs the 5 gram daily dosing in p-values in all areas measured. There is also a clear difference in adverse events, primarily GI related between the 2 doses. This clearly demonstrates that the significantly higher dose is effective while the lower dose is not. However, it also shows that the high dose of the regular resveratrol administered cause unacceptable high gastro-intestinal side effects. Therefore, we believe that our JOTROL product in a Phase II/II trial will replicate the positive outcomes without any severe gastro-intestinal side effects.

Results – Clinical data

Resveratrol dose	1 g daily (n=12)		5 g daily (n=12)	
Outcome measure	Difference Mean (95% CI)	p-value	Difference Mean (95% CI)	p-value
Total FARS score	-2.7 (-6.8, 1.4)	0.17	-3.4 (-6.6, -0.3)	**0.04**
Total ICARS score	-0.3 (-3.2, 2.6)	0.80	-1.9 (-3.1, -0.8)	**0.004**
Total SARA score	-0.3 (-1.8, 1.3)	0.73	-1.0 (-2.1, 0.1)	0.08
Phoneme score	1.3 (-2.3, 4.9)	0.45	4.6 (1.0, 8.2)	**0.02**
Mean pause length	-0.005 (-0.03, 0.02)	0.60	-0.011 (-0.018, -0.004)	**0.006**

FARS - Friedreich Ataxia Rating Scale; ICARS – International Cooperative Ataxia Rating Scale; SARA – Scale for the Assessment and Rating of Ataxia; FACS – Freidreich Ataxia Composite Score; Phoneme score – percentage phonemes correct in 50 word speech perception test in background noise; Mean pause length – total pause duration / number of pauses, in seconds for 'days of the week' speech task

Murdoch Childrens Research Institute
Healthier Kids. Healthier Future.

	1g daily n=13	5g daily n=14
Adverse event	n (%)	n (%)
Infections		
Upper respiratory tract infection	4 (31)	5 (36)
Nervous system disorders		
Headache	4 (31)	3 (21)
Fatigue	3 (23)	2 (14)
Gastrointestinal disorders		
Loose stools	1 (8)	12 (86)
Diarrhoea	1 (8)	11 (79)
Abdominal pain	2 (15)	10 (71)
Nausea	1 (8)	5 (36)
Raised transaminases	2 (15)	1 (7)
Raised GGT	1 (8)	3 (21)
Cardiac disorders		
Palpitations	1 (8)	0
Renal disorders		
Microalbuminuria	1 (8)	3 (21)

Murdoch Childrens Research Institute

JNS102 Phase II trial for Mucopolysaccharidosis Type 1 (MPS I)

JNS102 is utilizing JOTROL for the 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 of, 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 cost 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 and Joints, it leaves the patients with a gradually worsening quality of life including loss of hearing, blindness and severe arthritis.

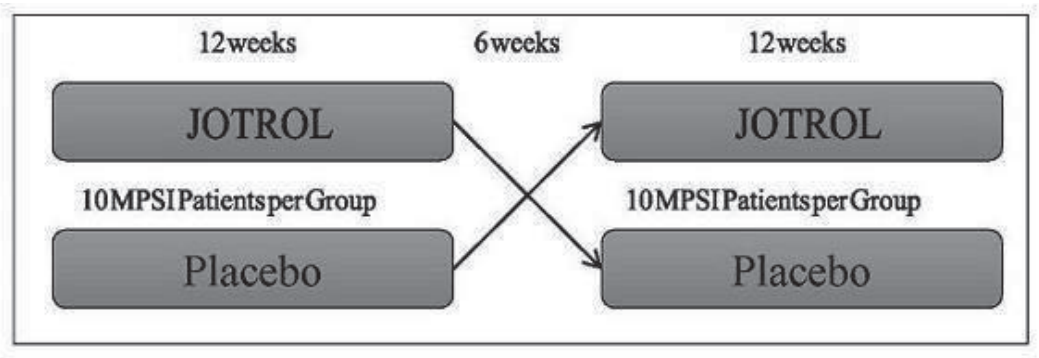
JNS102 is targeting the specific areas that ERT cannot treat, with JOTROL™ treatment.

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 and the clinical trial is completed. Results documented in the section **JOTROL Phase I Pharmacokinetic ("PK") and Safety Study**.
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 Phase II trial for MELAS Syndrome

JNS107 is utilizing JOTROL as the product 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%, which is expected to lead to an increase in the mitochondria levels in MELAS patients and thereby show positive patient outcomes.

Symptoms of MELAS syndrome usually begin between the ages of two and fifteen years, but delayed onset cases have also been reported in people aged fifteen to forty years and older. In approximately 75 percent 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. 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.

Competition

The following is an overview of JNS's competitors. 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 gets 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. 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, approved by a panel of experts, is expected to receive 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, can potentially have a successful product approved before us and have a more effective treatment.

In the MPS-1 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 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-1.

In the treatment of Friedreich's Ataxia, several products compete with Jupiter's offerings. Reata Pharmaceuticals' Omaveloxolone, branded as SKYCLARYS, received approval in 2023 following successful Phase II and pivotal trials. Despite its effectiveness, Jupiter anticipates conducting future studies in Europe and Australia due to market competition in the USA, especially after Biogen's acquisition of Reata. Minoryx Therapeutics has completed a Phase II trial for MIN-102, a selective PPAR gamma agonist, showing promise in this space. Additionally, Larimar Therapeutics is developing CTI-1601, a recombinant fusion protein intended to deliver human frataxin to mitochondria, currently in Phase I trials. These advancements highlight the competitive landscape in Friedreich's Ataxia treatment.

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 2/3 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 for the following reasons:

We believe that the focus on a new product based on resveratrol with higher bioavailability, JOTROL, will enable us to utilize the same product for several indications, subject to FDA's approval. 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 (KOL's) 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 14,000 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 for the pharmaceutical industry, due to its poor solubility and bioavailability, as well as adverse effects, such as severe gastro-intestinal side effects when taken at effective 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 since the existing natural supplements cannot provide high enough levels of resveratrol in blood plasma to be able to provide a therapeutically effective dose without generating severe gastro-intestinal side effects. This means that we need to take JOTROL through the full regulatory NDA (New Drug Application) requirement to obtain a marketing approval. We were able to receive, through a confidential agreement from a major pharmaceutical company, a chronic toxicology study 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

In March 2025, the Company announced that it had entered into a partnership with Aquanova AG to develop a series of nutritional products targeting longevity, aging and Healthspan. The first three products, which will focus on the concept of "Beauty from Within", are slated to hit the market in the third quarter of 2025 through a Direct-to-Consumer model. The Company will focus on the consumer market, and will market its products on a to-be-developed website targeting the US market, along with social media marketing. Internationally, the Company is focusing on partners who can market and accelerate sales, with an initial focus on the Asian region.

In addition, we may also consider out-license JOTROL to one or more companies that has 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 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 the larger indications. All international distributions will 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 Key Opinion Leaders (KOL), patient advocacy groups and directly to patients, which may reduce marketing costs.

We are already using information regarding our development progress through KOL's and the respective patient organizations that exist for each indication. We have also initiated a collaboration with several patient organizations such as the FARA organization, www.curefa.org, the National MPS Society, UMDF, www.umdf.org, and the EveryLife Foundation in USA.

We have been approached by several large and mid-size pharmaceutical companies discussing future collaborations once we have more clinical data available. We will try to utilize this interest by out-licensing primarily the Asian territories while waiting to conduct out-licensing in 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.

Regulatory Approval

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 get 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 regulatory review in about six months rather than the standard ten months. The Food and Drug Administration (FDA) awards a voucher following approval of a treatment for a neglected disease, rare pediatric disease, or medical countermeasure. Two drugs can receive priority review for each voucher: the drug winning a voucher for a neglected or rare pediatric disease, and the drug using a voucher for another indication. The voucher may be sold. For example, a small company might win a voucher for developing a drug for a neglected disease and sell the voucher to a large company for use on a commercial disease.

There are four specific approval pathways applicable for 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 the Prescription Drug User Fee Act (PDUFA) which created the two-tiered FDA drug review system (standard v. priority). This pathway shortens application review from 10 months (standard) to 6 months (priority). The FDA determines if a drug receives a standard or priority review, although sponsors may request a priority review. Priority review is granted if a new drug would result in a significant improvement in safety and effectiveness compared to existing therapies.

Fast Track

Drugs for the treatment of serious conditions that address an unmet medical need receive an expedited review. The purpose of this pathway is to get important new drugs to patent earlier, for conditions such as Alzheimer's disease, epilepsy, depression, and multiple sclerosis. Any drug being developed to treat or prevent a condition with no current therapy is prioritized. If there are available therapies, the new drug must:

1. Show superior efficacy;
2. Avoid serious side effects of the available therapy;
3. Decrease clinically significant toxicity of an available therapy; and
4. Address an emerging or anticipated public health need

Fast Track designation should come at the time of submission and be requested by the manufacturer, although it can be requested at any time in the approval process. Once in the Fast Track pathway, there are more frequent meetings with the FDA to discuss the development plan and appropriate data needed to support drug approval. 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 applied to new therapies that treat serious or life- threatening conditions for which there is an unmet medical need and have a "clinically meaningful" outcome. Drugs that are eligible for this pathway must be reasonably likely to improve a surrogate endpoint if a standard endpoint would require long-term evaluation. If given conditional approval, the sponsor must conduct post-marketing clinical trials to ensure endpoints are met. If the standard endpoints are not met, the FDA can withdraw approval.

Breakthrough Therapy

This designation is designed to expedite the development and review of drugs that are intended to treat serious conditions and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapies on clinically significant endpoints.

There is however no guarantee that an accelerated pathway will lead to an accelerated FDA review and that a pediatric approval leads to a PRV. Additionally, there can be no guarantee that the Company can be successful in its plans under any FDA pathway.

Research Agreement

On July 1, 2022, the Company entered into a research agreement with the University of Miami to conduct a preclinical study to evaluate the effect of JOTROL in Parkinson's Disease models. The cost of the research agreement activities, to be paid by the Company, is $72,844. The Company owns any intellectual property generated from the research. The agreement is for 1 year from the start date, July 1, 2022. Either the Company or the University of Miami may terminate this agreement upon thirty (30) days written notice for any reason. In the event of such termination, both the Company and the University of Miami shall take all reasonable steps to cancel further costs in connection with this agreement. The Company and the University of Miami will be entitled to reimbursement for costs and non-cancelable obligations incurred prior to effective day of the termination, not to exceed the total amount of the project.

Asian Business Development Activities

We have recently agreed to service agreements in the areas of CMC (Chemistry, Manufacturing, and Controls), regulatory affairs and clinical trial management with companies with operations in SE Asia. These agreements are with companies that, we believe, have the knowledge and network in the South-East Asian market. The agreements are further described in the section "Other Material Agreements". In addition, we are in active negotiations with Dominant Treasure Health ("DTH"), a BVI company. DTH has demonstrated to us, through several company introductions, that they have business relationships, either directly or through affiliates, with many South-East Asian pharmaceutical companies as well as companies involved in distribution and sales of TCM, Traditional Chinese Medicine. We are therefore planning to engage DTH in active business development in China, Malaysia and Singapore as soon as we have financing in place for their engagement. DTH has already introduced us to 3 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 South-East Asian territories. However, there are no assurances that this approach will be successful.

Our rationale for the strong approach into the South-East 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 SE Asian pharmaceutical companies.
- The Company is too small, both financially as well as internal manpower, to manage developments in the territory.
- The Company has a history of poor financial status and not being able to fulfill commitments and finalize clinical studies.
- 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. The studies were conducted at Charles River Laboratories, and there are no payments associated with this agreement.

Recent Agreements – South-East Asia

On June 3, 2024, the Company entered into three service agreements to expand in South-East 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 three service agreements were paid for with an upfront issuance of 1,162,500 shares of common stock, which were registered for resale as part of the initial public offering, and have a term of three years.

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 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.

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 $3,783 per month and a share of the building's operating expenses, such as taxes and maintenance, of $476 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, 2024, we had a total of four full-time employees, two full-time consultants, one part-time consultant, 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:

- We are early in our development efforts, with a limited operating history, and have no products approved for commercial sale.
- We have not generated any 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 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 candidate.
- We will require substantial additional capital to finance our 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.
- We are substantially dependent on the success of our product candidate, JOTROL. 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 prospects depend upon developing product candidate JOTROL for particular indications and possibly discovering, developing other product candidates in future programs.
- Clinical drug development involves a lengthy and expensive process with an uncertain outcome. The clinical trials of our product candidate JOTROL may not demonstrate safety and efficacy to the satisfaction of the U.S. Food and Drug Administration (FDA), European Medicines Agency (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 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 product candidates we develop, our commercial opportunities will be negatively impacted. In particular, we face competition for patients with MPS-I, Friedreich's ataxia, MELAS, Parkinson's Disease, Mild Cognitive Impairment, and early Alzheimer's disease from companies that produce drugs to treat such diseases. For more information regarding competition we face, see the section titled "Business — Competition.
- We rely on third parties to conduct our preclinical studies, clinical trials, and manufacturing and these third parties may not perform satisfactorily.
- 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 rely on our management team and other key employees, and the loss of one or more key employees could harm our business.
- The failure to attract and retain additional qualified personnel could prevent us from executing our business strategy.
- There can be no assurance that we will be able to comply with Nasdaq Capital Market's continued listing standards.
- The price of our common stock could be subject to rapid and substantial volatility. 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. 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.

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 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 developing one medication to treat rare diseases (MPS I, Friedreich's ataxia, and MELAS) as well as larger indications, Parkinson's Disease and Mild Cognitive Impairment / 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 products approved for commercial sale and have not generated any revenue. We initiated and completed our Phase I clinical trial for our sole product candidate, JOTROL, in March 2021. 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 New Drug Application ("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 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.

We do not have any products approved for sale, and consequently we have not generated any revenue. We have incurred significant net losses since our inception and have financed our operations principally through private placements of our common stock. To date, we have not been profitable and have incurred significant losses and cash flow deficits.

For the fiscal years ended December 31, 2024 and 2023, we generated no revenues from product sales and reported net losses of $2,439,625 and $4,783,689, respectively, and negative cash flow from operating activities of $3,911,004 and $480,953, respectively. As noted in our financial statements, as of December 31, 2024, we had an accumulated deficit of $26,022,129.

Our sole 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 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, 2024 and 2023.

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, 2024 and 2023.

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. We have no products approved for commercial sale and do not anticipate generating any revenue from product sales for the next several years, if ever. Our ability to generate revenue and achieve profitability depends significantly on our ability, or any future collaborator's ability, to achieve several objectives, including:

- successful and timely completion of clinical development of JOTROL research program, and our other future product candidates and programs;
- establishing and maintaining relationships with CROs and clinical sites for the clinical development of JOTROL and any other future product candidates and programs;
- the initiation and successful patient enrollment and completion of additional clinical trials on a timely basis;
- acceptable frequency and severity of adverse events in the clinical trials;
- the efficacy and safety profiles that are satisfactory to the U.S. Food and Drug Administration (FDA) or any comparable foreign regulatory authority for marketing approval;
- timely receipt of marketing approvals from applicable regulatory authorities for any product candidates for which we successfully complete clinical development;
- complying with any required post-marketing approval commitments to applicable regulatory authorities;
- developing an efficient and scalable manufacturing process for our product candidates;
- establishing and maintaining commercially viable supply and manufacturing relationships with third parties that can provide adequate, in both amount and quality, products and services to support clinical development and meet the market demand for our product candidate, if approved;
- successful commercial launch following any marketing approval, including the development of a commercial infrastructure, whether in-house or with one or more collaborators;
- a continued acceptable safety profile following any marketing approval of our product candidate;
- commercial acceptance of our product candidate by patients, the medical community and third-party payors;
- satisfying any required post-marketing approval commitments to applicable regulatory authorities;
- identifying, assessing and developing new product candidates;
- obtaining, maintaining and expanding patent protection, trade secret protection and regulatory exclusivity, both in the United States and internationally;
- protecting our rights in our intellectual property portfolio;
- defending against third-party infringement claims, if any;
- entering into, on favorable terms, any collaboration, licensing or other arrangements that may be necessary or desirable to develop, manufacture or commercialize our product candidate;
- obtaining coverage and adequate reimbursement by third-party payors for our products and patients' willingness to pay in the absence of such coverage and adequate reimbursement;
- obtaining additional funding to develop and potentially manufacture and commercialize our product candidates;
- addressing any competing therapies and technological and market developments;
- managing costs, including any unforeseen costs, that we may incur as a result of nonclinical study or clinical trial delays; and
- attracting, hiring and retaining qualified personnel including clinical, scientific, management and administrative 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, 2024, we had $3,769,510 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 (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 requirements will depend on may factors, including, but not limited to:

- the scope, progress, results and costs of researching and developing our product candidates including conducting preclinical studies and clinical trials;
- the costs, timing and outcome of regulatory review of our product candidates;
- the number and characteristics of other product candidates that we pursue;
- the costs of future activities, including product sales, medical affairs, marketing, manufacturing and distribution, for any of our product candidates for which we receive marketing approval;
- the costs of manufacturing commercial-grade products and sufficient inventory to support commercial launch;
- the revenue, if any, received from commercial sale of our products, should any of our product candidates receive marketing approval;
- the cost and timing of hiring new employees to support our continued growth;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- the effect of competing products that may limit market penetration of our products;
- the ability to establish and maintain collaborations on favorable terms, if at all;
- the extent to which we acquire or in-license other product candidates and technologies;
- the timing, receipt and amount of sales of, or milestone payments related to or royalties on, our current or future product candidates, if any;
- our need to implement additional internal systems and infrastructure, including financial and reporting systems;
- the compliance and administrative costs associated with being a public company; and
- the extent to which we acquire or invest in businesses, products, or technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

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 South-East 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.

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, 2024, we had outstanding indebtedness in the principal amount of $146,432 and accrued interest of approximately $1,064. 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, 2024, the Company had federal and state (post-apportioned basis) net operating losses of $26.0 million, as well as federal orphan drug tax credit carryforwards of approximately $1.06 million. Approximately $10.0 million of the foregoing federal and state NOLs will expire at various dates from 2026 through 2043, 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-percent shareholders" 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.

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. 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 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 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 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 development of our product in the South-East Asian territory immediately following the completion of the 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 our product in the South-East 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 (Chemistry, Manufacturing, and Controls), 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 other approved products or investigational new drugs that may result in a safety 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 may 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 well-controlled clinical trials that our product candidates are safe and effective for use in a diverse population before we can seek marketing approvals for their commercial sale. 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 key opinion leaders (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 of 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 remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available. 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 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, Friedreich's ataxia, and MELAS is small and has not been established with precision. If the actual number of patients is smaller than we estimate, our 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, Friedreich's ataxia, 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. Friedreich's ataxia has a higher incidence of approximately 1 in every 50,000 live births. We estimate there are between 5,000 and 6,000 patients with Friedreich's ataxia in the United States, with slightly higher patient population estimated 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 is 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 amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. 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.

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. 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 are 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. 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, 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 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 Risk Evaluation and Mitigation Strategy (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 ongoing clinical trials are being undertaken 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 authority 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 or EMA 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 product candidates that target rare diseases, including MPS I, Friedreich's ataxia, 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 of our product candidates that target rare diseases, such as MPS I, Friedreich's ataxia, 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 require the submission of reports to regulatory authorities and on-going surveillance to monitor the safety and efficacy of the product candidate, may 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 cGMPs 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 discover 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, EMA and other comparable foreign regulatory requirements may subject our company to administrative or judicially imposed sanctions, including:

- delays in or the rejection of product approvals;
- restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials;
- restrictions on the products, manufacturers or manufacturing process;
- warning or untitled letters;
- civil and criminal penalties;
- injunctions;
- suspension or withdrawal of regulatory approvals;
- product seizures, detentions or import bans;
- 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 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 advantages and user-fee waivers. In addition, if a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusivity. Orphan drug exclusivity in the United States provides that the FDA may not approve any other applications, including a full NDA, to market the same drug for the same indication for seven years, except in limited circumstances. The applicable exclusivity period is 10 years in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified.

We submitted a request to FDA and received orphan drug designation for Friedreich's ataxia. 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. We may not be the first to obtain marketing approval of any product candidate for which we have obtained orphan drug designation for the orphan-designated indication 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 different 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 secure approval from the FDA or comparable foreign regulatory authorities through the use of accelerated registration pathways. If we are unable to obtain such approval, 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 accelerated approval 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 our 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 usually contingent on the sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit. If such post-approval studies fail to confirm the drug's clinical benefit, the FDA may 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.

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

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.

The regulatory framework for privacy and personal information security issues worldwide is rapidly evolving and is likely to remain uncertain for the foreseeable future. The U.S. federal and various state, local and foreign government bodies and agencies have adopted or are considering adopting laws and regulations limiting, or laws and regulations regarding, the collection, distribution, use, disclosure, storage, security and other processing of personal information.

Additionally, the collection and use of health data and other personal data is governed in the EU by the General Data Protection Regulation (GDPR), which extends the geographical scope of EU data protection law to entities and operations outside of the EU under certain conditions and imposes substantial obligations upon companies and new rights for individuals, and by certain EU Member State-level legislation. Failure to comply with the GDPR may result in fines up to €20,000,000 or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, and other administrative penalties. The GDPR may increase our responsibility and liability in relation to personal data that we may process, and we may be required to put in place additional measures in an effort to comply with the GDPR and with other laws and regulations in the EU, including those of EU Member States, relating to privacy and data protection. This may be onerous and if our efforts to comply with GDPR or other applicable EU laws and regulations are not successful, or are perceived to be unsuccessful, it could adversely affect our business in the EU. Further, the European Court of Justice (ECJ) invalidated the EU-U.S. Privacy Shield, which had enabled the transfer of personal data from the EU to the U.S. for companies that had self-certified to the Privacy Shield in July 2020. The ECJ decision also raised questions about the continued validity of one of the primary alternatives to the EU-U.S. Privacy Shield, namely the European Commission's Standard Contractual Clauses, and EU regulators have issued additional guidance regarding considerations and requirements that we and other companies must consider and undertake when using the Standard Contractual Clauses. Although the EU has presented a new draft set of contractual clauses, at present, there are few, if any, viable alternatives to the EU-U.S. Privacy Shield and the Standard Contractual Clauses. To the extent that we were to rely on the EU-U.S. or Swiss-U.S. Privacy Shield programs, we will not be able to do so in the future, and the ECJ's decision and other regulatory guidance or developments otherwise may impose additional obligations with respect to the transfer of personal data from the EU and Switzerland to the U.S., each of which could restrict our activities in those jurisdictions, limit our ability to provide our products and services in those jurisdictions, or increase our costs and obligations and impose limitations upon our ability to efficiently transfer personal data from the EU and Switzerland to the U.S.

Further, the exit of the United Kingdom (UK) from the EU, often referred to as Brexit, has created uncertainty with regard to data protection regulation in the UK. Specifically, the UK exited the EU on January 1, 2020, subject to a transition period that ended December 31, 2020. Under the post-Brexit Trade and Cooperation Agreement between the EU and the UK, the UK and EU have agreed that transfers of personal data to the UK from EEA member states will not be treated as 'restricted transfers' to a non-EEA country for a period of up to four months from January 1, 2021, plus a potential further two-month extension (the "Extended Adequacy Assessment Period"). Although the current maximum duration of the Extended Adequacy Assessment Period is six months, it may end sooner, for example, in the event that the European Commission adopts an 'adequacy decision' in respect of the UK, or the UK amends the UK GDPR and/or makes certain changes regarding data transfers under the UK GDPR/Data Protection Act 2018 without the consent of the EU (unless those amendments or decisions are made simply to keep relevant UK laws aligned with the EU's data protection regime). If the European Commission does not adopt an 'adequacy decision' in respect of the UK prior to the expiry of the Extended Adequacy Assessment Period, from

that point onwards the UK will be an 'inadequate third country' under the GDPR and transfers of personal data from the EEA to the UK will require a 'transfer mechanism' such as the Standard Contractual Clauses. The UK has implemented legislation similar to the GDPR, referred to as the UK GDPR, which provides for fines of up to the greater of £17.5 million or 4% of global turnover. As of January 1, 2021, the UK is a "third country" under the GDPR, and the relationship between the UK and EU in relation to aspects of data protection law in the medium and longer term remains unclear, including with respect to cross-border data transfers and the role of the UK Information Commissioner's Office with respect to the EU, which exposes us to further compliance risk. We may incur liabilities, expenses, costs, and other operational losses relating to the GDPR, the UK GDPR, and other laws and regulations in the EU and UK relating to privacy and data protection, including those of applicable EU Member States in connection with any measures we take to comply with them. Finally, state and foreign laws may apply generally to the privacy and security of information we maintain, and may differ from each other in significant ways, thus complicating compliance efforts and potentially requiring us to undertake additional measures to comply with them.

In the United States, there are a broad variety of data protection laws and regulations that may apply to our activities such as state data breach notification laws, state personal data privacy laws (for example, the California Consumer Privacy Act of 2018 (CCPA)), state health information privacy laws, and federal and state consumer protection laws. A range of enforcement agencies exist at both the state and federal levels that can enforce these laws and regulations. For example, the CCPA requires covered businesses that process personal information of California residents to disclose their data collection, use and sharing practices. Further, the CCPA provides California residents with new data privacy rights (including the ability to opt out of certain disclosures of personal data), imposes new operational requirements for covered businesses, provides for civil penalties for violations as well as a private right of action for data breaches and statutory damages (that is expected to increase data breach class action litigation and result in significant exposure to costly legal judgements and settlements). Aspects of the CCPA and its interpretation and enforcement remain uncertain. In addition, it is anticipated that the CCPA will be expanded on January 1, 2023, when the California Privacy Rights Act of 2020 (CPRA) becomes operative. The CPRA will, among other things, give California residents the ability to limit use of certain sensitive personal information, further restrict the use of cross-contextual advertising, establish restrictions on the retention of personal information, expand the types of data breaches subject to the CCPA's private right of action, provide for increased penalties for CPRA violations concerning California residents under the age of 16, and establish a new California Privacy Protection Agency to implement and enforce the new legislation. Although there are limited exemptions for clinical trial data under the CCPA, the CCPA and other similar laws could impact our business activities, depending on their interpretation.

With the GDPR, CCPA, CRPA and other laws, regulations and other obligations relating to privacy and data protection imposing new and relatively burdensome obligations, and with substantial uncertainty over the interpretation and application of these and other obligations, 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, if third parties we work with, such as vendors or service providers, violate applicable laws or regulations or our policies, such violations may also put our or our customers' data at risk and could in turn have an adverse effect on our business. Any failure or perceived failure by us or our service providers to comply with our applicable policies or notices relating to privacy or data protection, our contractual or other obligations to third parties, or any of our other legal obligations relating to privacy or data protection, may result in governmental investigations or enforcement actions, litigation, claims and other proceedings, harm our reputation, and could result in significant liability.

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, including in 2018 and 2019, 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. If a prolonged government shutdown 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 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 will adopt a code of conduct, which will become effective as of the date of the effectiveness of the registration statement of which this prospectus forms a part, 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, 2024, we had a total of four 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.

Our computer systems, or those of any of our CROs, manufacturers, other contractors or consultants or potential future collaborators, may fail or suffer security or data privacy breaches or other unauthorized or improper access to, use of, or destruction of our proprietary or confidential data, employee data, or personal data, which could result in additional costs, loss of revenue, significant liabilities, harm to our brand and material disruption of our operations.

Despite the implementation of security measures in an effort to protect systems that store our information, 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, other contractors (including sites performing our clinical trials) and consultants, these systems are potentially vulnerable to breakdown or other damage or interruption 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 (including supply chain cyber attacks or the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information), which may compromise our system infrastructure or lead to the loss, 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. For example, in 2019, one our CROs experienced a cybersecurity breach which resulted in unauthorized access to certain of our preclinical data. We have received phishing attacks, and companies have, in general, experienced an increase in phishing and social engineering attacks from third parties, and the increase in remote working further increases security threats. To the extent that any disruption or security incident were to result in any loss, destruction, unavailability, alteration, disclosure, or dissemination of, or damage or unauthorized access to, our applications, any other data processed or maintained on our behalf or other assets, or for it to be believed or reported that any of these occurred, we could incur liability, financial harm and reputational damage and the development and commercialization of our product candidates could be delayed. We cannot assure you that our data protection efforts and our investment in information technology, or the efforts or investments of CROs, 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. For example, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our programs and the development of our product candidates could be delayed. In addition, the loss of clinical trial data for our product candidates could result in delays in our marketing approval efforts and significantly increase our costs to recover or reproduce the data. Further, any such event that leads to loss, damage, or unauthorized access to, or use, alteration, or disclosure or dissemination of, personal information, including personal information regarding our clinical trial subjects or employees, could harm our reputation directly, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information, which could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business.

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. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the lost data. 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. We also rely on third parties to manufacture our product candidates, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security incident were to result in any loss, destruction, or alteration of, or damage or unauthorized access to, our data or other information that is processed or maintained on our behalf, or inappropriate disclosure of or dissemination of any such information, we could be exposed to litigation and governmental investigations, the further development and commercialization of our product candidates could be delayed, and we could be subject to significant fines or penalties for any noncompliance with certain state, federal and/or international privacy and security laws.

Our insurance policies may not be adequate to compensate us for the potential losses arising from any such disruption in or, failure or security breach of our systems or third-party systems where information important to our business operations or commercial development is stored. 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.

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 if we obtain the necessary approvals, including:

- differing regulatory requirements and reimbursement regimes in foreign countries;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the FCPA or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism.

These and other risks associated with our international operations may materially adversely affect our ability to attain 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 shareholders, 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 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 shareholders will not be deemed to have waived our compliance with these laws, rules and regulations.

This exclusive forum provision may limit a shareholder'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, shareholders 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 shareholder would otherwise choose to bring the action, and such judgments or results may be more favorable to us than to our shareholders. 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 shareholder lawsuits that might otherwise benefit the Company and its shareholders.

Section 7.4 of our amended and restated bylaws provides that "[i]f 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.

Risks Related to Our Intellectual Property

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 our 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.

Presently, we have a worldwide license for use of JOTROL from Aquanova AG, the patent holder of a micellar technology ("NovaSol™"). Aquanova AG, a German company, filed an international patent on January 29, 2017 entitled "Resveratrol solubilization product for pharmaceutical purposes" (PCT/EP2017/O51659). The patent in jointly owned by the Company and Aquanova AG. The priority date of the patent was June 16, 2016 with expiration in 2036. The patent has been examined by the International Preliminary Examining Authority of the Patent Cooperation Treaty (PCT), and 15 claims of this patent are deemed Novel, have an Inventive Step, and have Industrial Applicability. In accordance with the Patent Cooperation Treaty's procedures and with this favorable examination report, this patent has been granted in USA, specific EU countries, Japan, China and Hong Kong.

Our license agreement with Aquanova AG is our most important agreement and critical to maintain as long as JOTROL remains our main and only product. A loss of this agreement will cause the Company a delay in its plans and would cause the Company to seek out other similar licensing agreements. Accordingly, the loss of this agreement will have a material adverse effect on our business.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our potential future collaborators will be successful in protecting our product candidates by obtaining and defending patents. These risks and uncertainties include the following:

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

The patent prosecution process is also expensive and time-consuming, and we 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 degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

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

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

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

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

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

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

Although no third-party has asserted a claim of patent infringement against us as of the date of this prospectus, 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 or trade names to brand and market ourselves and our products. Our trademarks or trade names 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.

In addition, we rely on the protection of our trade secrets, including unpatented know-how, technology and other proprietary information to maintain our competitive position. Although we have taken steps to protect our trade secrets and unpatented know-how, including entering into confidentiality agreements with third parties, and confidential information and inventions agreements with employees, consultants and advisors, we cannot provide any assurances that all such agreements have been duly executed, and any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets.

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

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

We have entered into and may enter in the future into non-disclosure and confidentiality agreements to protect the proprietary positions of third parties, such as outside scientific collaborators, CROs, third-party manufacturers, consultants, advisors, potential partners, lessees of shared multi-company property and other third parties. We may become subject to litigation where a third-party asserts that we or our employees inadvertently or otherwise breached the agreements and used or disclosed trade secrets or other information proprietary to the third parties. Defense of such matters, regardless of their merit, could involve substantial litigation expense and be a substantial diversion of employee resources from our business. We cannot predict whether we would prevail in any such actions. Moreover, 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. Failure to defend against any such claim could subject us to significant liability for monetary damages or prevent or delay our developmental and commercialization efforts, 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.

Parties making claims against us may be able to sustain the costs of complex intellectual property 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, 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, operating results, 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 AG, a German company, 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 third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.

Disputes may arise between us and our licensor or potential licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patents and other rights to third parties;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- our right to transfer or assign the license;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

In addition, the agreements under which we license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

In spite of our best efforts, our licensor or potential licensors might conclude that we have materially breached our license agreements and might therefore terminate the license agreements, thereby removing our ability to develop and commercialize products and technology covered by these license agreements. If these in-licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, competitors would have the freedom to seek regulatory approval of, and to market, products identical to ours. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

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 AG, 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 do not have the ability to independently conduct our clinical trials. We currently rely on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to conduct our current and planned clinical trials of JOTROL and we expect to continue to rely upon third parties to conduct additional clinical trials for JOTROL and other product candidates. Third parties have a significant role in the conduct of our clinical trials and the subsequent collection and analysis of data. These third parties are not our employees, and except for remedies available to us under our agreements with such third parties, we have limited ability to control the amount or timing of resources that any such third-party will devote to our clinical trials. The third parties we rely on for these services may also have relationships with other entities, some of which may be our competitors. Some of these third parties may terminate their engagements with us at any time. If we need to enter into alternative arrangements with a third-party, it would delay our drug development activities.

Our reliance on these third parties for such drug development activities will reduce our control over these activities but will not relieve us of our regulatory responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with GCP standards, regulations for conducting, recording and reporting the results of clinical trials to assure that data and reported results are reliable and accurate and that the rights, integrity and confidentiality of trial participants are protected. The EMA also requires us to comply with similar standards. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, EMA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials substantially comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under current cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the marketing approval process.

If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates.

We also expect to rely on third parties to store and distribute drug supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of our product candidates or commercialization of our products, producing additional losses and depriving us of potential product revenue.

We contract with third parties for the production of our product candidates for preclinical studies and, in the case of JOTROL, our ongoing clinical trial, and expect to continue to do so for additional clinical trials and ultimately for commercialization. This reliance on third parties 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 do not currently have the infrastructure or internal capability to manufacture supplies of our product candidates for use in development and commercialization. We rely, and expect to continue to rely, on third-party manufacturers for the production of our product candidates for preclinical studies and clinical trials under the guidance of members of our organization. We are presently relying on a single third-party manufacturer and are presently evaluating a second source alternative manufacturer. Changing our third-party manufacturer could result in delays in our manufacturing supply chain which could delay or otherwise impact our development of JOTROL and result in increased costs related to JOTROL. We do not have long-term supply agreements, and we purchase our required drug product on a purchase order basis, which means that aside from any binding purchase orders we have from time to time, our supplier could cease supplying to us or change the terms on which it is willing to continue supplying to us at any time. If we were to experience an unexpected loss of supply of JOTROL or any other product candidates for any reason, whether as a result of manufacturing, supply or storage issues or otherwise, we could experience delays, disruptions, suspensions or terminations of, or be required to restart or repeat, any pending or ongoing clinical trials.

We expect to continue to rely on third-party manufacturers for the commercial supply of any of our product candidates for which we obtain marketing approval. We may be unable to maintain or establish required agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- the failure of the third-party to manufacture our product candidates according to our schedule and specifications, or at all, including if our third-party contractors give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of the agreements between us and them;
- the termination or nonrenewal of arrangements or agreements by our third-party contractors at a time that is costly or inconvenient for us;
- the breach by the third-party contractors of our agreements with them;
- the failure of third-party contractors to comply with applicable regulatory requirements, including cGMPs;
- the failure of the third-party to manufacture our product candidates according to our specifications;
- the mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or active drug or placebo not being properly identified;
- clinical supplies not being delivered to clinical sites on time, leading to clinical trial interruptions, or of drug supplies not being distributed to commercial vendors in a timely manner, resulting in lost sales; and
- the misappropriation of our proprietary information, including our trade secrets and know-how.

We do not have complete control over all aspects of the manufacturing process of our CDMOs and are dependent on these CDMOs for compliance with cGMP regulations for manufacturing both active pharmaceutical ingredients (API) and finished drug products. We are in the process of developing our supply chain for each of our product candidates and intend to put in place framework agreements under which CDMOs will generally provide us with necessary quantities of API and drug product on a project-by-project basis based on our development needs. As we advance our product candidates through development, we will consider our lack of redundant supply for the API and drug product for each of our product candidates to protect against any potential supply disruptions. However, we may be unsuccessful in putting in place such framework agreements or protecting against potential supply disruptions.

Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside of the United States. If our CDMOs cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA, EMA or others, they will not be able to secure and/or maintain marketing approval for their manufacturing facilities. In addition, we do not have control over the ability of our CDMOs to maintain adequate quality control, quality assurance and qualified personnel. If the FDA, EMA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we will need to find alternative manufacturing facilities, and those new facilities would need to be inspected and approved by FDA, EMA or comparable regulatory authority prior to commencing manufacturing, which would significantly impact our ability to develop, obtain marketing approval for or market our product candidates, if approved. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates or drugs and harm our business and results of operations.

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

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.

From time to time, we may evaluate various acquisition opportunities and strategic partnerships, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses. Any potential acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- the issuance of our equity securities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and marketing approvals; and
- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated 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 the potential commercialization of our product candidates will require substantial additional cash to fund expenses. We may seek to selectively form collaborations to expand our capabilities, potentially accelerate research and development activities and provide for commercialization activities by third parties. In addition, we intend to explore strategic partnering and collaboration opportunities to out-license rights to our research programs and drug candidates for indications in which we are unlikely to pursue development and commercialization. In parallel, we will also evaluate select external opportunities to strategically expand our portfolio. Any of these relationships may require us to incur non-recurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our existing stockholders, or disrupt our management and business.

We would face significant competition in seeking appropriate collaborators and the negotiation process is time-consuming and complex. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA, EMA or comparable foreign regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing drugs, the existence of uncertainty with respect to our ownership of intellectual property and industry and market conditions generally. The potential collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such collaboration could be more attractive than the one with us for our product candidate. Further, we may not be successful in our efforts to establish a collaboration or other alternative arrangements for product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view them as having the requisite potential to demonstrate safety and efficacy.

In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. Even if we are successful in entering into a collaboration, the terms and conditions of that collaboration may restrict us from entering into future agreements on certain terms with potential collaborators.

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

We may 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.

If we enter into any collaboration arrangements with any third parties, we will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities and efforts to successfully perform the functions assigned to them in these arrangements. Collaborations involving our product candidates would pose numerous risks to us, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to, and the manner in which they perform their obligations under, these collaborations and may not perform their obligations as expected;
- collaborators may deemphasize or not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus, including as a result of a business combination or sale or disposition of a business unit or development function, or available funding or external factors such as an acquisition that diverts resources or creates competing priorities;

- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- a collaborator with marketing and distribution rights to multiple products may not commit sufficient resources to the marketing and distribution of our product relative to other products;
- we may grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- collaborators may not properly obtain, maintain, defend or enforce our intellectual property rights or may use our proprietary information and intellectual property in such a way as to invite litigation or other intellectual property related proceedings that could jeopardize or invalidate our proprietary information and intellectual property or expose us to potential litigation or other intellectual property related proceedings;
- disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates;
- collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all;
- collaborators may not provide us with timely and accurate information regarding development progress and activities under the collaboration or may limit our ability to share such information, which could adversely impact our ability to report progress to our investors and otherwise plan our own development of our product candidates;
- collaborators may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property; and
- a collaborator's sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings.

We also collaborate with a network of experts who advise and support our development efforts. In the future, such experts may not collaborate with us which could affect our ability to develop our product candidates and proprietary delivery platform as such experts potentially provide us with access to ideas to address the needs of muscle diseases.

Risks Related to Ownership of Our Common Stock

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 Nasdaq. On March 21, 2025, the Company received Notice from Nasdaq stating that the Company it is 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. 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 the Notice (February 6, 2025 through March 20, 2025), the Company no longer meets the minimum bid price requirement.

Pursuant to Nasdaq Listing Rules, the Company has been provided 180 calendar days, or until September 17, 2025, to regain compliance with NASDAQ Listing Rule 5550(a)(2). In addition, the Company may have an opportunity for an additional extension of time to meet the minimum bid price requirement, if certain conditions are met. If the Company is not able to demonstrate compliance with the minimum bid price required by September 17, 2025, it may be delisted from Nasdaq. If Nasdaq takes steps to de-list the Company's common stock, it would likely have a negative effect on the price of the Company's common stock 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.

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

We cannot predict the prices at which our common stock will trade. The market price of our common stock may fluctuate substantially. The market price of our common stock will depend on a number of factors, including those described in this "Risk Factors" section, many of which are beyond our control and may not be related to our operating performance. In addition, the limited public float of our common stock will tend to increase the volatility of the trading price of our common stock. The stock market in general, and pharmaceutical and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. These fluctuations could cause you to lose all or part of your investment in our common stock. Factors that could cause fluctuations in the market price of our common stock include, but are not limited to, the following:

- the timing and results of preclinical studies and clinical trials of our product candidates, those conducted by third parties or those of our competitors;
- the success of competitive products or announcements by potential competitors of their product development efforts;
- regulatory actions with respect to our products or our competitors' products;
- actual or anticipated changes in our growth rate relative to our competitors;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures, collaborations or capital commitments;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- market conditions in the pharmaceutical and biotechnology sector;
- changes in the structure of healthcare payment systems;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders or our other stockholders;
- expiration of market stand-off or lock-up agreements;
- the impact of any natural disasters or public health emergencies; and
- general economic, political, industry and market conditions.

The realization of any of the above risks or any of a broad range of other risks, including those described in this "Risk Factors" section, could have a dramatic and adverse impact on the market price of our common stock.

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 quarterly and annual operating results may fluctuate significantly in the future, which makes it difficult for us to predict our future operating results. From time to time, we may enter into license or collaboration agreements or strategic partnerships with other companies that include development funding and significant upfront and milestone payments and/or royalties, which may become an important source of our revenue. These upfront and milestone payments may vary significantly from period to period and any such variance could cause a significant fluctuation in our operating results from one period to the next.

In addition, we measure compensation cost for stock-based awards made to employees at the grant date of the award, based on the fair value of the award as determined by our board of directors, and recognize the cost as an expense over the employee's requisite service period. As the variables that we use as a basis for valuing these awards change over time, including, after the closing of our initial public offering, our underlying stock price and stock price volatility, the magnitude of the expense that we must recognize may vary significantly.

Furthermore, our operating results may fluctuate due to a variety of other factors, many of which are outside of our control and may be difficult to predict, including the following:

- the timing and cost of, and level of investment in, research and development activities relating to our current product candidates and any future product candidates and research-stage programs, which will change from time to time;
- our ability to enroll patients in clinical trials and the timing of enrollment;
- the cost of manufacturing our current product candidates and any future product candidates, which may vary depending on FDA, EMA or other comparable foreign regulatory authority guidelines and requirements, the quantity of production and the terms of our agreements with manufacturers;
- expenditures that we will or may incur to acquire or develop additional product candidates and technologies or other assets;
- the timing and outcomes of clinical trials for JOTROL and any of our other possible future product candidates, or competing product candidates;
- the need to conduct unanticipated clinical trials or trials that are larger or more complex than anticipated;
- competition from existing and potential future products that compete with JOTROL and any of our other future product candidates or programs, and changes in the competitive landscape of our industry, including consolidation among our competitors or partners;
- any delays in regulatory review or approval of JOTROL or any of our other product candidates;
- the level of demand for JOTROL and any of our other product candidates, if approved, which may fluctuate significantly and be difficult to predict;
- the risk/benefit profile, cost and reimbursement policies with respect to our product candidates, if approved, and existing and potential future products that compete with JOTROL and any of our other product candidates;
- our ability to commercialize JOTROL and any of our other product candidates, if approved, inside and outside of the United States, either independently or working with third parties;

- our ability to establish and maintain collaborations, licensing or other arrangements;
- our ability to adequately support future growth;
- potential unforeseen business disruptions that increase our costs or expenses;
- future accounting pronouncements or changes in our accounting policies; and
- the changing and volatile global economic and political environment.

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

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, 2024, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 77% 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 Capital Market, if we are unable to maintain that listing and our common stock is no longer listed on the Nasdaq Capital Market, 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" may include the following:

- If a "penny stock" is sold to the investor in violation of the requirements listed above, or other federal or states securities laws, the investor may be able to cancel the purchase and receive a refund of the investment.
- If a "penny stock" is sold to the investor in a fraudulent manner, the investor may be able to sue the persons and firms that committed the fraud for damages.

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.

We qualify as an "emerging growth company" under the JOBS Act. As a result, we are permitted to, and intend to, rely on exemptions from certain disclosure requirements. For so long as we are an emerging growth company, we will not be required to:

- have an auditor report on our internal control over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act;
- comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditors' report providing additional information about the audit and the financial statements (i.e., an auditor discussion and analysis);
- submit certain executive compensation matters to stockholder advisory votes, such as "say-on-pay" and "say-on-frequency"; and
- disclose certain executive compensation related items such as the correlation between executive compensation and performance and comparisons of the chief executive officer's compensation to median employee compensation.

In addition, Section 102 of the JOBS Act also provides that an emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. In other words, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to take advantage of the benefits of this extended transition period. Our financial statements may therefore not be comparable to those of companies that comply with such new or revised accounting standards.

We will remain an emerging growth company until the earliest to occur of: (i) the end of the first fiscal year in which our annual gross revenue is $1.235 billion or more; (ii) the end of the fiscal year in which the market value of our shares of common stock that are held by non-affiliates is at least $700.0 million as of the last business day of our most recently completed second fiscal quarter; (iii) the date on which we have, during the previous three-year period, issued more than $1.0 billion in non-convertible debt; and (iv) the end of the fiscal year during which the fifth anniversary of our initial public offering occurs.

Until such time, however, we cannot predict if investors will find our securities less attractive because we may rely on these exemptions. If some investors find our securities less attractive as a result, there may be a less active trading market for our securities and the price of our securities may be more volatile.

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.

Rule 12b-2 of the Exchange Act defines a "smaller reporting company" as an issuer that is not an investment company, an asset-backed issuer, or a majority-owned subsidiary of a parent that is not a smaller reporting company and that:

- had a public float of less than $250 million as of the last business day of its most recently completed second fiscal quarter, computed by multiplying the aggregate worldwide number of shares of its voting and non-voting common equity held by non-affiliates by the price at which the common equity was last sold, or the average of the bid and asked prices of common equity, in the principal market for the common equity; or
- in the case of an initial registration statement under the Securities Act, or the Exchange Act of 1934, as amended, which we refer to as the Exchange Act, for shares of its common equity, had a public float of less than $250 million as of a date within 30 days of the date of the filing of the registration statement, computed by multiplying the aggregate worldwide number of such shares held by non-affiliates before the registration plus, in the case of a Securities Act registration statement, the number of such shares included in the registration statement by the estimated public offering price of the shares; or
- in the case of an issuer whose public float as calculated under paragraph (1) or (2) of this definition was zero or whose public float was less than $700 million, had annual revenues of less than $100 million during the most recently completed fiscal year for which audited financial statements are available.

As a smaller reporting company, we will not be required and may not include a Compensation Discussion and Analysis section in our proxy statements; we will provide only two years of financial statements; and we need not provide the table of selected financial data. We also will have other "scaled" disclosure requirements that are less comprehensive than issuers that are not smaller reporting companies which could make our common stock less attractive to potential investors, which could make it more difficult for our stockholders to sell their 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.

We incur significant legal, accounting and other expenses as a public company. In addition, the Sarbanes-Oxley Act has imposed various requirements on public companies including requiring establishment and maintenance of effective disclosure and financial controls. Our management and other personnel need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have increased and will continue to increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain directors' and officers' liability insurance, which could make it more difficult for us to attract and retain qualified members of our board of directors. We cannot predict or estimate the amount of additional costs we will incur as a public company or the timing of such costs.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal control over financial reporting and disclosure controls and procedures. In particular, we must perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. In addition, we will be required to have our independent registered public accounting firm attest to the effectiveness of our internal control over financial reporting the later of our second Annual Report on Form 10-K or the first Annual Report on Form 10-K following the date on which we are no longer an emerging growth company or a smaller reporting company. Our compliance with Section 404 of the Sarbanes-Oxley Act will require that we incur substantial accounting expense and expend significant management efforts. We currently do not have an internal audit group, and we will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge. If we are not able to comply with the requirements of Section 404 in a timely manner, or if we or our independent registered public accounting firm identify deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the value of our securities could decline and we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources.

Our ability to successfully implement our business plan and comply with Section 404 requires us to be able to prepare timely and accurate financial statements. We expect that we will need to continue to improve existing, and implement new operational and financial systems, procedures and controls to manage our business effectively. Any delay in the implementation of, or disruption in the transition to, new or enhanced systems, procedures or controls, may cause our operations to suffer and we may be unable to conclude that our internal control over financial reporting is effective and to obtain an unqualified report on internal controls from our auditors as required under Section 404 of the Sarbanes-Oxley Act. This, in turn, could have an adverse impact on value of our securities, and could adversely affect our ability to access the 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 33,103,760 shares of our common stock and 1,626,037 restricted stock units outstanding as of December 31, 2024, 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.

The Company's certificate of incorporation, as amended, and amended and restated bylaws contain provisions that could have the effect of delaying or preventing changes in control or changes in our management without the consent of our board of directors. These provisions include:

- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;

- 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;
- the ability of our board of directors to determine whether to issue shares of our preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer;
- limiting the liability of, and providing indemnification to, our directors and officers;
- providing that a special meeting of the stockholders may only be called by a majority of the board of directors;
- providing 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; and
- 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.

These provisions, alone or together, could delay hostile takeovers and changes in control of the Company or changes in our board of directors and management.

Any provision of our certificate of incorporation, as amended, or amended and restated bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our security holders to receive a premium for their securities and could also affect the price that some investors are willing to pay for our securities.

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 provide 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 $3,783 per month and a share of the building's operating expenses, such as taxes and maintenance, of $476 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 28, 2025 was $0.70.

Holders

As of March 28, 2025, there were 33,103,860 shares of common stock issued and outstanding, and we had approximately 31 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 28, 2025, there were 2,139,240 shares available for issuance under the 2023 Plan.

Recent Sales of Unregistered Securities

Name	Date	Type	Type of Award	Quantity	Price
A consultant	January 24, 2024	Granted	Non-qualified Stock Option; Common Stock	180,000	$ 1.33
Dana Eschenburg Perez, our former Chief Financial Officer	March 15, 2024	Granted	Non-qualified Stock Option; Restricted Stock	7,500	$ 1.33
Dana Eschenburg Perez, our former Chief Financial Officer	March 15, 2024	Granted	Non-qualified Stock Option; Common Stock	49,605	$ 1.33
A consultant	April 17, 2024	Granted	Non-qualified Stock Option; Common Stock	67,500	$ 1.33

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

We are a clinical stage research and development company. We have developed a unique resveratrol platform product primarily targeting treatment of neuro-inflammation. Our platform product, JOTROL, an enhanced oral formulation of resveratrol, has many potential indications of use for rare diseases. In the larger disease areas, we are primarily targeting Parkinson's Disease and Mild Cognitive Impairment/early Alzheimer's disease.

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, par value $0.0001 per share ("common stock") at a price of $4.00 per share for gross proceeds of $11 million before deducing 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."

Business Overview

The Company's platform product, JOTROL, is an enhanced orally administered resveratrol formulation designed and intended to deliver therapeutically relevant, safe levels of resveratrol. This platform has many potential indications of use for rare diseases, which include Mucopolysaccharidoses Type 1, Friedreich's ataxia and MELAS. In the larger disease areas, we are primarily targeting Parkinson's Disease and Mild Cognitive Impairment/early Alzheimer's disease.

The present primary target for the Company is treatment of Parkinson's Disease (PD). The Company completed preclinical activities in a validated mouse model of Parkinson's Disease (PD) at the University of Miami in 2021. See our "Clinical Studies". The model of Parkinson's Disease that was used in this preclinical study mimics many aspects of the disease utilizing a unilateral injection of a neurotoxin precursor that elicits nigral cell loss, striatal dopamine loss and behavior deficits similar to physiological characteristics of human disease. We believe that results from this preclinical study indicate that Parkinson's Disease might be the best target for treatment and financial opportunity among the multiple indications where JOTROL might play a role. The Company is now in the process to start its first Phase II clinical trial in a patient population. This will be a Phase IIa study conducted with the assistance of Zina Biopharmaceuticals that is led by Dr. Charbel Moussa, MBBS,Ph.D. The study is expected to start in the third quarter of 2025 and have results available approximately 12 months thereafter.

We are also targeting the treatment of MCI/early Alzheimer's Disease. We received funding of $2.2 million from the National Institute of Aging ("NIA") in in 2020 and 2022 from a grant application for a Phase 1 study for Mild Cognitive Impairment/ Alzheimer'. In the NIA scientific review summary statement of our Phase I study application, it is stated that the NIA is looking forward to a Phase II study with an enhanced resveratrol product, based on the earlier study results from the well published Turner et al. Alzheimer's study. We presently have a pending grant application, $16.5 Million, for a Phase II trial in MCI/early Alzheimer's Disease with the NIA. This is an application for a 3-year Phase II trial that is expected to be completed with approximately 100 patients that have Mild Cognitive Impairment. We expect a decision on this grant application in May 2025. There is no guarantee that the application will be approved, and the trial will be put on hold if an approval is not awarded to the Company. A draft of the final study design is not yet determined but a draft synopsis is described in "Item 1. Business - " of this Annual Report on Form 10-K.

We have recently entered into service agreements in the areas of Business Development, CMC (Chemistry, Manufacturing, and Controls), regulatory affairs and clinical trial management with companies that has their main operation in Hong Kong. These agreements are with companies that, we believe, have the knowledge and network in the South-East Asian market to accelerate steps that is needed to have a product that can have treatment value in the territory. The agreements are further described in the section "Activities in Asia".

In March 2025, the Company announced that it had entered into a partnership with Aquanova AG to develop a series of nutritional products targeting longevity, aging and Healthspan. The first three products, which will focus on the concept of "Beauty from Within", are slated to hit the market in the third quarter of 2025 through a Direct-to-Consumer model. The Company will form a wholly-owned subsidiary to focus on the consumer market, and will market its products on a to-be-developed website targeting the US market, along with social media marketing. Internationally, the Company is focusing on partners who can market and accelerate sales, with an initial focus on the Asian region.

Financial Position

For the fiscal years ended December 31, 2024 and 2023, we generated no revenues from product sales and reported net losses of $2,439,625 and $4,783,689, respectively, and negative cash flow from operating activities of $3,911,004 and $480,953, respectively. As noted in our financial statements, as of December 31, 2024, we had an accumulated deficit of $26,022,129. 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, 2024 and 2023.

Results of Operations

Year Ended December 31, 2024 Compared to Year Ended December 31, 2023

Revenue and Federal Awards

There was no revenue from product sales during the years ended December 31, 2024 or 2023 as we are focused on research and development.

Research and Development Expenses

Research and development ("R&D") expenses were $492,660 for the year ended December 31, 2024 compared to $954,793 for the year ended December 31, 2023.

R&D expenses related to the federal grant were segregated in the chart of accounts from non-federal award costs. At this time, we are not tracking R&D expenses per indication as all of the R&D expenses incurred to date related to JOTROL, which is the platform product used in each indication defined in our product pipeline.

In addition, the probability of success for JOTROL will depend on numerous factors, including manufacturing capability, satisfactory results in follow on clinical trials, regulatory approvals and commercial viability. See "Risk Factors".

General and Administrative Expenses

General and administrative expenses were $2,598,622 for the year ended December 31, 2024 compared to $2,915,978 for the year ended December 31, 2023. The decrease relates directly to the reduction of employee salaries that began in December 2023.

Interest Expense

Interest expenses were $248,366 for the year ended December 31, 2024, compared to $218,705 for the year ended December 31, 2023. Interest expense is primarily attributable to interest expense associated with our previously outstanding notes payable, convertible notes payable, notes payable to our Chief Executive Officer, Christer Rosén, and interest expense on our corporate credit card.

Loss (Gain) on Change in Fair Value of Derivative Liability

As of December 31, 2024 and 2023 and at each quarter end during these years, 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)/gain of $(53,257) and $148,751, in the years ended December 31, 2024 and 2023, respectively.

Gain (Loss) on Extinguishment of Debt

During the years ended 2024 and 2023, the Senior Secured Convertible Note was amended several times with materially different economics thus requiring for the recording of debt as an extinguishment and re-recording the debt with the amended terms. This resulted in a gain/(loss) on extinguishment of debt in the years ended December 31, 2024 and 2023 of $857,723 and $(887,946), respectively.

Liquidity and Capital Resources; Plan of Operations

As of December 31, 2024, we had cash and cash equivalents of $3,769,510. 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, 2024, we had an accumulated deficit of $26,022,129.

Historically, we have financed our operations primarily by selling common stock and convertible debt. 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. On April 11, 2022, we issued a senior secured convertible note in the principal amount of $1,111,111 in exchange for $1,000,000 as described above in "Item 1. Business" of this Annual Report on Form 10-K, which was paid down with the proceeds from the initial public offering.

For the fiscal years ended December 31, 2024 and 2023, we generated no revenues from product sales and reported net losses of $2,439,625 and $4,783,689, respectively, and negative cash flow from operating activities of $3,911,004 and $480,953, 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 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, 2024 and 2023.

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, 2024 and 2023

The following table shows a summary of our cash flows for the years ended December 31, 2024 and 2023.

	Fiscal Years Ended December 31,	
	2024	**2023**
Net cash used in operating activities	$ (3,911,004)	$ (480,953)
Net cash used in investing activities	-	-
Net cash provided by financing activities	$ 7,652,036	$ 445,000
Net increase (decrease) in cash	$ 3,741,032	$ (35,953)
Cash - beginning of the period	$	$
Cash - end of the period	$ 3,769,510	$ 28,478

Net Cash Used in Operating Activities:

Net cash used in operating activities during the year ended December 31, 2024 increased $3,430,051 from December 31, 2023 mainly attributable to an increase of $2,300,000 in prepaid contracts due to stock issuances associated with Asian Business Development service agreements, an increase of $118,796 in other current assets, a decrease of $2,187,051 in accrued compensation, a decrease of $314,412 in accounts payable and accrued expenses, a decrease of $1,517,085 in changes associated with debt (amortization of debt discounts, loss on extinguishment of debt, gain/loss on change in fair value of derivative liabilities, and increase in accrued interest), an increase in amortization of prepaid contracts of $54,612, an increase of $642,329 in stock-based compensation, partially offset a decrease of $2,334,064 in Net Loss.

Net Cash Used in Investing Activities:

No net cash was provided by or used in investing activities during the years ended December 31, 2024 and 2023.

Net Cash Provided by Financing Activities:

Net cash provided by financing activities for the year ended December 31, 2024 increased by $7,207,036 from the year ended December 31, 2023. The increase is mainly attributed the proceeds raised from the Company's initial public offering, net of offering costs of $9,725,213 partially offset by the repayments of notes payables of $2,361,677.

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 South-East 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

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") 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 bears interest at a rate of 10% per year, payable monthly in arrears, and mature 12 months from issuance. A "Qualified Offering" is a debt or equity financing for the account of the Company or any of its subsidiaries in which shares of common stock, or securities, directly or indirectly, convertible into or exchangeable or exercisable for shares of common stock are issued, which financing results in cumulative aggregate proceeds to the Company of at least $8,000,000. The principal and interest on the Note will be amortized on a straight-line basis at 110% of the principal amount commencing sixth months after the closing. On October 10, 2022, the Note was amended to postpone the commencement of the amortization amount from October 11, 2022 to November 11, 2022. On November 10, 2022, the Note was amended to postpone the commencement of the amortization from November 11, 2022 to February 11, 2023 and payable in three monthly installments. As consideration for the amendment, an additional 11,431 shares of common stock were issued to the accredited investor on October 10, 2022 and 34,293 shares issued to the accredited investor on November 10, 2022. On January 13, 2023, the Note was amended to delay the interest payment due and payable on January 11, 2023 to the earlier of (i) January 31, 2023 and (ii) the closing of a Qualified Offering.

Upon an Event of Default and after a Qualified Offering, the principal and interest are convertible at any time at the option of the holder into shares of the Company's common stock at a conversion price equal to 30% discount to the lowest closing price of the common stock for the 20 prior trading days; provided, however, the holder will not have the right to convert any portion of the Note, to the extent that after giving effect to the conversion, the holder, together with its affiliates, would beneficially own in excess of 4.99% of the number of shares of the Company's common stock outstanding immediately after giving effect to its conversion. The holder may increase or decrease its ownership limitation to any percentage not exceeding 9.99% upon 61 days prior written notice to the Company.

The Company will have the right at any time to redeem in cash all or a portion of the Note at 120% (or 125% on or after the first six months from the closing; provided, however, if interest due and payable on January 31, 2023 is not paid in full, 130% on or after the first six months from the closing) of the principal amount thereof plus any unpaid accrued interest to the date of repayment.

The Company will be required to offer to prepay in cash the aggregate principal amount of the Note at 120% (or 125% on or after the first six months from the closing; provided, however, if interest due and payable on January 31, 2023 is not paid in full, 130% on or after the first six months from the closing) of the principal amount thereof plus any unpaid accrued interest to the date of repayment, on the sale of all or substantially all of the assets of the Company and its subsidiaries, upon a Change of Control (as defined in the Note), or on a Qualified Offering.

Upon an Event of Default (as defined therein) interest shall accrue at 1 1/2% per month and the 125% (or 130% if interest due and payable on January 31, 2023 is not paid in full) of principal and interest through maturity shall be due and payable. At the holder's option the holder shall be entitled to be paid in cash or after the Qualified Offering (as defined in the Purchase Agreement) common stock with the conversion price of the common stock equal to a 30% discount to the lowest closing price of the common stock for the 20 prior trading days.

On February 6, 2023, the Note was amended to postpone the commencement of the principle to February 28, 2023. On March 6, 2023, the Note was amended to postpone the commencement of the principal from February 11, 2023 to May 31, 2023. The Company and the note holder agreed to a repayment plan on past due interest. In addition, the Company agreed to prepay in cash the aggregate principal amount of the Note of 120% (or 137.5% on or after the first six months from closing) plus any accrued interest on the sale of all the assets of the Company and its subsidiaries, upon the Change of Control, or on a Qualified Offering. Upon default of the Note the Company agrees to pay 137.5% of the outstanding note principal, and accrued interest through maturity and all liquidation damages. As a result of the material modification, the incremental fair value of the modified derivative was classified as a debt extinguishment. Due to the extension of the maturity date of the convertible note, the fair value of the derivative liability increased. This resulted in the Company recording a loss on extinguishment of debt of $670,419.

On September 22, 2023, the Note was amended to postpone the commencement of the principle to December 31, 2023. The Company and the note holder agreed to a repayment plan on past due interest. In addition, the Company agreed to prepay in cash the aggregate principal amount of the Note of 120% (or 150% on or after the first six months from closing) plus any accrued interest on the sale of all the assets of the Company and its subsidiaries, upon the Change of Control, or on a Qualified Offering. Upon default of the Note the Company agrees to pay 150% of the outstanding note principal, and accrued interest through maturity and all liquidation damages. In addition, upon closing the Note holder will receive 175% stock coverage. As a result of the material modification, the incremental fair value of the modified derivative was classified as a debt extinguishment. Due to the extension of the maturity date of the convertible note, the fair value of the derivative liability increased. This resulted in the Company recording a loss on extinguishment of debt of $217,527.

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.

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.

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.

The Shares. In connection with the issuance of the Note, 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 and 2023 was $146,432 and $358,479, respectively. The loan is due on demand and accrues interest at 3% per year. Accrued interest relating to the loan was $1,064 and $11,308 as of December 31, 2024 and 2023, respectively, and is included in accrued interest on the accompanying balance sheets. 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.

During the year ended December 31, 2023, an employee loaned the Company $25,000. The balance of the loan as of December 31, 2024 and 2023, was $0 and $25,000, respectively. The loan is due on demand and accrues interest at 3% per year. Accrued interest related to the loan was $0 and $723 as of December 31, 2024 and 2023, respectively, and is included in accrued interest on the accompanying balance sheet. The Company repaid a total of $26,422 during the year ended December 31, 2024, $25,000 in principal and $1,421 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 agrees 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 of 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. During 2020, the Company began paying salaries at 50% of the respective employment agreements. As of September 2021, the Company began paying full salaries. During the first quarter of 2022, the Company returned to paying partial salaries in an effort to conserve cash outflows in an effort to conserve cash outflows.

On September 29, 2023, various employees and board members agreed to forgive accrued compensation in the amount of $4,189,626. In exchange of the forgiveness the Company issued an aggregate of 2,353,661 stock options with an exercise price of $1.33 and an aggregate of 1,399,834 restricted stock units with a grant date value of $1.33 in exchange for the aggregate forgiveness of compensation in the amount of $4,189,626. Additionally, the Company agreed to a bonus of $513,013 for the employees and a bonus of $70,200 to the board members, to be paid upon the occurrence of a successful IPO in exchange for the forgiveness of the afore-mentioned accrued compensation.

On December 18, 2023, various employees and board members agreed to amend the accrued compensation debt forgiveness dated September 29, 2023. Pursuant to the amendment the cash bonuses of $513,013 for the employees and a bonus of $70,200 to the board members agreed to on September 29, 2023, were forgiven, and no cash is to be paid upon a successful IPO. In addition, the options issued in connection with the forgiveness dated September 29, 2023, were amended to vest fully on the effective date of the new amendment. In addition, the restricted stock unit issued in connection with the forgiveness dated September 29, 2023, were terminated and replaced with 1,399,834 restricted stock units that vest upon the earlier occurrence of the initial public offering or a change of control of the Company. In exchange for the forgiveness of the accrued bonuses the Company issued an aggregate of 289,294 stock options with an exercise price of $1.33 and an aggregate of 218,703 restricted stock units with a grant date value of $1.33 in exchange for the aggregate forgiveness of compensation in the amount of $583,213.

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, 2024 and 2023, $64,105 and $67,750, respectively, was due to a Company wholly owned by the Company's Chief Financial Officer, who also is an option holder. 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.

Recent Developments

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. The management approach requires companies to report segment financial information consistent with information used by management for making operating decisions and assessing performance as the basis for identifying the Company's reportable segments. The Company has identified one single reportable operating segment. The Company manages its business on the basis of one operating and reportable segment and derives revenues from selling its product and related services.

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, 2024 and 2023, respectively, include valuation of stock-based compensation, uncertain tax positions, 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, 2024 and 2023 were $492,660 and $954,793, respectively.

Stock-Based Compensation

The Company accounts for stock-based compensation in accordance with the provisions of Accounting Standards Codification (ASC) Topic 718, Compensation—Stock Compensation, or ASC 718, which requires the recognition of expense related to the fair value of stock-based awards in the statements of operations. 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, 2024 and 2023, stock-based compensation expenses totaled $1,840,908 and $1,198,579, respectively.

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 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 to be separately accounted for in accordance with ASC 815-10 – *Derivative and Hedging – Contract in Entity's Own Equity*. 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-24 comprising a portion of this Annual Report on Form 10-K.

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

Not applicable.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

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, 2024, pursuant to Rule 13a-15(b) under the Exchange Act. Based upon that evaluation, our Certifying Officers concluded that, as of December 31, 2024, our disclosure controls and procedures were effective.

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, 2024. 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, 2024, our Company's internal control over financial reporting was adequate in material aspects.

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 three months ended December 31, 2024, 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	73	Chairman of Board, Chief Executive Officer and Director
Saleem Elmasri	39	Chief Financial Officer and Secretary
Marshall Hayward, Ph.D.	70	Chief Scientific Officer and Director
Alexander Rosén	34	Chief Administrative Officer
Alison D. Silva	46	President, Chief Business Officer, and Director
Nicholas H. Hemmerly	42	Independent Director
Julie Kampf	63	Independent Director
Allison W. Brady	54	Independent Director
Holger Weis	62	Independent Director

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

Executive Officers

Christer Rosén. Mr. Rosén is our Co-Founder and has served as our Chief Executive Officer and Chairman of our Board of Directors since January 1, 2016. From 1997 through May 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 position at EffRx, invented, developed and received 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 in all the aspects of pharmaceutical development, regulatory paths and distribution. Mr. Rosén is a graduate of Malmo Trade Schools/Lund University, Sweden, with a degree in Computer Sciences in 1971.

Saleem Elmasri. Mr. Elmasri has served as our Chief Financial Officer and Secretary since January 1, 2023. From September 2020 to December 2022, he served as a Principal at Titan Advisory Services LLC, a boutique advisory firm focused on providing collaborative and customized financial operations and CFO services to early-stage companies. 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, 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 PricewaterhouseCoopers 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 is one of our Co-Founders, serves as our Chief Scientific Officer, and is a member of our Board of Directors since January 1, 2016. Since May 2013, Dr. Hayward has served as the managing member of Marshall Hayward Associates LLC. From September 2003 to May 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 and did postdoctoral work there 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.

Alexander Rosén. Mr. Rosén 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 - 2012. Mr. Rosén does not hold, and has not previously held, any directorships in any reporting companies.

Alison D. Silva. Alison Silva, who has been a member of our Board of Directors since 2018, has now expanding 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 July 2016 through August 2021. She continues to serve 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 the University of Massachusetts Medical Center in 2002.

Independent Directors

Allison W. Brady. Ms. Brady has served as an independent director at Jupiter Neurosciences, Inc. since September 8, 2021. She serves on the board of Gene Spotlight, Inc., where she is co-founder, a non-profit dedicated to raising money to sponsor medical research for rare diseases, since April 2011. Since 2016, 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. Ms. Brady does not hold, and has not previously held, any directorships in any reporting companies.

Nicholas H. Hemmerly. Mr. Hemmerly 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 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. Prior to PwC 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 also serves as an independent director for Liberty Star Uranium & Metals Corp.

Julie Kampf. Ms. Kampf has served as an independent director at Jupiter Neurosciences, Inc. since September 8, 2021. Ms. Kampf is currently a Director and CEO of JBK Associates International an Executive Search firm focused on the Life Science Industry, which she founded in 2003. Ms. Kampf is also currently a Director at Marizyme, Inc. a Florida-based Biotech Company. Ms. Kampf has significant not-for-profit board and advisory committee experience having served on Howard University's School of Communications Board of Visitors, where she helped launch an entrepreneurial incubator and established an award for student entrepreneurs. Deeply committed to enhancing the careers and well-being of other women, Ms. Kampf was president of the 1,750-member HBA (Healthcare Businesswomen's Association) Metro Chapter, where she co-founded a successful mentoring program. 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.

Holger Weis. Mr. Weis has served as an independent director at Jupiter Neurosciences, Inc. since September 8, 2021. Since December 2020, he has served as a Director, member of Audit and Compensation Committees as Alaunos Therapeutics, Inc. 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.

Scientific Advisory Board

We want to emphasize that our Scientific Advisory Board members and business advisors take a very active role in our company and specific projects. This is one important reason how a company with our small staff can execute so many different pipeline projects effectively.

Shaun P. Brothers, Ph.D. Dr. Brothers has served as a member of our Scientific Advisory Board and our Consulting VP of Scientific Research since January 1, 2016. Dr. Brothers is an expert reviewer for molecular probes and drug discovery in neuroscience NIH study sections. Since June 2017, Dr. Brothers has served as an Associate Professor at the University of Miami, Miller School of Medicine. Since June 2016, Dr. Brothers has served as Director at Sylvester Cancer Center Molecular Therapeutics Shares Resource at University of Miami, Miller School of Medicine. From March 2011 through May 2017, Dr. Brothers served as an Assistant Professor at the University of Miami, Miller School of Medicine. Since September 2012, Dr. Brothers has served as Director of Pharmacology at Epigenetix Inc. From 2016 through 2018, Dr. Brothers served as Director Preclinical Research at DemeRx, Inc. From October 2006 to March 2011, Dr. Brothers served as a researcher at Scripps Research Institute in Jupiter, Florida. Dr. Brothers has also co-founded 2 biotech companies. Dr. Brothers received an MBA from West Texas A&M University in 2019, Ph.D. in physiology and pharmacology from Oregon Health and Science University in 2006, and Bachelor of Science degree in Microbiology from Oregon State University in 2000.

Dalton Dietrich, Ph.D. Dr. Dietrich has served as a member of our Scientific Advisory Board since June 22, 2021. Dr. Dietrich currently is the Scientific Director at The Miami Project to Cure Paralysis and the Kinetic Concepts Distinguished Chair in Neurosurgery at the University of Miami Miller School of Medicine which is where he has been since 1997. Dr. Dietrich also currently serves as the Senior Associate Dean for Discovery Science at the University of Miami Miller School of Medicine and Co-Director of the Institute for Neural Engineering at the University of Miami. Between 1995 to 1997 Dr. Dietrich served as Vice-Chairman for Basic Science in the Department of Neurology at the University of Miami. He attained the rank of Professor in 1993. In 1981, Dr. Dietrich joined the Department of Neurology at the University of Miami with a joint appointment in Cell Biology and Anatomy. Dr Dietrich has published over 375 refereed journal articles, 75 book chapters and 4 books. His published work has been cited over 38,000 times. He has been listed by the Institute of Scientific Information as a "Highly Cited Researcher", placing him in the top 0.5% of all scientists based on the impact his research has made on other scientists. Dr. Dietrich received his Ph.D. in Anatomy from the Medical College of Virginia in 1979 and completed a postdoctoral fellowship in the Department of Pharmacology at Washington University, St. Louis, MO in 1981.

Peter Elliott, Ph.D. Dr. Elliott has served as a member of our Scientific Advisory Board since October, 2016. Since 2009, Dr. Elliott has served as a consultant to the pharmaceuticals industry. From 2005 to 2009, Dr. Elliott served as Senior Vice President of R&D at Sirtris Pharmaceuticals. As part of work from his teams at Sirtris, three SIRT1 activators entered clinical development, SRT501, SRT2104 and SRT2379. He was also an integral part of the road-show to take Sirtris public with a successful IPO in 2007, leading to it being purchased by GSK in 2008 for $720 million. From 2001 to 2005, Dr. Elliott served as Executive Vice President of Product Development at CominatoRx leading efforts in 8 Phase II programs in inflammation and oncology. From 1996 to 2001, Dr. Elliott served as Vice President of Pharmacology and Development at ProScript which was acquired by LeukoSite, and ultimately Millennium where he co-developed the multiple myeloma drug, Velcade© and PS-519 for stroke. From 1993 to 1996, Dr. Elliott served as Associate Director of Pharmacology at Alkermes. From 1988 to 1993, Dr. Elliott served as Group & Research Leader at Glaxo Group Research where he led a number of CNS programs focusing on movement disorders, neurodegeneration as well as pain. Dr. Elliott received a B.Sc. in Pharmacology from London University and a Ph.D. in Psychopharmacology from Cambridge University.

Charbel Moussa, MBBS, Ph.D. Dr. Moussa has served as a member of our Scientific Advisory Board since April, 2020. Since July 2017, Dr. Moussa has served as an Associate Professor of Neurology at Georgetown University Medical Center. Since March 2015, Dr. Moussa has served as the director of Translational Neurotherapeutics Program at Georgetown University Medical Center. Since January 2018, Dr. Moussa has served as the Principal Investigator of the Lewy Body Disease Association (LBDA) Research Center of Excellence at Georgetown University Medical Center. Since March 2015, Dr. Moussa has served as Clinical Research Director at the Parkinson's Foundation Center of Excellence. Since August 2016, Dr. Moussa has served as Director of Neurosciences Grand Rounds at Georgetown University Medical Center. Dr. Moussa received a Bachelor of Medicine, Bachelor of Surgery (MBBS), and Doctor of Philosophy (Ph.D.) in Biomedical Sciences from the University of Sydney Australia in 1996 and 2002, respectively. Dr. Moussa has expertise in geriatric neurology with a special focus on movement and memory disorders.

Rudolph Tanzi Ph.D. Dr. Tanzi has served as the Co-Chairman of our Scientific Advisory Board since November, 2019. Since 2013, Dr. Tanzi has served as the Vice-Chair of Neurology and Director of the Genetics and Aging Research Unit at Massachusetts General Hospital. Since 2008, Dr. Tanzi has also served as the Joseph P. and Rose F. Kennedy Professor of Neurology at Harvard Medical School. Dr. Tanzi received his B.S. (microbiology) and B.A. (history) at the University of Rochester in 1980 and his Ph.D. (neurobiology) at Harvard Medical School in 1990. In his research achievements, Dr. Tanzi served on the team that was the first to find a disease gene ((Huntington's disease) using human genetic markers, helping to launch the field of neurogenetics. He later co-discovered all three early-onset familial Alzheimer's disease genes and identified several others as leader of the Cure Alzheimer's Fund Alzheimer's Genome Project. He also co-discovered the Wilson's disease gene and several other neurological disease genes. Most recently, he and his team used Alzheimer's genes and human stem cells to create what the New York Times coined, "Alzheimer's-in-a-Dish". This is a three-dimensional human stem cell-derived neural culture system that is considered to be the first true model of Alzheimer's disease, recapitulating both pathological hallmarks of Alzheimer's disease: plaques and tangles. The model has made drug screening for Alzheimer's disease 10 times cheaper and 10 times faster. Dr. Tanzi has developed novel therapeutics for Alzheimer's disease including gamma secretase modulators and metal chaperones (PBT; Prana) aimed at lowering plaque and tangle pathology. Both have been entered into clinical trials for Alzheimer's patients. Dr. Tanzi is also very active in the areas of integrative medicine and applications to brain health. In this regard, along with Dr. Deepak Chopra, Dr. Tanzi co-directs the Self-Directed Biological Transformation Initiative (SBTI) aimed at exploring and quantifying the effects of lifestyle interventions on neuroplasticity and epigenetics.

Dr. Tanzi has published over 500 research papers and has received the highest awards in his field, including the Metropolitan Life Foundation Award, Potamkin Prize, Ronald Reagan Award, Silver Innovator Award, and many others. He was named to TIME magazine's 2015 list of TIME100 Most Influential People in the World, and received the Smithsonian American Ingenuity Award, the top national award for invention and innovation. He co-authored the popular trade books "Decoding Darkness", New York Times best seller, "Super Brain", and international best seller "Super Genes" with Dr. Deepak Chopra. He was named by GQ magazine as a Rock Star of Science, and in his spare time, has played keyboards with the band Aerosmith. With singer, Chris Mann, he also composed the beautiful ballad, "Remember Me", which honors Alzheimer's patients, and is being used to raise funds for Alzheimer's research at the Cure Alzheimer's Fund, for which, Dr. Tanzi serves as Chair of the Cure Alzheimer's Fund Research Consortium.

Li-Huei Tsai, Ph.D. Dr. Tsai has served as a member of our Scientific Advisory Board since June, 2016. Since May 2006, Dr. Tsai has served as the Director of the Picower Institute for Learning and Memory at the Massachusetts Institute of Technology, a Picower Professor of Neuroscience, and an Associate Member of the Broad Institute. From 1994 to May 2006, Dr. Tsai served as an Assistant Professor of Pathology at Harvard Medical School and was promoted to tenure Professor at Harvard in 2002. From 1997 to 2013, Dr. Tsai served as an Investigator of the Howard Hughes Medical Institute from 1997 to 2013. Dr. Tsai is also a Fellow of the American Association for the Advancement of Science, a member of the National Academy of Medicine, and an Academician of the Academia Sinica in Taiwan. Dr. Tsai obtained a Ph.D. from University of Texas Southwestern Medical Centre in Dallas, Texas in 1990 and postdoctoral training at Cold Spring Harbor Laboratories and Massachusetts General Hospital from 1990 to 1994.

Raymond Scott Turner, MD, Ph.D. Dr. Turner has served as a member of our Scientific Advisory Board since August, 2016. Since April 2020, Dr. Turner has served as the Vice Chair for Clinical Research, Department of Neurology at Georgetown University Medical Center. Since July 2008, Dr. Turner has served as a Professor at the Department of Neurology and the Director of the Memory Disorders Program, Department of Neurology at Georgetown University Medical Center. From March 2007 to July 2008, Dr. Turner served as the Associate Chair in the Department of Neurology, University of Michigan at Ann Arbor, Michigan. From October 2003 to July 2008, Dr. Turner served as Associate Professor in the Department of Neurology, University of Michigan. From July 1995 to October 2003, Dr. Turner served as Assistant Professor in the Department of Neurology, University of Michigan. From September 2002 to July 2008, Dr. Turner served as Chief of Neurology Service at VA Ann Arbor Healthcare System in Ann Arbor, Michigan. From July 1995 to July 2008, Dr. Turner served as Attending Neurologist and Research Scientist, Geriatric Research Education and Clinical Center at VA Ann Arbor Healthcare System in Ann Arbor, Michigan. Dr. Turner received a Bachelor of Science degree in microbiology/molecular biology from Clemson University in 1979. Dr. Turner obtained a Ph.D. in pharmacology and an MD from Emory University in 1984 and 1988, respectively, and completed his internship, residency, and fellowship at the University of Pennsylvania, Philadelphia in 1992. Dr. Turner has received numerous prestigious awards, including a fellowship from the Howard Hughes Medical Institute and a Paul Beeson Scholarship. Dr. Turner serves as a reviewer for granting agencies and biomedical journals, has published more than seventy peer-reviewed paper, editorials, and book chapters, as well as lectures widely. He became board-certified in Psychiatry and Neurology in 1993.

Claes Wahlestedt, MD, Ph.D. Dr. Wahlestedt has served as the Co-Chairman of our Scientific Advisory Board and our Consulting Chief Medical Officer since January 1, 2016. From January 1, 2016 through October 1, 2021, he previously served as a member of our Board of Directors. Dr. Wahlestedt is a renowned scientist throughout the pharmaceutical industry. Since March 2011, Dr. Wahlestedt has served as the Leonard M. Miller Professor & Associate Dean for Therapeutic Innovation at the University of Miami Miller School of Medicine. From 2005 to March 2011, Dr. Wahlestedt was the founding Professor and Director of Neuroscience at The Scripps Research Institute in Florida. From 1997 to 2005, Dr. Wahlestedt was the Professor and Department Chair at Karolinska Institute in Stockholm, Sweden. Dr. Wahlestedt was the Director of Worldwide Genomics for Pharmacia between 1997 to 2004. From 1994 to 1997, Dr. Wahlestedt was a faculty member at McGill University. From 1993 to 1997, Dr. Wahlestedt directed the research and development team for Astra-Zeneca Research Centre in Montreal, Canada. From 1989 to 1993, Dr. Wahlestedt was the Assistant Professor of the Department of Neurology and Neurosciences at Cornell University Medical College in New York, NY. Dr. Wahlestedt has also co-founded 2 other biotech companies, including CuRNA, Inc. and Epigenetix, Inc. Dr. Wahlestedt is a graduate of Lund University, Sweden with a M.D. in Medicine and Ph.D. in Pharmacology in 1986 and 1987, respectively.

Business Advisors

Ulf Wiinberg. Mr. Wiinberg is an experienced healthcare industry professional who has served on the boards of several healthcare industry associations. Since April 2017, Mr. Wiinberg has had the position of Chief Executive Officer at X-VAX Technology, Inc. From June 2008 to December 2014, Mr. Wiinberg served as the Chief Executive Officer at Lundbeck, a pharmaceutical company specialized in psychiatric and neurological disorders. Mr. Wiinberg served as President of the European pharma business at Wyeth from June 2005 to May 2008. At Wyeth, Mr. Wiinberg also served as President of the global consumer health care business from 2002 to 2005. From 1997 to 2002, Mr. Wiinberg served as Managing Director at Wyeth UK and Ireland. Ulf is presently a non-executive member of the board of Alfa Laval AB, Agenus Inc and at the Belgian pharmaceutical company UCB. He is also chairman of the board of Sigrid Therapeutics AB, Chairman of the Board at Hansa Biopharma as well as CEO and chairman of the board of Ulf Wiinberg Consulting & Invest AB.

Arthur Kirsch. Mr. Kirsch has advised the Company since June 2020 on a variety of financial and strategic initiatives. Previously he was a Senior Advisor and Head of Global Healthcare at GCA Global from 2005 to 2019, an investment bank providing strategic M&A and capital markets advice for growth companies. From 1994 to 2004 he was Head of Research for Vector Securities with over 200 companies under coverage and later became Head of Capital Markets that acquired by Prudential Securities. From 1990 to 1993 Mr. Kirsch was CEO OF Natwest Markets the investment banking division of Natwest Bank in the U.K. He began his career at Drexel Burnham where he was an Executive Vice President running the global equity division as well as being on the Executive Committee. Mr. Kirsch has served on the Board of Kadmon since 2019, a publicly traded bio pharmaceutical company where he serves on the Audit Committee. He also serves on the board of Liquidia Technologies a public nano technology healthcare company as well as being the Chairman of the Audit Committee. Mr. Kirsch received his B.A. in Finance from the University of Rhode Island and an M.B.A. from Bernard M. Baruch College.

Mark Dant. Mr. Dant, EveryLife Foundation for Rare Diseases Board Chair, is a parent advocate and retired Carrolton, Texas Police Department Chief of Police. Mark and his wife Jeanne are the parents of Ryan, who is 33 years old and the longest treated person in the world with MPS I. Mark and Jeanne spearheaded the funding for the first MPS Enzyme Replacement Therapy, Aldurazyme, through their Foundation, the Ryan Foundation. In partnership with Dr. Emil Kakkis, Mr. Dant and his family were also key advocates speaking to the FDA about the importance and significant impact of ERT for the treatment of mucopolysaccharidoses. In 2009, Mr. Dant and his family successfully championed Congress to pass the Ryan Dant Health Care Opportunity Act, H.R. 1441-111.

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, 2024, the Board held five meetings, the Audit Committee held four meetings, the Compensation Committee held no meetings, and the Nominating and Governance Committee held no meetings. During 2024, 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.

Limitation on Liability and Indemnification 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

2024 Summary Compensation Table

The following summary compensation table provides information regarding the compensation earned during our fiscal years ended December 31, 2024 and 2023 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	2024	134,750	-	-	-	-	-	19,326[2]	$ 154,076
Chief Executive Officer	2023[3]	-	-	661,531	771,550	-	-	4,286[4]	1,437,367
Saleem Elmasri	2024	127,006	-	-	-	-	-	-[5]	127,006
Chief Financial Officer	2023[6]	-	-	88,168	690,335	-	-	-[7]	778,503
Marshall Hayward	2024	107,800	-	-	-	-	-	-[8]	107,800
Chief Scientific Officer	2023[9]	-	-	518,426	604,638	-	-	18,646[10]	1,141,710
Alexander Rosén	2024	77,000						26,655[11]	103,655
Chief Administration Officer	2023[12]			218,855	255,248			27,259[13]	501,362
Alison Silva	2024	96,250						42,294[14]	138,544
Chief Business Officer and President	2023[15]	-	-	146,602	363,481			35,000[16]	545,083

(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 $19,326 and $0, respectively, for the fiscal year ended December 31, 2024.

(3) During 2023, Mr. Rosén agreed to defer all salary compensation and to reduce his salary to $84,000 beginning on October 1, 2023. The deferred compensation is recorded in accrued compensation as of December 31, 2023. No interest was accrued or due on the deferred compensation for 2023.

On September 29, 2023, Mr. Rosén agreed to forgive $1,433,938 of earned compensation in exchange for 710,344 options to purchase common stock, 430,181 restricted stock units, and $179,242 to be paid out as a bonus upon an IPO. The options to purchase common stock have a strike price of $1.33. On December 18, 2023, the restricted stock units issued on September 29, 2023 were cancelled and reissued as part of an additional forgiveness, whereby Mr. Rosén agreed to forgive the $179,242 of accrued bonus in exchange for 88,909 options to purchase common stock and an additional 67,215 restricted stock units (total of 497,392 restricted stock units). The options to purchase common stock have a strike price of $1.33.

(4) Includes healthcare benefits and 401(k) contribution of $4,286 and $0, respectively, for the fiscal year ended December 31, 2023.

(5) Includes healthcare benefits and 401(k) contribution of $0 and $0, respectively, for the fiscal year ended December 31, 2024.

(6) During 2023, Mr. Elmasri, through his consulting company, Titan Advisory Services, LLC ("Titan") agreed to defer all salary compensation and to reduce his salary to $250,000 beginning on February 1, 2023, and further reduced to $60,000 beginning on October 1, 2023. The deferred compensation is recorded in accrued compensation as of December 31, 2023. No interest was accrued or due on the deferred compensation for 2023. Mr. Elmasri and his wife are the only shareholders of Titan.

On September 29, 2023, Mr. Elmasri, on behalf of Titan, agreed to forgive $164,720 of earned compensation in exchange for 81,599 options to purchase common stock, 49,417 restricted stock units, and $45,000 to be paid out as a bonus upon an IPO. The options to purchase common stock have a strike price of $1.33. On December 18, 2023, the restricted stock units issued on September 29, 2023 were cancelled and reissued as part of an additional forgiveness, whereby Mr. Elmasri agreed to forgive the $45,000 of accrued bonus in exchange for 22,320 options to purchase common stock and an additional 16,875 restricted stock units (total of 66,292 restricted stock units). The options to purchase common stock have a strike price of $1.33.

(7) Includes healthcare benefits and 401(k) contribution of $0 and $0, respectively, for the fiscal year ended December 31, 2023.

(8) Includes healthcare benefits and 401(k) contribution of $0 and $0, respectively, for the fiscal year ended December 31, 2024.

(9) During 2023, Mr. Hayward agreed to defer all salary compensation and to reduce his salary to $67,200 beginning on October 1, 2023. The deferred compensation is recorded in accrued compensation as of December 31, 2023. No interest was accrued or due on the deferred compensation for 2023.

On September 29, 2023, Mr. Hayward agreed to forgive $1,123,727 of earned compensation in exchange for 556,672 options to purchase common stock, 337,118 restricted stock units, and $140,466 to be paid out as a bonus upon an IPO. The options to purchase common stock have a strike price of $1.33. On December 18, 2023, the restricted stock units issued on September 29, 2023 were cancelled and reissued as part of an additional forgiveness, whereby Mr. Hayward agreed to forgive the $140,466 of accrued bonus in exchange for 69,675 options to purchase common stock and an additional 52,676 restricted stock units (total of 389,794 restricted stock units). The options to purchase common stock have a strike price of $1.33.

(10) Includes healthcare benefits and 401(k) contribution of $18,646 and $0 respectively, for the fiscal year ended December 31, 2023.

(11) Includes healthcare benefits and 401(k) contribution of $26,655 and $0 respectively, for the fiscal year ended December 31, 2024.

(12) During 2023, Mr. Rosén agreed to defer all salary compensation and to reduce his salary to $48,000 beginning on October 1, 2023. The deferred compensation is recorded in accrued compensation as of December 31, 2023. No interest was accrued or due on the deferred compensation for 2023.

On September 29, 2023, Mr. Rosén agreed to forgive $477,382 of earned compensation in exchange for 234,998 options to purchase common stock, 142,316 restricted stock units, and $59,298 to be paid out as a bonus upon an IPO. The options to purchase common stock have a strike price of $1.33. On December 18, 2023 the restricted stock units issued on September 29, 2023 were cancelled and reissued as part of an additional forgiveness, whereby, Mr. Rosén agreed to forgive the $59,298 of accrued bonus in exchange for 29,415 options to purchase common stock and an additional 22,237 restricted stock units (total of 164,553 restricted stock units). The options to purchase common stock have a strike price of $1.33.

(13) Includes healthcare benefits and 401(k) contribution of $27,259 and $0 respectively, for the fiscal year ended December 31, 2023.

(14) Includes healthcare benefits and 401(k) contribution of $42,294 and $0 respectively, for the fiscal year ended December 31, 2024.

(15) During 2023, Ms. Silva agreed to defer all salary compensation of salary and to reduce her salary to $60,000 beginning on October 1, 2023. The deferred compensation is recorded in accrued compensation as of December 31, 2023. No interest was accrued or due on the deferred compensation for 2023.

On September 29, 2023, Ms. Silva agreed to forgive $317,774 of earned compensation in exchange for 157,418 options to purchase common stock, 95,333 restricted stock units, and $39,722 to be paid out as a bonus upon an IPO. On December 18, 2023 the restricted stock units issued on September 29, 2023 were cancelled and reissued as part of an additional forgiveness, whereby, Ms. Silva agreed to forgive the $39,722 of accrued bonus in exchange for 19,703 options to purchase common stock and an additional 14,895 restricted stock units (total of 110,227 restricted stock units). The options to purchase common stock have a strike price of $1.33.

(16) Includes healthcare benefits and 401(k) contribution of $35,000 and $0 respectively, for the fiscal year ended December 31, 2023.

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. C. 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 December 18, 2023

Mr. C. 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.

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

Mr. 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. Mr. 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 December 18, 2023

Mr. Hayward's employment agreement was amended on December 18, 2023. The amendment reduces Mr. M. 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.

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 shareholders 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 shareholders 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.

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 the 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.

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) for the 2025 calendar year. In addition, Titan is eligible for cash bonuses and additional equity compensation, at the Company's discretion.

Elements of Compensation

Our NEOs were provided with the following primary elements of compensation in 2024 and 2023:

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 "—2024 Summary Compensation Table."

Stock Option Grants

On January 1, 2023, the Company granted non-qualified stock option to purchase 562,500 of common stock to Saleem Elmasri, CPA, as Chief Financial Officer, at an exercise price of $1.33 per share.

On September 29, 2023, the Company granted non-qualified stock options to purchase 710,344 of common stock to Christer Rosén at an exercise price of $1.33 per share.

On September 29, 2023, the Company granted non-qualified stock options to purchase 556,673 of common stock to Marshall Hayward at an exercise price of $1.33 per share.

On September 29, 2023, the Company granted non-qualified stock options to purchase 81,600 of common stock to Saleem Elmasri, CPA at an exercise price of $1.33 per share.

On December 18, 2023, the Company granted non-qualified stock options to purchase 88,909 of common stock to Christer Rosén at an exercise price of $1.33 per share.

On December 18, 2023, the Company granted non-qualified stock options to purchase 69,675 of common stock to Marshall Hayward at an exercise price of $1.33 per share.

On December 18, 2023, the Company granted non-qualified stock options to purchase 22,320 of common stock to Saleem Elmasri, CPA at an exercise price of $1.33 per share.

Other Benefits

In 2024 and 2023, our NEOs were reimbursed for healthcare expenses. The amounts paid to our NEOs in respect of these benefits is reflected above in "—2024 Summary Compensation Table."

2023 Equity Incentive Plan

Overview

The Board of Directors and shareholders 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.

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 2024. 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 2024, 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 "—2024 Summary Compensation Table" for more information about compensation to our NEOs for 2024 and 2023. The following table presents the total compensation for each person who served as a non-employee director during 2024.

2024 Director Compensation Table

Name	Year	Fees Earned or Paid in Cash ($)	Stock Awards ($)	Option Awards ($)	Total ($)
Nicholas H. Hemmerly	2024	$ 49,000	$ 0	$ 0	$ 49,000
Julie Kampf	2024	$ 42,500	$ 0	$ 0	$ 42,500
Holger Weis	2024	$ 44,000	$ 0	$ 0	$ 44,000
Alison W. Brady	2024	$ 40,000	$ 0	$ 0	$ 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 $7,500 annually to be paid $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 12, 2025 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 33,103,860 shares of our common stock issued and outstanding as of March 12, 2025. 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	12,571,758[2]	38.0%
Marshall Hayward, Ph.D	3,625,382[3]	11.0
Saleem Elmasri	666,420[4]	2.0
Alison D. Silva	870,871[5]	2.6
Alexander Rosén	1,624,546[6]	4.9
Nicholas H. Hemmerly	193,737[7]	*
Julie Kampf	176,993[8]	*
Allison W. Brady	192,409[9]	*
Holger Weis	191,636[10]	*
All executive officers and directors as a group (9 persons)	20,113,752[11]	60.8%
Other 5% Stockholders:		
Claes Wahlestedt, M.D., Ph.D.	3,318,583[12]	10.0
Shaun Brothers	2,025,553[13]	6.1

* less than 1%.

[1] The percentages in the table have been calculated based on 33,103,860 shares of our common stock outstanding on March 12, 2025. 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 12, 2025. 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 28, 2025 upon exercise of vested options.

(3) Includes 1,245,098 shares of common stock that may be acquired within 60 days of March 28, 2025 upon exercise of vested options.

(4) Includes 666,420 shares of common stock that may be acquired within 60 days of March 28, 2025 upon exercise of vested options.

(5) Includes 870,871 shares of common stock that may be acquired within 60 days of March 28, 2025 upon exercise of vested options.

(6) Includes 1,171,688 shares of common stock that may be acquired within 60 days of March 28, 2025 upon exercise of vested options.

(7) Includes 193,737 shares of common stock that may be acquired within 60 days of March 28, 2025 upon exercise of vested options.

(8) Includes 176,993 shares of common stock that may be acquired within 60 days of March 28, 2025 upon exercise of vested options.

(9) Includes 170,659 shares of common stock that may be acquired within 60 days of March 28, 2025 upon exercise of vested options.

(10) Includes 180,855 shares of common stock that may be acquired within 60 days of March 28, 2025 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 514,609 shares of common stock that may be acquired within 60 days of March 12, 2025 upon exercise of vested options.

(13) Includes 326,319 shares of common stock that may be acquired within 60 days of March 12, 2025 upon exercise of vested options.

Securities Authorized for Issuance under Equity Compensation Plans

The following table provides information as of December 31, 2024, 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	8,311,224	$ 0.94	5,849,061
Equity compensation plans not approved by security holders	5,308,303	1.20	0
Total	13,619,527	$ 1.04	5,849,061

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.

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.

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 28, 2025, there were 2,139,240 shares available for issuance under the 2023 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, 2024 and 2023 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 and 2023 was $146,432 and $358,479, respectively. The loan is due on demand and accrues interest at 3% per year. Accrued interest relating to the loan was $1,064 and $11,308 as of December 31, 2024 and 2023, respectively, and is included in accrued interest on the accompanying balance sheets. 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.

During the year ended December 31, 2023, an employee loaned the Company $25,000. The balance of the loan as of December 31, 2024 and 2023, was $0 and $25,000, respectively. The loan is due on demand and accrues interest at 3% per year. Accrued interest related to the loan was $0 and $723 as of December 31, 2024 and 2023, respectively, and is included in accrued interest on the accompanying balance sheet. The Company repaid a total of $26,422 during the year ended December 31, 2024, $25,000 in principal and $1,421 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 agrees 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 of 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. During 2020, the Company began paying salaries at 50% of the respective employment agreements. As of September 2021, the Company began paying full salaries. During the first quarter of 2022, the Company returned to paying partial salaries in an effort to conserve cash outflows in an effort to conserve cash outflows.

On September 29, 2023, various employees and board members agreed to forgive accrued compensation in the amount of $4,189,626. In exchange of the forgiveness the Company issued an aggregate of 2,353,661 stock options with an exercise price of $1.33 and an aggregate of 1,399,834 restricted stock units with a grant date value of $1.33 in exchange for the aggregate forgiveness of compensation in the amount of $4,189,626. Additionally, the Company agreed to a bonus of $513,013 for the employees and a bonus of $70,200 to the board members, to be paid upon the occurrence of a successful IPO in exchange for the forgiveness of the afore-mentioned accrued compensation.

On December 18, 2023, various employees and board members agreed to amend the accrued compensation debt forgiveness dated September 29, 2023. Pursuant to the amendment the cash bonuses of $513,013 for the employees and a bonus of $70,200 to the board members agreed to on September 29, 2023, were forgiven, and no cash will be paid upon a successful IPO. In addition, the options issued in connection with the forgiveness dated September 29, 2023, have been amended to vest fully on the effective date of the new amendment. In addition, the restricted stock unit issued in connection with the forgiveness dated September 29, 2023, were terminated and replaced with 1,399,834 restricted stock units that vest upon the earlier occurrence of the initial public offering or a change of control of the Company. In exchange for the forgiveness of the accrued bonuses the Company issued an aggregate of 289,294 stock options with an exercise price of $1.33 and an aggregate of 218,703 restricted stock units with a grant date value of $1.33 in exchange for the aggregate forgiveness of compensation in the amount of $583,213.

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, 2024 and 2023, $64,105 and $67,750, respectively, was due to a Company wholly owned by the Company's Chief Financial Officer, who also is an option holder. The amount is included in accrued compensation on the Company's balance sheets.

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 ACCOUNTING FEES AND SERVICES

Our Audit Committee has appointed Assurance Dimensions to serve as the Company's independent registered accounting firm. The following is a summary of fees paid or to be paid to Assurance Dimensions for the fiscal years ended December 31, 2024 and 2023.

	Year Ended December 31,	
	2024	2023
Audit Fees	$ 84,000	$ 70,000
Audit-Related Fees	14,300	5,500
Tax Fees	-	-
All Other Fees	-	-
Total	$ 98,300	$ 75,500

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 (filed as Exhibit 3.1 to the Company's Registration Statement on Form S-1 filed with the SEC on October 12, 2021)
3.2	Certificate of Validation of the Company dated July 9, 2021 (including Certificate of Amendment to Certificate of Incorporation of the Company) (filed as Exhibit 3.2 to the Company's Registration Statement on Form S-1 filed with the SEC on October 12, 2021)
3.3	Certificate of Amendment to Certificate of Incorporation of the Company dated August 30, 2021 (filed as Exhibit 3.3 to 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 November 19, 2021 (filed as Exhibit 3.4 to the Company's Registration Statement on Form S-1/A filed with the SEC on December 17, 2021)
3.5	Certificate of Amendment to Certificate of Incorporation of the Company dated January 25, 2022 (filed as Exhibit 3.5 to the Company's Registration Statement on Form S-1/A filed with the SEC on January 26, 2022)
3.6	Certificate of Amendment to Certificate of Incorporation of the Company dated June 14, 2024 (filed as Exhibit 3.6 to the Company's Registration Statement on Form S-1/A filed with the SEC on July 12, 2024)
3.7	Amended and Restated Bylaws (filed as Exhibit 3.4 to the Company's Registration Statement on Form S-1 filed with the SEC on October 12, 2021)
4.1*	Description of Capital Stock.
10.1	Jupiter Orphan Therapeutics, Inc. 2021 Equity Incentive Plan† (filed as Exhibit 10.1 to 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 (filed as Exhibit 10.2 to 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 (filed as Exhibit 10.3 to the Company's Registration Statement on Form S-1 filed with the SEC on October 12, 2021)†
10.4	Employment Agreement, dated as of September 1, 2021, between the Company and Marshall Hayward, Ph.D. (filed as Exhibit 10.4 to the Company's Registration Statement on Form S-1 filed with the SEC on October 12, 2021)†
10.5	Amendment No. 1 to Executive Employment Agreement, dated as of September 29, 2021, between the Company and Marshall Hayward, Ph.D. (filed as Exhibit 10.5 to the Company's Registration Statement on Form S-1 filed with the SEC on October 12, 2021)†
10.6	Employment Agreement, dated as of June 6, 2021, between the Company and Alexander Rosén (filed as Exhibit 10.6 to the Company's Registration Statement on Form S-1 filed with the SEC on October 12, 2021)†
10.7	Amendment No. 1 to Executive Employment Agreement, dated as of September 29, 2021, between the Company and Alexander Rosén (filed as Exhibit 10.7 to the Company's Registration Statement on Form S-1 filed with the SEC on October 12, 2021)†
10.8	Employment Agreement, dated as of September 1, 2021, between the Company and Alison Silva (filed as Exhibit 10.8 to 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 Alison D. Silva (filed as Exhibit 10.9 to the Company's Registration Statement on Form S-1 filed with the SEC on October 12, 2021)†
10.10	Employment Agreement, dated as of June 1, 2021, between the Company and Dana Eschenburg Perez (filed as Exhibit 10.10 to 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 Dana Eschenburg Perez (filed as Exhibit 10.11 to the Company's Registration Statement on Form S-1 filed with the SEC on October 12, 2021)†
10.12	Independent Director Agreement, dated as of September 8, 2021, between the Company and Nicholas H. Hemmerly (filed as Exhibit 10.12 to the Company's Registration Statement on Form S-1 filed with the SEC on October 12, 2021)†
10.13	Independent Director Agreement, dated as of September 8, 2021, between the Company and Julie Kampf (filed as Exhibit 10.13 to the Company's Registration Statement on Form S-1 filed with the SEC on October 12, 2021)†
10.14	Independent Director Agreement, dated as of September 8, 2021 between the Company and Allison W. Brady (filed as Exhibit 10.14 to the Company's Registration Statement on Form S-1 filed with the SEC on October 12, 2021)†

Exhibit No.	Exhibit
10.15	Independent Director Agreement, dated as of September 8, 2021, between the Company and Holger Weis (filed as Exhibit 10.16 to the Company's Registration Statement on Form S-1 filed with the SEC on October 12, 2021)†
10.16	License Agreement with Aquanova AG (filed as Exhibit 10.16 to the Company's Registration Statement on Form S-1/A filed with the SEC on November 9, 2021)
10.17	Grant Agreement between Company and National Institute on Aging (filed as Exhibit 10.17 to the Company's Registration Statement on Form S-1/A filed with the SEC on November 9, 2021)
10.18	Agreement between Company and Murdoch Children's Research Institute (filed as Exhibit 10.18 to the Company's Registration Statement on Form S-1/A filed with the SEC on November 9, 2021)
10.19	Manufacturing Agreement between Company and Catalent (filed as Exhibit 10.19 to the Company's Registration Statement on Form S-1/A filed with the SEC on November 9, 2021)
10.20	Agreement between the Company and Syneos Health (filed as Exhibit 10.20 to the Company's Registration Statement on Form S-1/A filed with the SEC on November 9, 2021)
10.21	Material Transfer Agreement between the Company and University of Miami (filed as Exhibit 10.21 to the Company's Registration Statement on Form S-1/A filed with the SEC on November 9, 2021)
10.22	Services Agreement between the Company and Technical Resources International, Inc. (filed as Exhibit 10.22 to the Company's Registration Statement on Form S-1/A filed with the SEC on November 9, 2021)
10.23	Amendment to Services Agreement between the Company and Technical Resources International, Inc. (filed as Exhibit 10.23 to the Company's Registration Statement on Form S-1/A filed with the SEC on November 9, 2021)
10.24	Debt Forgiveness and Exchange Agreement, dated as of December 1, 2021, between the Company and Aquanova AG (filed as Exhibit 10.24 to the Company's Registration Statement on Form S-1/A filed with the SEC on December 17, 2021)
10.25	Securities Purchase Agreement, dated April 11, 2022, between the Company and Puritan Partners LLC (filed as Exhibit 10.25 to the Company's Registration Statement on Form S-1/A filed with the SEC on April 25, 2022)
10.26	Senior Secured Convertible Promissory Note, dated as of April 11, 2022, issued by the Company in favor of Puritan Partners LLC (filed as Exhibit 10.26 to the Company's Registration Statement on Form S-1/A filed with the SEC on April 25, 2022)
10.27	Security Agreement, dated April 11, 2022, between the Company and Puritan Partners LLC (filed as Exhibit 10.27 to the Company's Registration Statement on Form S-1/A filed with the SEC on April 25, 2022)
10.28	Intellectual Property Security Agreement, dated April 11, 2022, between the Company and Puritan Partners LLC (filed as Exhibit 10.28 to the Company's Registration Statement on Form S-1/A filed with the SEC on April 25, 2022)
10.29	Research Agreement, dated July 1, 2022, between the Company and University of Miami (filed as Exhibit 10.30 to the Company's Registration Statement on Form S-1/A filed with the SEC on August 26, 2022)
10.30	Amendment to the Securities Purchase Agreement, dated as of October 10, 2022, between the Company and Puritan Partners LLC (filed as Exhibit 10.31 to the Company's Registration Statement on Form S-1/A filed with the SEC on December 2, 2022)
10.31	Second Amendment to the Securities Purchase Agreement, dated as of November 10, 2022, between the Company and Puritan Partners LLC (filed as Exhibit 10.32 to the Company's Registration Statement on Form S-1/A filed with the SEC on December 2, 2022)
10.32	Master Services Agreement, dated as of December 27, 2022, between the Company and Titan Advisory Services (filed as Exhibit 10.33 to the Company's Registration Statement on Form S-1/A filed with the SEC on January 6, 2023)†
10.33	Peer Review Summary Statement of FA Grant Application (filed as Exhibit 10.34 to the Company's Registration Statement on Form S-1/A filed with the SEC on January 6, 2023)
10.34	Third Amendment to the Securities Purchase Agreement, dated as of January 13, 2013, between the Company and Puritan Partners LLC (filed as Exhibit 10.35 to the Company's Registration Statement on Form S-1/A filed with the SEC on January 17, 2023)
10.35	CRO Services Agreement, dated June 3, 2024, between the Company and Optimize Wellness Limited (filed as Exhibit 10.35 to the Company's Registration Statement on Form S-1/A filed with the SEC on July 12, 2024)
10.36	Regulatory Services Agreement, dated June 3, 2024, between the Company and Regis Healthcare Group Limited (filed as Exhibit 10.36 to the Company's Registration Statement on Form S-1/A filed with the SEC on July 12, 2024)
10.37	Product Services Agreement, dated June 3, 2024, between the Company and Longevity Technology Group Limited (filed as Exhibit 10.37 to the Company's Registration Statement on Form S-1/A filed with the SEC on July 12, 2024)

Exhibit No.	Exhibit
10.38	Scientific Review of Alzheimer's Phase II Trial Grant Application (filed as Exhibit 10.38 to the Company's Registration Statement on Form S-1/A filed with the SEC on July 12, 2024)
10.39	Form of Strategic Services Agreement between the Company and Dominant Treasure Health Company Limited (filed as Exhibit 10.39 to the Company's Registration Statement on Form S-1/A filed with the SEC on July 12, 2024)
10.40	Jupiter Neurosciences, Inc. 2023 Equity Incentive Plan (filed as Exhibit 10.40 to the Company's Registration Statement on Form S-1/A filed with the SEC on July 12, 2024)†
10.41	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)
10.42	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)
10.43	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)
10.44	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)
14.1*	Code of Ethics and Business Conduct.
19.1*	Policy on Insider Trading.
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.

ITEM 16. FORM 10-K SUMMARY

Not applicable.

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JUPITER NEUROSCIENCES, INC.
Index to Financial Statements

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 sheets of Jupiter Neurosciences, Inc, (the Company) as of December 31, 2024 and 2023, and the related statements of operations, stockholders' equity (deficit), cash flows for each of the years in the two-year period 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 2023, and the results of its operations and its cash flows for each of the years in the two-year period 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.

Critical Audit Matters

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

We did not identify any critical audit matters that need to be communicated.

We have served as the Company's auditor since 2021
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, 2024	December 31, 2023
Assets		
Current Assets:		
Cash	$ 3,769,510	$ 28,478
Prepaid contracts	766,667	-
Prepaid and Other current assets	114,086	261
Total current assets	4,650,263	28,739
Operating lease right of use asset, net	69,642	116,070
Prepaid contract, less current portion	1,478,721	
Other current assets	3,783	3,783
Total assets	$ 6,202,409	$ 148,592
Liabilities and Stockholders' Equity (Deficit)		
Current Liabilities:		
Accounts payable and accrued expenses	$ 396,483	$ 546,014
Accrued compensation	1,415,093	1,562,041
Accrued interest	1,064	88,000
Current portion of operating lease liability	50,082	48,213
Convertible notes payable, net of discount of $0	-	1,638,760
Notes payable, related parties	146,432	383,479
Derivative liability	-	1,505,398
Total current liabilities	2,009,154	5,771,905
Convertible notes payable, net of discount of $0 and $43,288	-	106,712
Operating lease liability, net of current portion	21,247	71,329
Total liabilities	2,030,401	5,949,946
Commitments and Contingencies (Note 8)		
Stockholders' Equity (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; 125,000,000 shares authorized; 33,103,860 and 26,526,405 issued and outstanding	3,310	2,652
Additional paid in capital	30,190,827	17,778,498
Accumulated deficit	(26,022,129)	(23,582,504)
Total stockholders' equity (deficit)	4,172,008	(5,801,354)
Total liabilities and stockholders' equity (deficit)	$ 6,202,409	$ 148,592

The accompanying notes are an integral part of these financial statements

JUPITER NEUROSCIENCES, INC.
STATEMENTS OF OPERATIONS

	For the Years Ended	
	December 31, 2024	**December 31, 2023**
Expenses:		
Research and development	492,660	954,793
General and administrative	2,598,622	2,915,978
Total operating expenses	3,091,282	3,870,771
Operating loss	(3,091,282)	(3,870,771)
Other Income (Expenses):		
Interest income	5,557	482
(Loss) gain on change in fair value of derivative liability	(53,257)	148,751
Interest expense	(248,366)	(218,705)
Gain (Loss) on extinguishment of debt	857,723	(887,946)
Other income	90,000	44,500
Total other income (expenses), net	651,657	(912,918)
Net loss	$ (2,439,625)	$ (4,783,689)
Net loss per common share:		
Basic	$ (0.08)	$ (0.18)
Diluted	$ (0.08)	$ (0.18)
Weighted average number of common stock outstanding:		
Basic	28,783,045	26,405,109
Diluted	28,783,045	26,405,109

The accompanying notes are an integral part of these financial statements

JUPITER NEUROSCIENCES, INC.
STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)

	Common Stock		Additional Paid	Accumulated	Total Stockholders' Equity
	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	Accumulated	Total Stockholders' Equity
	Shares	Amount	in Capital	Deficit	(Deficit)
December 31, 2022	26,371,519	$ 2,637	$11,652,094	$ (18,798,815)	$ (7,144,084)
Stock-based compensation	-	-	1,198,579	-	1,198,579
Selling of common stock	41,250	4	54,996	-	55,000
Stock issued for exercise of options in exchange for note payable, related party	113,636	11	99,989	-	100,000
Issuance of restricted stock for forgiveness of accrued salaries and accrued bonuses	-	-	2,158,050	-	2,158,050
Issuance of stock options for forgiveness of accrued salaries and accrued bonuses	-	-	2,614,790	-	2,614,790
Net operating loss	-	-	-	(4,783,689)	(4,783,689)
December 31, 2023	26,526,405	$ 2,652	$17,778,498	$ (23,582,504)	$ (5,801,354)

The accompanying notes are an integral part of these financial statements

JUPITER NEUROSCIENCES, INC.
STATEMENTS OF CASH FLOWS

	December 31, 2024	December 31 2023
Cash Flows from Operating Activities:		
Net Loss	$ (2,439,625)	$ (4,783,689)
Adjustments to reconcile net loss to net cash used in operating activities:		
Loss (Gain) on change in fair value of derivative liability	53,257	(148,751)
Amortization of debt discounts	43,288	16,712
(Gain) Loss on extinguishment of debt	(857,723)	887,946
Gain on forgiveness of accrued compensation	(40,000)	-
Amortization of prepaid contracts	54,612	-
Stock-based compensation	1,840,908	1,198,579
Changes in operating assets and liabilities:		
Decrease (increase) in prepaid contracts	(2,300,000)	-
Decrease (increase) in prepaid and other current assets	(113,826)	4,971
Increase (Decrease) in operating lease right of use asset	(1,785)	25
Increase (Decrease) in accounts payable and accrued expenses	(149,530)	164,881
Increase (Decrease) in accrued compensation	(46,948)	2,140,103
Increase in accrued interest	46,368	38,270
Net cash used in operating activities	(3,911,004)	(480,953)
Cash Flows from Financing Activities:		
Proceeds from note payable, related parties	138,500	390,000
Payment on notes payable, related parties	(108,880)	-
Payment on notes payable	(2,102,797)	-
Payment on convertible note payable	(150,000)	-
Proceeds from offering, net of offering costs	9,725,213	-
Proceeds from sale of common stock	150,000	55,000
Net cash provided by financing activities	7,652,036	445,000
Net Change in Cash	3,741,032	(35,953)
Beginning of period	28,478	64,431
End of period	$ 3,769,510	$ 28,478
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 147,776	$ 28,128
Cash paid for income taxes	$ -	$ -
Schedule of Non-Cash Investing and Financing Activities:		
Convertible note issued as a settlement of a previously accrued liability	$ -	$ 150,000
Restricted stock issued for forgiveness of salary	$ 10,000	$ 2,158,050
Stock options issued for forgiveness of salary	$ 50,000	$ 2,614,790
Note payable, related party assigned to Note payable	$ 266,667	$ -
Stock issued for exercise of options in exchange for note payable, related parties	$ -	$ 100,000
Discount on convertible note payable	$ -	$ 60,000
Stock issued for conversion of notes	$ 636,866	

The accompanying notes are an integral part of these financial statements

JUPITER NEUROSCIENCES, INC.
NOTES TO FINANCIAL STATEMENTS
December 31, 2024 and 2023

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 has developed a unique resveratrol platform product primarily targeting treatment of neuro-inflammation. The product candidate, called JOTROL, has many potential indications of use for rare diseases. We are primarily targeting Mucopolysaccharidoses Type 1, Friedreich's Ataxia, and MELAS. In the larger disease areas, we are primarily targeting Parkinson's Disease and Mild Cognitive Impairment/early Alzheimer's disease.

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.

The Company's activities and operations include a project funded by the U.S. National Institute on Aging, an institute of the U.S. National Institutes of Health ("NIH"): Safety and Pharmacokinetics of JOTROL for Alzheimer's Disease, Federal Award Identification Number R44AG067907-01A1 (the "Award"). The project encompassed a Phase 1 dose finding pharmacokinetics ("PK") study which was completed before December 31, 2021. The award end date was May 31, 2022. This Phase 1 PK study will be homogeneous for all indications where JOTROL will be used in Phase II and Phase III clinical trials.

On January 9, 2020, the Company effected a three-for-one (3:1) forward stock split whereby the Company (i) increased the number of authorized shares of common stock, $0.0001 par value per share, to 25,000,000 from 5,000,000 and (ii) increased by a ratio of three-for-one (3:1) 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.

On November 11, 2021, the Company increased the number of authorized shares of common stock, $0.0001 par value per share, to 45,000,000 from 25,000,000.

On January 25, 2022, the Company effected a one-for-two (1:2) reverse stock split whereby the Company (i) decreased the number of issued and outstanding shares of common stock, $0.0001 per share, from 13,076,608 to 6,538,304 and (ii) decreased by a ratio of one-for two (1:2) the number of retroactively issued and outstanding shares of common stock. Proportional adjustments for the reverse 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 reverse stock split.

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.

Note 2 – Significant Accounting Policies

Basis of presentation and 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, 2024 and 2023, the Company had no revenues from product sales and incurred a net loss of $2,439,625 and $4,783,689, respectively. Net cash used in operations for the years ended December 31, 2024 and 2023 was $3,911,004 and $480,953, respectively. As of December 31, 2024, the Company had a working capital surplus and accumulated deficit of $2,641,110 and $26,022,129, respectively.

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. It is the management's opinion that 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. The management approach requires companies to report segment financial information consistent with information used by management for making operating decisions and assessing performance as the basis for identifying the Company's reportable segments. The Company has identified one single reportable operating segment. The Company manages its business on the basis of one operating and reportable segment and derives revenues from selling its product and related services.

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, 2024 and 2023, respectively, include valuation of stock-based compensation, uncertain tax positions, 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. As of December 31, 2024 and 2023, the Company invested a portion of cash balances in a high yield savings account, which are included as cash equivalents on the balance sheets. As of December 31, 2024 and 2023, the cash balances exceed the FDIC limit of $250,000 by $3,519,510 and $0, respectively.

Note 2 – Significant Accounting Policies, continued

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, 2024, and 2023 were $492,660 and $954,793, 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, 2024 and 2023, 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, 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.

As of December 31, 2023, there were 1,359,375 warrants outstanding, 1,618,537 restricted stock units, and 10,336,882 stock options and 14 convertible notes payable, which are convertible into restricted fully-paid and non-assessable shares of the Company's common stock or units of common stock and warrants to purchase common stock, if units are offered in the Initial Public Offering equal to the indebtedness divided by 70% of the offering price paid per share of at which the IPO is made. These securities are considered dilutive securities which were excluded from the computation since the effect is anti-dilutive.

Note 2 – Significant Accounting Policies, continued

Stock-Based Compensation

The Company accounts for stock-based compensation in accordance with the provisions of Accounting Standards Codification ("ASC") Topic 718, Compensation—Stock Compensation, or ASC 718, which requires the recognition of expense related to the fair value of stock-based awards in the statements of operations. 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.

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

The following table represents the Company's financial instruments that are measured at fair value on a recurring basis at each reporting period for each fair value hierarchy level:

	Derivative Liability December 31, 2024	Derivative Liability December 31, 2023
Level I	$ -	$ -
Level II	$ -	$ -
Level III	$ -	$ 1,505,398
Total	$ -	$ 1,505,398

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 principle 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 to be separately accounted for in accordance with ASC 815-10 – *Derivative and Hedging – Contract in Entity's Own Equity*. 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.

Leases

In February 2016, the Financial Accounting Standards Board ("FASB") issued ASU 2016-02, Leases (Topic 842). The updated guidance requires lessees to recognize lease assets and lease liabilities for most operating leases. In addition, the updated guidance requires that lessors separate lease and non-lease components in a contract in accordance with the new revenue guidance in ASC 606.

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.

Note 2 – Significant Accounting Policies, continued

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.

In August 2020, the FASB issued ASU 2020-06, Debt - Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging – Contracts in Entity's Own Equity (Subtopic 815-40) – Accounting for Convertible Instruments and Contracts in an Entity's Own Equity. The ASU simplifies accounting for convertible instruments by removing major separation models required under current GAAP. Consequently, more convertible debt instruments will be reported as a single liability instrument with no separate accounting for embedded conversion features. The ASU removes certain settlement conditions that are required for equity contracts to qualify for the derivative scope exception, which will permit more equity contracts to qualify for the exceptions. The ASU also simplifies the diluted net income per share calculation in certain areas. The new guidance is effective for fiscal years beginning after December 15, 2023, including interim periods within those fiscal years, and early adoption is permitted. The Company's adoption of this standard did not have a material impact on the Company's financial statements.

In November 2023, the FASB issued Accounting Standards Update 2023-07 - Segment Reporting (Topic ASC 280) Improvements to Reportable Segment Disclosures. The ASU improves reportable segment disclosure requirements, primarily through enhanced disclosure about significant segment expenses. The enhancements under this update require disclosure of significant segment expenses that are regularly provided to the Chief Operating Decision Maker ("CODM") and included within each reported measure of segment profit or loss, require disclosure of *other segment items* by reportable segment and a description of the composition of *other segment items*, require annual disclosures under ASC 280 to be provided in interim periods, clarify use of more than one measure of segment profit or loss by the CODM, require that the title of the CODM be disclosed with an explanation of how the CODM uses the reported measures of segment profit or loss to make decisions, and require that entities with a single reportable segment provide all disclosures required by this update and required under ASC 280. The Company adopted ASU 2023-07 for the annual period ending December 31, 2024.

The Company's Chief Executive Officer serves as the CODM.

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 and 2023 was $146,432 and $358,479, respectively. The loan is due on demand and accrues interest at 3% per year. Accrued interest relating to the loan was $1,064 and $11,308 as of December 31, 2024 and 2023, respectively, and is included in accrued interest on the accompanying balance sheets. 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.

During the year ended December 31, 2023, an employee loaned the Company $25,000. The balance of the loan as of December 31, 2024 and 2023, was $0 and $25,000, respectively. The loan is due on demand and accrues interest at 3% per year. Accrued interest related to the loan was $0 and $723 as of December 31, 2024 and 2023, respectively, and is included in accrued interest on the accompanying balance sheet. The Company repaid a total of $26,422 during the year ended December 31, 2024, $25,000 in principal and $1,421 in accrued interest.

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. 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 November 2022 the Company stopped paying 100% salaries in an effort to conserve cash.

Note 3 – Related Party Transactions, continued

On September 29, 2023, various employees and board members agreed to forgive accrued compensation in the amount of $4,189,626. In exchange of the forgiveness the Company issued an aggregate of 2,353,661 stock options with an exercise price of $1.33 and an aggregate of 1,399,834 restricted stock units with a grant date value of $1.33 in exchange for the aggregate forgiveness of compensation in the amount of $4,189,626. Additionally, the Company agreed to a bonus of $513,013 for the employees and a bonus of $70,200 to the board members, to be paid upon the occurrence of a successful IPO in exchange for the forgiveness of the afore-mentioned accrued compensation.

On December 18, 2023, various employees and board members agreed to amend the accrued compensation debt forgiveness dated September 29, 2023. Pursuant to the amendment the cash bonuses of $513,013 for the employees and a bonus of $70,200 to the board members agreed to on September 29, 2023, were forgiven, and no cash will be paid upon a successful IPO. In addition, the options issued in connection with the forgiveness dated September 29, 2023, have been amended to vest fully on the effective date of the new amendment. In addition, the restricted stock unit issued in connection with the forgiveness dated September 29, 2023, were terminated and replaced with 1,399,834 restricted stock units that vest upon the earlier occurrence of the initial public offering or a change of control of the Company. In exchange for the forgiveness of the accrued bonuses the Company issued an aggregate of 289,294 stock options with an exercise price of $1.33 and an aggregate of 218,703 restricted stock units with a grant date value of $1.33 in exchange for the aggregate forgiveness of compensation in the amount of $583,213.

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 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. 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, 2024	December 31, 2023
Accounts payable	$ 278,676	$ 189,495
Professional fees	40,271	174,053
License fee	75,000	150,000
Credit cards	2,536	32,466
Total accounts payable and accrued expenses	$ 396,483	$ 546,014

As of December 31, 2024 and 2023, $64,105 and $67,750, respectively, was due to a Company wholly owned by the Company's Chief Financial Officer, who also is an option holder. The amount is included in accrued compensation on the Company's balance sheets.

Accrued compensation of $1,415,093 and $1,562,041 as of December 31, 2024 and 2023, 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

Convertible Debt I

Between August and December 2021, the Company executed twelve convertible promissory notes ("Notes I") for $527,650 in proceeds with a maturity date of July 31, 2022, and interest rate of 1%. The Notes I will automatically convert into equity securities on the first business day following effectiveness of an initial public offering of common stock with the Securities and Exchange Commission ("IPO"). Upon IPO, the outstanding principle of the Notes I and all unpaid accrued interest will automatically convert into a number of restricted fully paid and non-assessable shares of common stock, or units of common stock and warrants to purchase common stock if units are offered to the public in the IPO, equal to the indebtedness divided by 70% of the offering price paid per share at which the IPO is made. For the avoidance of doubt, in the event the IPO is not declared effective prior to the maturity date, none of the indebtedness shall convert or be convertible into shares of Common Stock.

At the time of execution, the Company recorded a debt discount of $257,650 based on the fair value of the embedded conversion feature of Notes I, which was amortized into interest expense over term of Notes I, each with a maturity date of July 31, 2022. On August 6, 2022, the Notes I were amended to extend the maturity date to January 31, 2023, and increase the interest rate to 5%. All other terms remain the same as previously stated in Notes I. The impact of the amendment is prospective and increased accrued interest by $23,072 and is included in accrued interest on the accompanying balance sheet. On February 2, 2023, the Notes I were amended to extend the maturity date to December 31, 2023. During January 31, 2024, the Company and all Note I holders agreed to amend and extend the maturity date of their notes to December 31, 2024. The holders waived any default under the original notes prior to the amendment date. With the amendments the applicable interest rate to Notes I increased to 10% effective from January 1, 2024. The amendments were accounted for as a modification and not an extinguishment of debt, therefore there was no gain recorded in the statement of operations.

Convertible Debt I

Upon the closing of the IPO on December 4, 2024, the outstanding principal and all unpaid accrued interest, totalling $636,852, 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.

Senior Secured Note – Formerly Known as the Convertible Debt II

The Note - On April 11, 2022, the Company entered into a securities purchase agreement with an accredited investor (the "Holder"). Pursuant to the terms of the securities purchase agreement, the Company received aggregate gross proceeds of $1,000,000, less loan origination costs of $22,667, and issued a (i) 10% original issue discount senior secured convertible note (the "Note II") in the principal amount of $1,111,111 and (ii) 514,403 shares of common stock.

The Company will have the right at any time to redeem in cash all or a portion of Note II at 120% (or 125% on or after the first six months from the closing) of the principal amount thereof plus any unpaid accrued interest to the date of repayment.

Pursuant to the terms of the securities purchase agreement, the Company received aggregate gross proceeds of $1,000,000, less loan origination costs of $22,667, and issued a (i) 10% original issue discount senior secured convertible note (the "Note II") in the principle amount of $1,111,111 and (ii) 514,403 shares of common stock.

Upon an Event of Default (as defined therein) interest shall accrue at 1 1/2% per month and the 125% of principal and interest through maturity shall be due and payable. At the Holder's option the Holder shall be entitled to be paid in cash or after the Qualified Offering (as defined in the Purchase Agreement) common stock with the conversion price of the common stock equal to a 30% discount to the lowest closing price of the common stock for the 20 prior trading days.

On October 10, 2022, Note II was amended to postpone the commencement of the principal payments from October 11, 2022 to November 11, 2022. As consideration for the amendment, an additional 42,867 shares of common stock were issued to the Holder on October 10, 2022, valued at $1/12^{th}$ of the original 514,403 shares issued at commencement of Note II.

Note 5 – Convertible Debt and Derivative Liability, continued

On November 10, 2022, Note II was amended to postpone the commencement of the principle from November 11, 2022 to February 11, 2023 and payable in three monthly instalments. An additional 128,599 shares of common stock were issued to the Holder on November 10, 2022, value at 1/4th of the original 514,403 shares issued at commencement of Note II.

On February 6, 2023, Note II was amended to postpone the commencement of the principle to February 28, 2023. On March 6, 2023, Note II was amended to postpone the commencement of the principal from February 11, 2023 to May 31, 2023. The Company and the noteholder agreed to a repayment plan on past due interest. In addition, the Company agreed to prepay in cash the aggregate principal amount of the Note II of 120% (or 137.5% on or after the first six months from closing) plus any accrued interest on the sale of all the assets of the Company and its subsidiaries, upon the Change of Control, or on a Qualified Offering. Upon default of Note II, the Company agrees to pay 137.5% of the outstanding note principal, and accrued interest through maturity and all liquidation damages. As a result of the material modification, the incremental fair value of the modified derivative was classified as a debt extinguishment. Due to the extension of the maturity date of the convertible note, the fair value of the derivative liability increased. This resulted in the Company recording a loss on extinguishment of debt of $670,419.

Senior Secured Note – Formerly Known as the Convertible Debt II, continued

On September 22, 2023, Note II was amended to postpone the commencement of the principle to December 31, 2023. The Company and the noteholder agreed to a repayment plan on past due interest. In addition, the Company agreed to prepay in cash the aggregate principal amount of the Note II of 120% (or 150% on or after the first six months from closing) plus any accrued interest on the sale of all the assets of the Company and its subsidiaries, upon the Change of Control, or on a Qualified Offering. Upon default of Note II, the Company agrees to pay 150% of the outstanding note principal and accrued interest through maturity and all liquidation damages. In addition, upon closing the Note Holder will receive 175% stock coverage. As a result of the material modification, the incremental fair value of the modified derivative was classified as a debt extinguishment. Due to the extension of the maturity date of the convertible note, the fair value of the derivative liability increased. This resulted in the Company recording a loss on extinguishment of debt of $217,527.

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.

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.

Ancillary Agreements - In connection with the Company's obligations under Note II, 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 Note II and the other transaction documents.

Note 5 – Convertible Debt and Derivative Liability, continued

Convertible Debt III

On March 1, 2023, the Company issued a convertible promissory note (the "Note III") with a principal amount of $150,000 as part of a settlement agreement with an investor relations firm. Note III matures on February 28, 2026 and accrues interest at 5% annually which compounds quarterly. Note III is convertible upon election of the holder upon a qualified financing of at least $5,000,000 into shares of common stock equal to 70% of the per share price of the equity issued in the qualified financing. Note III is also convertible upon the completion of an IPO by the Company into shares of common stock equal to 70% of the per share price of the equity issued in connection with the IPO. In both cases the Holder can elect to receive the principal and accrued interest instead of converting the note.

During December 2024, the Company fully repaid the Convertible Debt III pursuant to the terms in the amount of $178,386.

Summary

During the years ended December 31, 2024 and 2023, $147,705 and $143,761, respectively, are included in interest expense for the combined convertible Notes I, II and III on the accompanying statements of operations. As of December 31, 2024 and 2023 the balance of the combined convertible promissory Note I, II and III was $0 and $1,745,472, respectively, net of the debt discount and loan origination costs of $0 and $43,288, respectively.

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, under the provisions of ASC 815-40 *–Derivatives and Hedging – Contracts in an Entity's Own Stock*, 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 years ended December 31, 2024 and 2023, the derivative liabilities were revalued, and a $857,723 and $(887,946), respectively, adjustment was recorded as a gain/ (loss) on extinguishment of debt to other expenses reflected in the accompanying statements of operations.

The Company also recorded $(53,257) and $148,751 as a (loss) / gain on the change in the fair value of the derivative liability for the years ended December 31, 2024 and 2023, respectively.

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:

	NOTE III	NOTES I, II & III	NOTES I, II & III
	March 1, 2023 (Issuance)	December 31, 2023	December 31, 2024
Dividend Rate	-	-	-
Term	0.25	0.25	0.13
Volatility	90%	90%	90%
Risk-free rate	N/A	4.70%	5.00%
Probability of IPO	60%	60%	60%

Note 5 – Convertible Debt and Derivative Liability, continued

Derivative Liability Pursuant to Convertible Debt, continued

A summary of activity of the derivative liability pertaining to the Notes is presented below:

	Derivative Liability
Balance at December 31, 2022	$ 710,599
Fair value at issuance March 1, 2023	55,604
Fair value adjustment on date of amendment, net	887,946
Fair value change	(148,751)
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	**$ -**

Note 6 – Stockholders' Equity (Deficit)

Common Stock

The Company is authorized to issue 125,000,000 shares of common stock and 5,000,000 shares of preferred stock. The Company had 33,103,860 shares of common stock issued and outstanding as of December 31, 2024. There was no preferred stock issued and outstanding as of December 31, 2024.

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, 2024, the Company recorded compensation expense for services provided of $893,781 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.

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.

The Company intends to use the proceeds primarily to fund the Phase II clinical trial of its product candidate JOTROL™ in patients with Parkinson's Disease, Strategic Service Agreements to accelerate business activities in South-East Asia, research and development activities regarding evaluation of new product opportunities, payment of the outstanding annual license fees due to Aquanova AG, the repayment of debt, working capital and other general corporate purposes.

Stock Options

The Company grants stock awards to officers, employees, directors, and other key persons pursuant to its 2021 Equity Incentive Plan ("the Plan").

Note 6 – Stockholders' Equity (Deficit), continued

During the year ended December 31, 2024 and 2023, the Company recognized stock-based compensation of $947,124 and $1,198,579, respectively, related to vested stock options. There was $355,829 unvested stock options expense as of December 31, 2024.

On January 1, 2023, the Company granted a non-qualified stock option to purchase 562,500 shares of Common Stock to our Chief Financial Officer, at an exercise price of $1.33 per share. The option had a grant date fair value of $589,500.

On April 1, 2023, the Company granted non-qualified stock option to purchase an aggregate of 562,500 shares of Common Stock to an employee and consultants, at an exercise price of $1.33 per share. The options had an aggregate grant date fair value of $577,500.

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.

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, 2024 and 2023 is presented below:

	Number of Options	Weighted Average Exercise Price	Weighted Average Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2022	6,682,560	$ 0.89	6.40	$ 3,376,725
Granted	3,767,955	1.33		
Exercised	(113,633)	0.88		
Forfeited	-			
Outstanding as of December 31, 2023	10,336,883	$ 1.00	6.91	$ 3,316,119
Granted	297,105	1.33		
Exercised	-	-		
Forfeited	-	-		
Outstanding as of December 31, 2024	10,633,988	$ 1.02	6.25	$ 102,921,147
Exercisable as of December 31, 2024	10,297,412	$ 1.01	6.18	$ 99,768,543
Exercisable as of December 31, 2023	9,424,826	$ 1.00	6.76	$ 3,276,119

The following table summarized information about employee stock options outstanding as of December 31, 2024 and 2023:

	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
$ 0.80	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

Note 6 – Stockholders' Equity (Deficit), continued

	Outstanding Options		Vested Options	
Exercise Price	Number Outstanding at December 31, 2023	Weighted Average Remaining Life	Number Exercisable at December 31, 2023	Weighted Average Remaining Life
$ 0.01	675,000	2.51	675,000	2.51
$ 0.74	1,657,560	5.57	1,657,564	5.57
$ 0.80	2,783,243	5.80	2,708,239	5.62
$ 1.33	5,164,830	4.51	4,327,774	4.92
$ 2.16	56,250	7.96	56,250	7.71
	10,336,883	6.91	9,424,826	6.76

Warrants

The following is a summary of the Company's warrant activity for the year ended December 31, 2024 and 2023:

	Number of Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Life (Years)
Outstanding as of December 31, 2022	1,359,375	$ 0.80	0.98
Granted	-	-	-
Forfeited	-	-	-
Outstanding as of December 31, 2023	1,359,375	$ 0.80	0.64
Granted	-	-	-
Forfeited	-	-	-
Outstanding as of December 31, 2024	1,359,375	$ 0.80	0.93

Restricted Stock Units

On September 29, 2023, the Company issued an aggregate of 1,399,834 restricted stock units with a grant date value of $1.33 per unit in exchange for the forgiveness of accrued compensation. Pursuant to the amendment dated December 18, 2023, the restricted stock units shall vest on the on earlier event of either the occurrence of an initial public offering or in the event of change of control of the Company. The restricted stock units have an aggregate grant date fair value of $1,866,445.

On December 18, 2023, the Company terminated 1,399,384 restricted stock units and issued an aggregate of 1,618,537 restricted stock units with a grant date value of $1.33 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. The restricted stock units have an aggregate grant date fair value of $2,158,050.

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 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:

	2024	2023
Federal	21.00%	21.00%
State	2.07%	2.55%
Nondeductible expenses	-2.33%	-3.85%
Change in valuation allowance	-20.74%	-19.70%
Effective tax rate	-	-

Note 7 – Income Taxes, continued

A summary of the Company's deferred tax assets is as follows:

	2024	2023
U.S Federal and State net operating loss	$ 3,083,545	$ 2,429,544
Stock based compensation	1,272,925	1,031,860
Accrued salaries	382,288	395,899
Orphan drug credit	1,060,118	924,171
Derivative liability	-	370,572
Other	260,481	392,486
Total net deferred tax assets	6,059,357	5,544,532
Valuation allowance	(6,059,357)	(5,544,532)
Total Deferred Tax Asset	**$ -**	**$ -**

As of December 31, 2024, the Company had federal and state (post-apportioned basis) net operating losses ("NOLs") of $26 million, as well as federal orphan drug tax credit carryforwards of approximately $1.06 million. Approximately $10.0 million of the foregoing federal and state NOLs will expire at various dates from 2026 through 2043, 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.

Note 8 – Commitments and Contingencies, continued

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. The Company adopted ASC Topic 842, Leases upon inception of the lease.

As of December 31, 2024 and 2023, the Company's operating lease right-of-use asset, net (ROU) is $69,642 and $116,070, respectively, and the total lease liability is $71,329 and $119,542, respectively, based on an incremental borrowing rate of 0.81% at lease inception.

	December 31, 2024	December 31, 2023
Operating lease right-of-use asset ("ROU") is summarized below:		
Office lease ROU	$ 236,009	$ 236,009
Less accumulated reduction	(166,367)	(119,939)
Balance of ROU, net	$ 69,642	$ 116,070
Operating lease liability related to the ROU asset is summarized below:		
Office lease liability	$ 236,009	$ 236,009
Reduction of lease liability	(164,680)	(116,467)
Total	$ 71,329	$ 119,542

Future minimum lease liability payments under non-cancelable operating lease at December 31, 2024 and 2023 are as follows:

2024	-	49,004
2025	50,476	50,476
2026	21,290	21,290
	71,766	120,770
Less: imputed interest	(437)	(1,228)
Total lease liabilities	$ 71,329	$ 119,542
Current operating lease liabilities	50,082	48,213
Non-current operating lease liabilities	21,247	71,329
Total lease liabilities	$ 71,329	$ 119,542

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 $17,740 and $20,844 for the years ended December 31, 2024 and 2023, 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.

Note 8 – Commitments and Contingencies, continued

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 year ended December 31, 2024, the Company recorded prepaid contract expense of $54,612.

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.

***Licensing and Royalty Agreements* - Aquanova AG**

On September 15, 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 License Agreement is in effect until product launch, which is undeterminable at this time. The Chief Scientific Officer of the Company and the CEO of Aquanova 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 September 30, 2024. As of December 31, 2024 and 2023, $75,000 and $150,000 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.

Upon mutual agreement, the Company can 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.

Note 8 – Commitments and Contingencies, continued

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.

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, 2024.

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 will recognize stock based compensation expense from the effective date of the agreement through the date the obligations are 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. The future stock based compensation expense as of December 31, 2024 is $3,744,591.

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 CODM and evaluates the financial performance of the business and makes resource allocation decisions on a consolidated basis. As a result, the Company operates as a single reportable segment under ASC 280, Segment Reporting, defined by the CODM as JOTROL Drug Development.

The Company operates in one reportable segment, JOTROL Drug Development, which includes all activities related to the development of JOTROL, to address unmet medical needs and improve the lives of patients. The determination of a single reportable segment is consistent with the financial information regularly provided to the Company's CODM, who reviews and evaluates net loss for purposes of assessing performance, making operating decisions, allocating resources and planning and forecasting for future periods. The measure of segment assets is reported on the balance sheet as total assets.

Note 10 – Subsequent Events

The Company evaluated events that have occurred after the balance sheet date but before the financial statements are issued. Based upon the evaluation and transactions, the Company did not identify any subsequent events that would have required adjustment or disclosure in the Financial Statements.

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: March 28, 2025

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)	March 28, 2025
/s/ Saleem Elmasri Saleem Elmasri	Chief Financial Officer (principal financial officer and principal accounting officer)	March 28, 2025
/s/ Marshall Hayward, Ph.D. Marshall Hayward, Ph.D.	Director	March 28, 2025
/s/ Alison D. Silva Alison D. Silva	Director	March 28, 2025
/*s/ Nicholas H. Hemmerly* Nicholas H. Hemmerly	Director	March 28, 2025
/s/ Julie Kampf Julie Kampf	Director	March 28, 2025
/s/ Allison W. Brady Allison W. Brady	Director	March 28, 2025
/s/ Holger Weis Holger Weis	Director	March 28, 2025

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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, 2024 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: March 28, 2025

/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, 2024 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: March 28, 2025

/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, 2024 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: March 28, 2025

/s/ Christer Rosén
Christer Rosén
Chief Executive Officer (principal executive officer)

Date: March 28, 2025

/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.

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