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 SECTIONS 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from_____ to _____

Commission file number 001-32188

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

Florida	**59-3410522**
(State or Other Jurisdiction of Incorporation or Organization)	**(IRS Employer Identification No.)**
1990 Main St Suite 750 Sarasota, FL	**34326**
(Address of Principal Executive Offices)	**(Zip Code)**

813-286-7900
(Registrant's Telephone Number, Including Area Code)

SECURITIES REGISTERED PURSUANT TO SECTION 12(b) OF THE ACT:

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock $0.001 par value per share	OGEN	NYSE AMERICAN

SECURITIES REGISTERED PURSUANT TO SECTION 12(g) OF THE ACT:
None

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

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

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the 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, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

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

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

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

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

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

The aggregate market value of the voting and non-voting common equity stock held by non-affiliates of the registrant, was approximately $4,740,189 computed based upon a last sales price of $1.04 as reported by the NYSE American as of June 28, 2024.

As of March 10, 2025, there were 21,475,289 shares of the registrant's Common stock outstanding.

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FORWARD LOOKING STATEMENTS AND CERTAIN CONSIDERATIONS

This report, along with other documents that are publicly disseminated by us, contains or might contain forward-looking statements within the meaning of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). All statements included in this report and in any subsequent filings made by us with the Securities and Exchange Commission (the "SEC") other than statements of historical fact, that address activities, events or developments that we or our management expect, believe or anticipate will or may occur in the future are forward-looking statements. These statements represent our reasonable judgment on the future based on various factors and using numerous assumptions and are subject to known and unknown risks, uncertainties and other factors that could cause our actual results and financial position to differ materially. We claim the protection of the safe harbor for forward-looking statements provided in the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act and Section 21E of the Exchange Act. Examples of forward-looking statements include: (i) projections of revenue, earnings, capital structure and other financial items, (ii) statements of our plans and objectives, (iii) statements of expected future economic performance, and (iv) assumptions underlying statements regarding us or our business. Forward-looking statements can be identified by, among other things, the use of forward-looking language, such as "believes," "expects," "estimates," "may," "will," "should," "could," "seeks," "plans," "intends," "anticipates" or "scheduled to" or the negatives of those terms, or other variations of those terms or comparable language, or by discussions of strategy or other intentions.

Forward-looking statements are subject to known and unknown risks, uncertainties and other factors that could cause the actual results to differ materially from those contemplated by the statements. The forward-looking information is based on various factors and was derived using numerous assumptions. Important factors that could cause our actual results to be materially different from the forward-looking statements include the following risks and other factors discussed under the Item 1A "Risk Factors" in this Annual Report on Form 10-K. These factors include:

- We have incurred significant operating losses since our inception and cannot assure you that we will generate revenues or achieve profitability;
- We need to raise additional capital to continue to implement our business strategy and we may not be able to do so;
- Our ability to obtain funding, non-dilutive or otherwise, necessary to do the research, development, manufacture, and commercialization of any one or all of our product candidates;
- Our ability to maintain our listing on the NYSE American;
- The timing, progress and results of clinical trials of our product candidates;
- Uncertainties regarding submission, approval and scope of filings for regulatory approval of our product candidates and our ability to obtain and maintain regulatory approvals for our product candidates for any indication;
- Uncertainties regarding the potential benefits, activity, effectiveness and safety of our product candidates including as to administration, distribution and storage;
- Uncertainties regarding the size of the patient populations, market acceptance and opportunity for and clinical utility of our product candidates, if approved for commercial use;
- Our manufacturing capabilities and strategy, including the scalability and commercial viability of our manufacturing methods and processes, and those of our contractual partners;
- Our ability to successfully commercialize our product candidates;
- Uncertainties regarding our expenses, ongoing losses, future revenue, capital requirements;
- Our ability to identify, recruit and retain key personnel and consultants;
- Our ability to obtain, retain, protect, and enforce our intellectual property position for our product candidates, and the scope of such protection;
- Our ability to advance the development of our new and existing product candidate under the timelines and in accord with the milestones projected;
- Our need to comply with extensive and costly regulation by worldwide health authorities, who must approve our product candidates prior to substantial research and development and could restrict or delay the future commercialization of certain of our product candidates;
- Our ability to successfully complete pre-clinical and clinical development of, and obtain regulatory approval of our product candidates and commercialize any approved products on our expected timeframes or at all;
- The safety, efficacy, and benefits of our product candidates;
- The effects of government regulation and regulatory developments, and our ability and the ability of the third parties with whom we engage to comply with applicable regulatory requirements;
- The capacities and performance of our suppliers and manufacturers and other third parties over whom we have limited control; and
- Our competitive position and the development of and projections relating to our competitors or our industry.

We caution investors that actual results or business conditions may differ materially from those projected or suggested in forward-looking statements as a result of various factors including, but not limited to, those described above and in the Risk Factors section of this report. We cannot assure you that we have identified all the factors that create uncertainties. Moreover, new risks emerge from time to time, and it is not possible for our management to predict all risks, nor can we assess the impact of all risks on our business or the extent to which any risk, or combination of risks, may cause actual results to differ from those contained in any forward-looking statements. Readers should not place undue reliance on forward-looking statements. Except as required by applicable law, we undertake no obligation to publicly release the result of any revision of these forward-looking statements to reflect events or circumstances after the date they are made or to reflect the occurrence of unanticipated events.

PART I

ITEM 1. BUSINESS.

This description contains certain forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from the results discussed in the forward-looking statements as a result of certain of the risks set forth herein. We assume no obligation to update any forward-looking statements contained herein.

Overview

We are a development-stage company dedicated to the research and development of nasal delivery pharmaceutical medications in neurology and fighting infectious diseases. Our lead product ONP-002 is a fully synthetic, non-naturally occurring neurosteroid, is lipophilic, and is designed to cross the blood-brain barrier with the goal of rapidly reducing swelling, oxidative stress and inflammation while restoring proper blood flow through gene amplification.

Our ONP-002 Neurology Asset for Brain Related Illness and Injury

Following our December 2023 acquisition of certain assets from Odyssey Health, Inc. ("Odyssey") related to the segment of Odyssey's business focused on developing medical products that treat brain related illnesses and diseases (the "Neurology Assets") our lead product and focus is on the development and commercialization of ONP-002 for the treatment of mild traumatic brain injury ("mTBI" or "Concussion").

ONP-002 to date has been shown to be stable up to 104 degrees for 18 months. The drug candidate is spray-dry manufactured into a powder and filled into the novel intranasal device. The drug is then administered through the nasal passage from the device. The novel intranasal device is lightweight and easy to use in the field.

We believe the proprietary powder formulation and intranasal administration allows for rapid and direct accessibility to the brain. The device is breath-propelled and we expect it to allow patients to blow into the device which closes the soft palate in the back of the nasopharynx, preventing the flow of drug to the lungs or esophagus, minimizes system exposure and side effects, and easily crosses the blood brain barrier. This mechanism is designed to trap ONP-002 in the nasal cavity allowing for more abundant and faster drug availability in the traumatized brain.

Expected ONP-002 Product Development Timeline:

Pre-clinical Animal Studies	Phase 1	Phase 2a Australia	Phase 2b	Phase 3
Complete	Complete	Estimated Q1/Q2 2025 start	Estimated Q1 2026 start	Estimated Q1 2027 start

This product development plan is an estimate and is subject to change based on funding, technical risks and regulatory approvals.

Validation and Stability of ONP-002

A Certificate of Analysis (COA) was issued by the manufacturer of the drug, indicating that testing methods were standard and include appearance, identification by 1H NMR (a technique used to determine the structure of organic molecules), identification by Mass Spectroscopy (MS), optical purity by HPLC, residual solvent analysis, elemental impurities, percent water, and residue on ignition. The manufacturer has shown both the specifications and the results, indicating that the material supplied passes all criteria. ONP-002 is supplied in pure form. As such, no excipients are present. Stability studies were performed by storing samples under carefully controlled conditions with respect to temperature and humidity. The stability testing protocol included storage at 25 °C± 2 °C at 60% relative humidity ± 5% relative humidity for 24 months and 40 °C± 2 °C at 75% relative humidity ± 5% for 18 months. Samples were pulled at the scheduled time and analyzed for appearance, purity, assay, optical purity, and water content. No changes in ONP-002 were seen.

Intellectual Property

Patent applications that concern ONP-002 and the nasal delivery device have been filed as follows:

- New chemical entity patent filings concerning the C-20 steroid compounds haves been filed with the USPTO and are pending in the U.S. To date, national patents in 9 different countries have been granted, including European countries and Canada. A bundle of patents under the European Patent Convention have also been granted.
    - C-20 steroid compounds, composition and uses thereof to treat traumatic brain injury (TBI), including concussion.
    - Inventions relate to, inter alia, ONP-002 compositions, methods of use to treat, minimize and/or prevent traumatic brain injury (TBI), including severe TBI, moderate TBI, and mild TBI, including concussions, methods of manufacture and/or synthesis, products by process, and intermediates.
    - An issued U.S. patent expiration with 5-year maximum patent term extension - 9/17/2040.
    - An issued U.S. patent expiration without patent term extension - 9/17/2035.
- Multiple nasal delivery device patent applications concerning the Breath-Powered Nasal Devices and Uses Thereof haves been filed in the U.S. with the USPTO as utility patent applications. In addition, multiple nationalized patent applications drawn to the Breath-Powered Nasal Devices and Uses Thereof have been filed in over 60 countries.
    - Breath-Powered Nasal Devices and Uses Thereof for Treatment of TBI, Including Concussion, and Methods.
    - Inventions relate to, inter alia, breath-powered nasal devices, single-directional breath-powered nasal devices for providing dual airflow for propelling a drug substance into a nasal cavity for targeted delivery to the olfactory region in high drug substance concentration for rapid diffusion into the brain for the treatment of local or systemic and/or central nervous system ("CNS") injury, disease or disorder, and methods of treating local or systemic and/or CNS injury, disease or disorder with such devices.
    - An exemplary issued U.S. patent expiration - 10/19/2042.

ONP-002 Development and Studies

ONP-002 Pre-Clinical Trials

The ONP-002 drug has completed toxicology studies in rats and dogs. Those studies show that ONP-002 has a large safety margin for its predicted efficacious dose. In preclinical animal studies, the drug demonstrated rapid and broad biodistribution throughout the brain while simultaneously reducing swelling, inflammation, and oxidative stress, along with an excellent safety profile.

Results from the preclinical studies suggest that ONP-002 has an equivalent, and potentially superior, neuroprotective effect compared to related neurosteroids. The animals treated with the drug post-concussion showed positive behavioral outcomes using various testing platforms including improved memory and sensory-motor performance, and reduced depression and anxiety-like behaviors.

ONP-002 Induction of Pregnane X Receptor (PXR)

The induction of the human CYP450 enzymes, CYP2B6, and CYP3A4, by ONP-002, as measured by mRNA expression, was tested in human hepatocytes from 3 donors at 3 concentrations: 1 μM, 10 μM and 100 μM. Results reflected that ONP-002, through the known PXR-mechanism, produced a modest induction of CYP3A4, up to 17% of the positive control, and a greater induction of CYP2B6, of up to 59% of the positive control, both at a concentration of 100 μM. Past data reflected that ONP-001 (ent-Progesterone) and Progesterone induce the PXR receptor. Receptor binding studies have been performed showing neither ONP-001 or ONP-002 activate the classical Progesterone Receptor.

ONP-002 Animal Studies

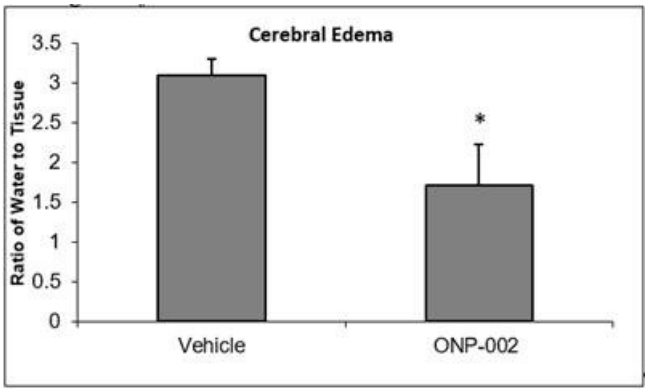
All surgical animals (male Sprague-Dawley rats weighing approximately 250 grams) were anesthetized with an initial isoflurane induction for 4 minutes, the minimum time necessary to sedate the animal. The scalp was shaved and cleaned with isopropanol and betadine. During the stereotaxic surgery, anesthesia was maintained with isoflurane. A medial incision was made, and the scalp was pulled back over the medial frontal cortex. A 6mm diameter craniotomy was performed exposing the brain tissue. An electrically controlled injury device using a 5mm metal impactor was positioned over the exposed brain. An impact speed of 1.6 m/s at a 90-degree angle from vertical was used to produce an open head injury at a depth of 1mm to create a milder TBI. All treatments were given intranasal (IN) as a liquid solution with a micro atomizer. Vehicle for all administrations was 22.5% Hydroxy-Propyl-β-cyclodextrin (HPβCD).

Molecular Studies - Brain tissue was taken from the penumbral region of injury.

Cerebral Edema

In Figure 1, we show that ONP-002 reduces swelling in rats compared to vehicle-treated at 24hours after brain injury by measure of brain water content through speed-vacuum dehydration and tissue weight comparisons. ONP-002-treated (4mg/kg) and vehicle-treated were compared to sham which was set at zero. Local edema can occur after mTBI. Severe cerebral edema is associated with poor outcomes including increased mortality after mTBI with Second Impact Syndrome (2). ***Denotes significance at p<0.05, n=6***

Figure 1



Inflammation

mTBI causes vascular and neuronal stress. Microglia and reactive astrocytes infiltrate the areas of injury and release inflammatory mediators like TNF-alpha. We show that ONP-002 (4mg/kg) reduces TNF-alpha-mediated neuroinflammation in brain tissue of rats compared to vehicle at 24 hours after mTBI (ELISA).

Pharmacokinetics and Safety of IN ONP-002 in Dogs

This pivotal GLP 14-day study used repeat dosing of ONP-002, 3X a day, approximately 4 hours apart, for 14 consecutive days at concentrations of 0, 3, 10 or 23 mg/mL at a volume of 1ml/nostril to beagle dogs (both nostrils had drug administered). The IN treatment was given as a liquid solution using a micro atomizer using 22.5% HPβCD as the vehicle. IN ONP-002 dosing revealed that ONP-002 was well tolerated up to the highest dose of 23mg/ml or 46mg in total per dosing. Clinical observations were limited to increased salivation in dogs which occurred in a dose-dependent manner. There were no effects on body weight, food consumption, ophthalmic parameters, clinical chemistry, hematology, or organ weights at any of the doses tested. Microscopic analysis revealed purulent exudates in the nasal turbinate and evidence of inflammatory infiltrates and fibrin deposition in the lungs. All of these events were classified as mild, reversed during the recovery period, and did not appear to show any dose dependency. Similar findings were evident in vehicle control treated dogs indicating the findings were vehicle related. The highest dose of 23mg/ml was thus determined to be the no-observed-adverse-effect level (NOAEL), which is equivalent to a ONP-002 dose of 1.5mg/kg and 2.3mg/kg in male and female dogs, respectively. Testing shows the dose-dependent increase in plasma exposure of ONP-002 in male and female dogs following IN administration. Plasma exposure levels were similar in males and females and there did not appear to be any evidence of drug accumulation following multiple doses.

Cardiopulmonary Safety Pharmacology

The effect of ONP-002 on the human ether-a-go-go related gene (hERG) tail currents was assessed in a non-Good Laboratory Practice (GLP) study using manual whole-cell patch clamp. ONP-002 tested at a single concentration of 10μM inhibited hERG tail currents by 42.6% (n=3). In order to achieve a safety factor of 30-fold between in vitro hERG IC50 and free plasma levels of ONP-002 in clinical studies, Cmax should not exceed a free drug concentration of 0.33μM (99ng/ml). ONP-002 is 97.2% human plasma protein bound and is estimated to reach a plasma Cmax of 12.5nM, the highest dose of 0.533mg/kg to be administered in the planned first in human (FIH) study, which provides a safety factor of 800-fold. A GLP study is planned at Charles River, Inc. and will be performed prior to IND submission.

ONP-002 Clinical Trials

ONP-002 has completed a Phase 1 clinical trial in healthy human subjects showing it is safe and well tolerated.

Safety studies have established a dosing regimen of 2X/day for fourteen days. The Phase I clinical trial was performed in Melbourne, Australia with a Contract Research Organization (CRO), Avance Clinical Pty Ltd and Nucleus Network Pty Ltd. The country of Australia provides a currency exchange advantage and a tax rebate at the end of our fiscal year from the Australian government on all Research and Development performed in Australia.

The Phase 1 study was double-blinded, randomized and placebo controlled (3:1, drug:placebo). Phase 1 used a Single Ascending/Multiple Ascending (SAD/MAD) drug administration design. The SAD component was a 1X treatment (low, medium, or high dose) and the MAD component was a 1X/day treatment for five consecutive days (low and medium dose). Blood and urine samples were collected at multiple time points for safety pharmacokinetics. Standard safety monitoring was provided for each body system.

Forty human subjects (31 males, 9 females) were successfully enrolled in Phase I. The Safety Review Board, made up of medical doctors, has reviewed the trial data and has determined the drug is safe and well tolerated at all dosing levels.

We anticipate preparing for Phase 2b clinical trials to further evaluate ONP-002's safety and efficacy. Based on the Phase I data, we plan to apply for an Investigational New Drug application (IND) with the FDA and conduct a Phase 2b trial in the U.S.

We anticipate a Phase 2 clinical trial will be performed administering ONP-002 intranasally in concussed patients 2x a day for up to fourteen days. The Phase 2a feasibility study is expected to be performed in Australia with a target initiation date in the first or second quarter of 2025 to be followed closely by a Phase 2b proof of concept study in the U.S.

Business Development Strategy

Success in the biopharmaceutical and product development industry relies on the continuous development of novel product candidates. Most product candidates do not make it past the clinical development stage, which forces companies to look externally for innovation. Accordingly, we expect, from time to time, to seek strategic opportunities through various forms of business development, which can include strategic alliances, licensing deals, joint ventures, collaborations, equity or debt-based investments, dispositions, mergers, and acquisitions. We view these business development activities as a necessary component of our strategies, and we seek to enhance shareholder value by evaluating business development opportunities both within and complementary to our current business, as well as opportunities that may be new and separate from the development of our existing product candidates.

Market Opportunity

Currently, we are focused on expanding our nasal drug delivery platform to the treatment of neurological brain disorders, illnesses and injuries, or concussions. We believe concussion treatment is a significant unmet need, and that, currently, there are no therapeutic treatments available for moderate to severe concussion. We further believe nasal delivery offers many advantages over standard systemic delivery systems, such as i) its non-invasive character, ii) fast onset of action, and iii) in most cases, reduced side effects due to a more targeted delivery.

Systemic approaches often fail to efficiently supply the central nervous system with drugs for the treatment of neurological disorders, which, we believe, presents a unique opportunity for intranasal drug delivery. The global nasal drug delivery technology market is projected to surpass $40 billion by 2030.

Growth Strategy

If the FDA clears or approves our product candidates to be marketed commercially, we intend to enter into agreements with industry partners or qualified distributors throughout the U.S. We intend to pursue a similar approach if our product candidates are cleared or approved for marketing outside of the U.S. We intend to require such partners or distributors to pay us an initial license fee, as well as royalties based on gross sales. Retaining exclusivity is expected to be based on a mutually agreeable semi-annual or quarterly sales minimum. We also anticipate focusing on international growth because, generally, we believe such international license agreements provide a stronger path to revenue and earnings than purely domestic products.

Our objective is to eventually grow revenue through marketing and sales of ONP-002 if it gains regulatory approvals. Although no assurances can be given, management anticipates company growth from the following areas:

1) **Distribution or License Agreements.** Once any of our products in development are approved by the appropriate regulatory agency, we plan to enter into distribution agreements with companies that have sales professionals with experience selling through a variety of sales methods. These distribution agreements should allow us to achieve sales and revenue more quickly in the medical products industries.
2) **Identify and develop our products for additional proprietary uses.** When funding allows, we intend to utilize our proprietary nasal delivery system to deliver other drugs to the brain to treat brain-related medical issues.
3) **The development and acquisition of new products.** We intend to pursue the development and acquisition of other product candidates and market any new products, if cleared or approved. We intend, as capital resources permit, to develop such opportunities if and when they present themselves.
4) **Seek partners to assist in the further development of our drug device combination products.** We intend to seek partners to assist with the further development and clinical trials of ONP-002. Partnerships could be in the form of government grants or from industry pharmaceutical companies who have an interest in brain-related drug therapies.

We currently have no products authorized for commercial distribution in the U.S., Europe, or any other country. We have development programs for devices and pharmaceutical drugs, which are in various stages of development. Currently we are only funding the development of ONP-002 which is intended to treat concussion. All of our products require regulatory clearance or approvals, and we cannot begin marketing and selling our product candidates until we obtain applicable authorizations from the respective regulatory agency.

Government Regulations

In the U.S., foods (including dietary supplements), drugs (including biological products), medical devices, cosmetics, tobacco products and radiation-emitting products are subject to extensive regulation by the FDA. The FDC Act and other federal and state statutes and regulations govern, among other things, the manufacture, distribution and sale of these products. These laws and regulations prescribe criminal and civil penalties that can be assessed, and violation of these laws and regulations can result in enforcement actions by the FDA and other regulatory agencies.

FDA Regulation of Drugs - New Drug Approval Process

Pharmaceutical products are subject to extensive regulation by the FDA. The FDC Act, and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of pharmaceutical products. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending NDAs or Biologics License Applications (BLAs), warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties and criminal prosecution.

Pharmaceutical product development for a new product or certain changes to an approved product in the U.S. typically involves the following steps before a biological product or new drug may be marketed in the U.S.:

- pre-clinical laboratory tests, animal studies and formulation studies in compliance with the FDA's Good Laboratory Practice and Good Manufacturing Practice regulations;
- submission to the FDA of an IND application for human clinical testing, which must become effective before human clinical trials may commence;
- performance of adequate and well-controlled clinical trials in three phases, as described below, to establish the safety and efficacy of the drug for each indication according to Good Clinical Practices;
- submission of an NDA or BLA to the FDA for review;
- random inspections of clinical sites to ensure validity of clinical safety and efficacy data;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with current good manufacturing practices;
- FDA approval of the NDA or BLA; and
- payment of user and establishment fees, if applicable.

Satisfaction of FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity and novelty of the product or disease.

Pre-clinical tests include laboratory evaluation of product chemistry, formulation and toxicity, as well as animal trials to assess the characteristics and potential safety and efficacy of the product. The conduct of the pre-clinical tests must comply with federal regulations and requirements, including good laboratory practices. The results of pre-clinical testing are submitted to the FDA as part of an IND along with other information, including information about product chemistry, manufacturing and controls, and a proposed clinical trial protocol. Long term pre-clinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted.

A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If the FDA has neither commented on nor questioned the IND within this 30-day period, the clinical trial proposed in the IND may begin.

Clinical trials involve the administration of the IND to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted: (i) in compliance with federal regulations; (ii) in compliance with good clinical practice, or GCP, an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators, and monitors; as well as (iii) under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND.

The FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. The trial protocol and informed consent information for patients in clinical trials must also be submitted to an institutional review board or IRB for approval. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions.

Clinical trials to support NDAs or BLAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap. In Phase 1, after the initial introduction of the drug into healthy human subjects or patients, the drug is tested to assess metabolism, pharmacokinetics, pharmacological actions, side effects associated with increasing doses, and, if possible, early evidence on effectiveness. Phase 2 usually involves trials in a limited patient population to determine the effectiveness of the drug for a particular indication, dosage tolerance, and optimum dosage, and to identify common adverse effects and safety risks. If a compound demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 trials are undertaken to obtain the additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit the FDA to evaluate the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the drug. In most cases the FDA requires two adequate and well-controlled Phase 3 clinical trials to demonstrate the efficacy of the drug. A single Phase 3 clinical trial with other confirmatory evidence may be sufficient in rare instances where the trial is a large multicenter trial demonstrating internal consistency and a statistically very persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity or prevention of a disease with a potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible.

The length of time and related costs necessary to complete clinical trials varies significantly and may be difficult to predict. Clinical trial results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. Additional factors that can cause delay or termination of our clinical trials, or cause the costs of these clinical trials to increase, include:

- slow patient enrollment due to the nature of the protocol, the proximity of patients to clinical sites, the eligibility criteria for the trial, competition with clinical trials for other drug candidates or other factors;
- inadequately trained or insufficient personnel at the trial site to assist in overseeing and monitoring clinical trials;
- delays in approvals from a trial site's IRB;
- longer than anticipated treatment time required to demonstrate effectiveness or determine the appropriate product dose;
- lack of sufficient supplies of the drug candidate for use in clinical trials;
- adverse medical events or side effects in treated patients; and
- lack of effectiveness of the drug candidate being tested.

Any drug is likely to produce some toxicities or undesirable side effects in animals and in humans when administered at sufficiently high doses and/or for sufficiently long periods of time. Unacceptable toxicities or side effects may occur at any dose level, and at any time in the course of animal studies designed to identify unacceptable effects of a drug candidate, known as toxicological studies, or in clinical trials of our drug candidates. The appearance of any unacceptable toxicity or side effect could cause us or regulatory authorities to interrupt, limit, delay or abort the development of any of our drug candidates and could ultimately prevent marketing approval by the FDA or foreign regulatory authorities for any or all targeted indications.

In addition, the manufacturer of an investigational drug in a Phase 2 or Phase 3 clinical trial for a serious or life-threatening disease is required to make available, such as by posting on its website, its policy on evaluating and responding to requests for expanded access.

After completion of the required clinical testing, an NDA or BLA is prepared and submitted to the FDA. FDA approval of the NDA or BLA is required before marketing of the product may begin in the U.S. The NDA or the BLA must include the results of all pre-clinical, clinical and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture and controls. The cost of preparing and submitting an NDA is substantial.

The FDA has 60 days from its receipt of an NDA or BLA to determine whether the application will be filed based on the agency's threshold determination that it is sufficiently complete to permit substantive review. If the NDA or BLA submission is filed, the FDA reviews the NDA or BLA to determine, among other things, whether the proposed product is safe and effective for its intended use. The FDA has agreed to certain performance goals in the review of NDAs or BLAs. Most such applications for standard review drug products are reviewed within ten to twelve months; most applications for priority review drugs are reviewed in six to eight months. Priority review can be applied to drugs that the FDA determines offer major advances in treatment or provide a treatment where no adequate therapy exists. For biologics, priority review is further limited to drugs intended to treat a serious or life-threatening disease relative to the currently approved products. The review process for both standard and priority review may be extended by the FDA for three additional months to consider certain late-submitted information, or information intended to clarify information already provided in the submission.

The FDA may also refer applications for novel drug products, or drug products that present difficult questions of safety or efficacy, to an advisory committee – typically a panel that includes clinicians and other experts – for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. Before approving an NDA or BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. The FDA will not approve the product unless compliance with current Good Manufacturing Processes (cGMPs) is satisfactory and the NDA or BLA contains data that provide substantial evidence that the drug is safe and effective in the indication studied.

After the FDA evaluates the NDA or BLA and the manufacturing facilities, it issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing, or information, in order for the FDA to reconsider the application. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA or BLA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included.

An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. As a condition of NDA or BLA approval, the FDA may require a risk evaluation and mitigation strategy, or REMS, to help ensure that the benefits of the drug outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use, or ETASU. ETASU can include, but is not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring and the use of patient registries. The requirement for a REMS can materially affect the potential market and profitability of the drug. Moreover, product approval may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained, or problems are identified following initial marketing.

Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or BLA supplement before the change can be implemented. An NDA or BLA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA or BLA supplements as it does in reviewing NDAs or BLAs.

The required testing, data collection, analysis and compilation of an IND and a BLA or NDA are labor intensive and costly and may take a great deal of time. Tests may have to be redone or new tests performed in order to comply with FDA requirements. It can take considerable time (e.g., 5-10 years) and resources to achieve enrollment sufficient to commence such trials and complete Phase 2 or 3 clinical trials. Moreover, there is no guarantee a product will be approved.

The Orphan Drug Act provides incentives to manufacturers to develop and market drugs for rare diseases and conditions affecting fewer than 200,000 people in the U.S. at the time of application for orphan drug designation. The first developer to receive FDA marketing approval for an orphan drug is entitled to a seven-year exclusive marketing period in the U.S. for the orphan drug indication. However, a drug that the FDA considers to be clinically superior to, or different from, another approved orphan drug, even though for the same indication, may also obtain approval in the U.S. during the seven-year exclusive marketing period.

Legislation similar to the Orphan Drug Act has been enacted in other countries outside of the U.S., including the EU. The orphan legislation in the EU is available for therapies addressing conditions that affect five or fewer out of 10,000 persons, are life-threatening or chronically debilitating conditions and for which no satisfactory treatment is authorized. The market exclusivity period is for ten years, although that period can be reduced to six years if, at the end of the fifth year, available evidence establishes that the product does not justify maintenance of market exclusivity.

Expedited Development and Review Programs

Under the FDA Modernization Act of 1997, designation as a Fast-Track product or a breakthrough therapy for a new drug or biological product means that the FDA will take such actions as are appropriate to The FDA has the authority to facilitate and expedite the development and review of a drug through various programs, such as fast track designation, breakthrough therapy designation and priority review designation. Each program may be utilized by the FDA in the context of particular circumstances. For example, fast track designation would generally be used to facilitate the development and review of a drug that addresses an unmet medical need. Breakthrough therapy designation applies similarly in cases where a drug demonstrates substantial improvement over existing and available therapies. Priority review designation suggests the FDA will take action on an application within six months of filing.

We cannot guarantee that the FDA will grant any of our requests for fast track or breakthrough therapy designations, that any such designations would affect the time of review or that the FDA will approve the NDA or BLA submitted for any of our drug candidates, whether these designations are granted or not. Additionally, FDA approval of a fast track/breakthrough product can include restrictions on the product's use or distribution (such as permitting use only for specified medical conditions or limiting distribution to physicians or facilities with special training or experience). Approval of such designated products can be conditioned on additional clinical trials after approval.

Accelerated approval is also possible in the event a product treats a serious or life-threatening condition and provides a meaningful advantage over available therapies. Products in this category must also meet a number of additional requirements. While a product may qualify for one or more of the foregoing programs, the FDA reserves the right to later decide the product no longer qualifies or that the product is no longer subject to priority regarding its review or approval.

Emergency Use Authorization

The FDA also has the authority to grant an Emergency Use Authorization ("EUA") to allow unapproved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions when there are no adequate, approved, and available alternatives, as designated by the U.S. government. An EUA granted by the FDA would permit a drug candidate to be able to be distributed under the conditions set forth in the EUA prior to FDA approval. Furthermore, the FDA may revoke an EUA for a variety of reasons, including where it is determined that the underlying health emergency no longer exists or warrants such authorizations.

Pediatric Information

Under the Pediatric Research Equity Act, or PREA, NDAs, BLAs or supplements to NDAs or BLAs must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. The FDA may grant full or partial waivers, or deferrals, for submission of data. Unless otherwise required by regulation, PREA does not apply to any drug for an indication for which orphan designation has been granted, except a product with a new active ingredient that is a molecularly targeted cancer product intended for the treatment of an adult cancer and directed at a molecular target determined by FDA to be substantially relevant to the growth or progression of a pediatric cancer that is subject to an NDA submitted on or after August 18, 2020.

The Best Pharmaceuticals for Children Act, ("BPCA"), provides NDA holders a six-month extension of any exclusivity – patent or non-patent – for a drug if certain conditions are met. For BLAs, the BPCA provides a six-month extension for non-patent exclusivity if certain conditions are met. Conditions for exclusivity include the FDA's determination that information relating to the use of a new drug in the pediatric population may produce health benefits in that population, the FDA making a written request for pediatric studies, and the applicant agreeing to perform, and reporting on, the requested studies within the statutory timeframe. Applications under the BPCA are treated as priority applications, with all of the benefits that designation confers.

Disclosure of Clinical Trial Information

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

The Hatch-Waxman Amendments

Orange Book Listing

In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent with claims covering the applicant's product or method of using the product. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential generic competitors in support of approval of an abbreviated new drug application, or ANDA. An ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths and dosage form as the listed drug and has been shown to be bioequivalent to the listed drug. Other than the requirement for bioequivalence testing, ANDA applicants are not required to conduct, or submit results of, pre-clinical or clinical tests to prove the safety or effectiveness of their drug product. Drugs approved in this way are commonly referred to as "generic equivalents" to the listed drug and can often be substituted by pharmacists under prescriptions written for the original listed drug.

The ANDA applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA's Orange Book. Specifically, the applicant must certify that: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. The ANDA applicant may also elect to submit a section viii statement certifying that its proposed ANDA labeling does not contain (or carves out) any language regarding the patented method-of-use rather than certify to a listed method-of-use patent. If the applicant does not challenge the listed patents, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired.

A certification that the new product will not infringe the already approved product's listed patents, or that such patents are invalid, is called a Paragraph IV certification. If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been received by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to the ANDA applicant.

The ANDA application also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the referenced product has expired.

Exclusivity

Exclusivity provisions under the FDC Act also can delay the submission or the approval of certain applications. The FDC Act provides a five-year period of non-patent exclusivity within the U.S. to the first applicant to gain approval of an NDA for a new chemical entity, or NCE. A drug is entitled to NCE exclusivity if it contains a drug substance with no active moiety of which has been previously approved by the FDA. During the exclusivity period, the FDA may not accept for review an ANDA or file a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a Paragraph IV certification. The FDC Act also provides three years of market exclusivity for an NDA, including a 505(b)(2) NDA, or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, for new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions for use associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs for the original conditions of use, such as the originally approved indication. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA; however, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all the non-clinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Patent Term Extension

After NDA approval, the owner of relevant drug patent may apply for up to a five-year patent term extension. Only one patent may be extended for each regulatory review period, which is composed of two parts: a testing phase, and an approval phase. The allowable patent term extension is calculated as half of the drug's testing phase – the time between the day the IND becomes effective and NDA submission – and all of the review phase – the time between NDA submission and approval up to a maximum of five years. The time can be shortened if the FDA determines that the applicant did not pursue approval with due diligence. The total patent term after the extension may not exceed 14 years and only one patent may be extended.

For patents that might expire during the application phase, the patent owner may request an interim patent extension. An interim patent extension increases the patent term by one year and may be renewed up to four times. For each interim patent extension granted, the post-approval patent extension is reduced by one year. The Director of the U.S. Patent and Trademark Office must determine that approval of the drug covered by the patent for which a patent extension is being sought is likely. Interim patent extensions are not available for a drug for which an NDA has not been submitted.

Section 505(b)(2) New Drug Applications

Most drug products obtain FDA marketing approval pursuant to an NDA or an ANDA. A third alternative is a special type of NDA, commonly referred to as a Section 505(b)(2), or 505(b)(2), NDA, which enables the applicant to rely, in part, on studies not conducted by, or for, the applicant and for which the applicant has not obtained a right of reference or use, such as the FDA's findings of safety and/or effectiveness for a similar previously approved product, or published literature, in support of its application.

505(b)(2) NDAs often provide an alternate path to FDA approval for new or improved formulations or new uses of previously approved products. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by, or for, the applicant and for which the applicant has not obtained a right of reference. If the 505(b)(2) applicants can establish that reliance on the FDA's previous approval is scientifically appropriate, it may eliminate the need to conduct certain pre-clinical or clinical trials of the new product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new product candidate for all, or some, of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant.

To the extent that the Section 505(b)(2) applicant is relying on studies conducted for an already approved product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the Orange Book to the same extent that an ANDA applicant would. Thus approval of a 505(b)(2) NDA can be stalled until all the listed patents claiming the referenced product have expired, until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced product has expired, and, in the case of a Paragraph IV certification and subsequent patent infringement suit, until the earlier of 30 months, settlement of the lawsuit or a decision in the infringement case that is favorable to the Section 505(b)(2) applicant.

Post-Approval Requirements

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

Adverse event reporting and submission of periodic reports are required following FDA approval of an NDA or BLA. The FDA also may require post-marketing testing, known as Phase 4 testing, REMS, and surveillance to monitor the effects of an approved product, or the FDA may place conditions on an approval that could restrict the distribution or use of the product. In addition, quality-control, drug manufacture, packaging and labeling procedures must continue to conform to cGMPs after approval. Drug manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies. Registration with the FDA subjects entities to periodic unannounced inspections by the FDA, during which the agency inspects manufacturing facilities to assess compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money and effort in the areas of production and quality control to maintain compliance with cGMPs. Regulatory authorities may withdraw product approvals or request product recalls if a company fails to comply with regulatory standards, if it encounters problems following initial marketing or if previously unrecognized problems are subsequently discovered. In addition, prescription drug manufacturers in the United States must comply with applicable provisions of the Drug Supply Chain Security Act and provide and receive product tracing information, maintain appropriate licenses, ensure they only work with other properly licensed entities, and have procedures in place to identify and properly handle suspect and illegitimate products.

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

In addition to regulations enforced by the FDA, we are also subject to regulation under the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act and other federal, state and local regulations. Our research and development activities involve the controlled use of hazardous materials, chemicals, biological materials and radioactive compounds.

Biologics Regulation

Biological products used for the prevention, treatment or cure of a disease or condition of a human being are subject to regulation under the FDC Act, except the section of the FDC Act which governs the approval of NDAs. Biological products are approved for marketing under provisions of the Public Health Service Act, or PHSA, via a BLA. However, the application process and requirements for approval of BLAs are very similar to those for NDAs, and biologics are associated with similar approval risks and costs as drugs. To help reduce the increased risk of the introduction of adventitious agents, the PHSA emphasizes the importance of manufacturing controls for products whose attributes cannot be precisely defined. The PHSA also provides authority to the FDA to immediately suspend licenses in situations where there exists a danger to public health, to prepare or procure products in the event of shortages and critical public health needs, and to authorize the creation and enforcement of regulations to prevent the introduction or spread of communicable diseases in the US and between states.

After a BLA is approved, the product may also be subject to official lot release as a condition of approval. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot. The FDA may also perform certain confirmatory tests on lots of some products, such as viral vaccines, before releasing the lots for distribution by the manufacturer. In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, potency, and effectiveness of biological products. As with drugs, after approval of biologics, manufacturers must address any safety issues that arise, are subject to recalls or a halt in manufacturing, and are subject to periodic inspection after approval.

The Biologics Price Competition and Innovation Act of 2009, or BPCIA, creates an abbreviated approval pathway for biological products shown to be highly similar to, or interchangeable with, an FDA-licensed reference biological product. Biosimilarity sufficient to reference a prior FDA-approved product requires that there be no differences in conditions of use, route of administration, dosage form, and strength, and no clinically meaningful differences between the biological product and the reference product in terms of safety, purity and potency. Biosimilarity must be shown through analytical studies, animal studies, and at least one clinical trial, absent a waiver by the Secretary. A biosimilar product may be deemed interchangeable with a prior approved product if it meets the higher hurdle of demonstrating that it can be expected to produce the same clinical results as the reference product and, for products administered multiple times, the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. To date, only four biosimilar products and no interchangeable products have been approved under the BPCIA. Complexities associated with the larger, and often more complex, structures of biological products, as well as the process by which such products are manufactured, particularly with respect to interchangeability, are still being evaluated by the FDA.

A reference biologic is granted twelve years of exclusivity from the time of first licensure of the reference product, and no application for a biosimilar can be submitted for four years from the date of licensure of the reference product. The first biologic product submitted under the abbreviated approval pathway that is determined to be interchangeable with the reference product has exclusivity against a finding of interchangeability for other biologics for the same condition of use for the lesser of (i) one year after first commercial marketing of the first interchangeable biosimilar, (ii) eighteen months after the first interchangeable biosimilar is approved if there is no patent challenge, (iii) eighteen months after resolution of a lawsuit over the patents of the reference biologic in favor of the first interchangeable biosimilar applicant, or (iv) 42 months after the first interchangeable biosimilar's application has been approved if a patent lawsuit is ongoing within the 42-month period.

Regulation Outside the United States

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

Regulation and Marketing Authorization in the European Union

The process governing approval of medicinal products in the European Union follows essentially the same lines as in the United States and, likewise, generally involves satisfactorily completing each of the following:

- pre-clinical laboratory tests, animal studies and formulation studies all performed in accordance with the applicable EU Good Laboratory Practice regulations;
- submission to the relevant national authorities of a clinical trial application, or CTA, which must be approved before human clinical trials may begin;
- performance of adequate and well-controlled clinical trials to establish the safety and efficacy of the product for each proposed indication;
- submission to the relevant competent authorities of a marketing authorization application, or MAA, which includes the data supporting safety and efficacy as well as detailed information on the manufacture and composition of the product in clinical development and proposed labeling;
- satisfactory completion of an inspection by the relevant national authorities of the manufacturing facility or facilities, including those of third parties, at which the product is produced to assess compliance with strictly enforced current cGMP;
- potential audits of the non-clinical and clinical trial sites that generated the data in support of the MAA; and
- review and approval by the relevant competent authority of the MAA before any commercial marketing, sale or shipment of the product.

Pre-Clinical Studies

Pre-clinical tests include laboratory evaluations of product chemistry, formulation and stability, as well as studies to evaluate toxicity in animal studies, in order to assess the potential safety and efficacy of the product. The conduct of the pre-clinical tests and formulation of the compounds for testing must comply with the relevant EU regulations and requirements. The results of the pre-clinical tests, together with relevant manufacturing information and analytical data, are submitted as part of the CTA.

Clinical Trial Approval

Requirements for the conduct of clinical trials in the European Union including GCP are implemented in the Clinical Trials Directive 2001/20/EC and the GCP Directive 2005/28/EC. Pursuant to Directive 2001/20/EC and Directive 2005/28/EC, as amended, a system for the approval of clinical trials in the European Union has been implemented through national legislation of the member states. Under this system, approval must be obtained from the competent national authority of an EU member state in which a study is planned to be conducted, or in multiple member states if the clinical trial is to be conducted in a number of member states. To this end, a CTA is submitted, which must be supported by an investigational medicinal product dossier, or IMPD, and further supporting information prescribed by Directive 2001/20/EC and Directive 2005/28/EC and other applicable guidance documents. Furthermore, a clinical trial may only be started after a competent ethics committee has issued a favorable opinion on the clinical trial application in that country.

In 2019 new Regulation (EU) No 536/2014 became applicable and aims to simplify and streamline the approval of clinical trials in the European Union. The main characteristics of the regulation include:

- A streamlined application procedure via a single-entry point, the EU portal.
- A single set of documents to be prepared and submitted for the application as well as simplified reporting procedures that will spare sponsors from submitting broadly identical information separately to various bodies and different member states.
- A harmonized procedure for the assessment of applications for clinical trials, which is divided into two parts. Part I is assessed jointly by all member states concerned. Part II is assessed separately by each member state concerned.
- Strictly defined deadlines for the assessment of clinical trial application.
- The involvement of the ethics committees in the assessment procedure in accordance with the national law of the member state concerned but within the overall timelines defined by the Regulation (EU) No 536/2014.

Marketing Authorization

Authorization to market a product in the member states of the European Union proceeds under one of four procedures: a centralized authorization procedure, a mutual recognition procedure, a decentralized procedure, or a national procedure.

Centralized Authorization Procedure

The centralized procedure enables applicants to obtain a marketing authorization that is valid in all EU member states based on a single application. Certain medicinal products, including products developed by means of biotechnological processes, must undergo the centralized authorization procedure for marketing authorization, which, if granted by the European Commission, is automatically valid in all 28 EU member states. The EMA and the European Commission administer this centralized authorization procedure pursuant to Regulation (EC) No 726/2004.

Pursuant to Regulation (EC) No 726/2004, this procedure is mandatory for:

- medicinal products developed by means of one of the following biotechnological processes;
- recombinant DNA technology;
- controlled expression of genes coding for biologically active proteins in prokaryotes and eukaryotes including transformed mammalian cells;
- hybridoma and monoclonal antibody methods;
- advanced therapy medicinal products as defined in Article 2 of Regulation (EC) No. 1394/2007 on advanced therapy medicinal products;
- medicinal products for human use containing a new active substance that, on the date of effectiveness of this regulation, was not authorized in the European Union, and for which the therapeutic indication is the treatment of any of the following diseases;
- acquired immune deficiency syndrome;
- cancer;
- neurodegenerative disorder;
- diabetes;
- auto-immune diseases and other immune dysfunctions;
- viral diseases; and
- medicinal products that are designated as orphan medicinal products pursuant to Regulation (EC) No 141/2000.

The centralized authorization procedure is optional for other medicinal products if they contain a new active substance or if the applicant shows that the medicinal product concerned constitutes a significant therapeutic, scientific or technical innovation or that the granting of authorization is in the interest of patients in the European Union.

Administrative Procedure

Under the centralized authorization procedure, the EMA's Committee for Human Medicinal Products, or CHMP, serves as the scientific committee that renders opinions about the safety, efficacy, and quality of medicinal products for human use on behalf of the EMA. The CHMP is composed of experts nominated by each member state's national authority for medicinal products, with an expert appointed to act as Rapporteur for the co-ordination of the evaluation with the possible assistance of a further member of the Committee acting as a Co-Rapporteur. After approval, the Rapporteur(s) continue to monitor the product throughout its life cycle. The CHMP has 210 days to adopt an opinion as to whether a marketing authorization should be granted. The process usually takes longer in case additional information is requested, which triggers clock-stops in the procedural timelines. The process is complex and involves extensive consultation with the regulatory authorities of member states and a number of experts. When an application is submitted for a marketing authorization in respect of a drug that is of major interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation, the applicant may be pursuant to Article 14(9) Regulation (EC) No 726/2004 request an accelerated assessment procedure. If the CHMP accepts such request, the time-limit of 210 days will be reduced to 150 days, but it is possible that the CHMP can revert to the standard time-limit for the centralized procedure if it considers that it is no longer appropriate to conduct an accelerated assessment. Once the procedure is completed, a European Public Assessment Report, or EPAR, is produced. If the opinion is negative, information is given as to the grounds on which this conclusion was reached. After the adoption of the CHMP opinion, a decision on the MAA must be adopted by the European Commission, after consulting the E.U. member states, which in total can take more than 60 days.

Conditional Approval

In specific circumstances, EU legislation (Article 14(7) Regulation (EC) No 726/2004 and Regulation (EC) No 507/2006 on Conditional Marketing Authorizations for Medicinal Products for Human Use) enables applicants to obtain a conditional marketing authorization prior to obtaining the comprehensive clinical data required for an application for a full marketing authorization. Such conditional approvals may be granted for product candidates (including medicines designated as orphan medicinal products) if (1) the risk-benefit balance of the product candidate is positive, (2) it is likely that the applicant will be in a position to provide the required comprehensive clinical trial data, (3) the product fulfills unmet medical needs and (4) the benefit to public health of the immediate availability on the market of the medicinal product concerned outweighs the risk inherent in the fact that additional data are still required. A conditional marketing authorization may contain specific obligations to be fulfilled by the marketing authorization holder, including obligations with respect to the completion of ongoing or new studies, and with respect to the collection of pharmacovigilance data. Conditional marketing authorizations are valid for one year, and may be renewed annually, if the risk-benefit balance remains positive, and after an assessment of the need for additional or modified conditions and/or specific obligations. The timelines for the centralized procedure described above also apply with respect to the review by the CHMP of applications for a conditional marketing authorization.

Marketing Authorization under Exceptional Circumstances

Under Article 14(8) Regulation (EC) No 726/2004, products for which the applicant can demonstrate that comprehensive data (in line with the requirements laid down in Annex I of Directive 2001/83/EC, as amended) cannot be provided (due to specific reasons foreseen in the legislation) might be eligible for marketing authorization under exceptional circumstances. This type of authorization is reviewed annually to reassess the risk-benefit balance. The fulfillment of any specific procedures/obligations imposed as part of the marketing authorization under exceptional circumstances is aimed at the provision of information on the safe and effective use of the product and will normally not lead to the completion of a full dossier/approval.

Market Authorizations Granted by Authorities of EU Member States

In general, if the centralized procedure is not followed, there are three alternative procedures as prescribed in Directive 2001/83/EC:

- The decentralized procedure allows applicants to file identical applications to several EU member states and receive simultaneous national approvals based on the recognition by EU member states of an assessment by a reference member state.
- The national procedure is only available for products intended to be authorized in a single EU member state.
- A mutual recognition procedure similar to the decentralized procedure is available when a marketing authorization has already been obtained in at least one E.U. member state.

A marketing authorization may be granted only to an applicant established in the EU.

Pediatric Studies

Prior to obtaining a marketing authorization in the European Union, applicants have to demonstrate compliance with all measures included in an EMA-approved Pediatric Investigation Plan, or PIP, covering all subsets of the pediatric population, unless the EMA has granted a product-specific waiver, a class waiver, or a deferral for one or more of the measures included in the PIP. The respective requirements for all marketing authorization procedures are set forth in Regulation (EC) No 1901/2006, which is referred to as the Pediatric Regulation. This requirement also applies when a company wants to add a new indication, pharmaceutical form or route of administration for a medicine that is already authorized. The Pediatric Committee of the EMA, or PDCO, may grant deferrals for some medicines, allowing a company to delay development of the medicine in children until there is enough information to demonstrate its effectiveness and safety in adults. The PDCO may also grant waivers when development of a medicine in children is not needed or is not appropriate, such as for diseases that only affect the elderly population.

Before a marketing authorization application can be filed, or an existing marketing authorization can be amended, the EMA determines that companies actually comply with the agreed studies and measures listed in each relevant PIP.

Periods of Authorization and Renewals

A marketing authorization is valid for five years in principle and the marketing authorization may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the authorizing member state. To this end, the marketing authorization holder must provide the EMA or the competent authority with a consolidated version of the file in respect of quality, safety and efficacy, including all variations introduced since the marketing authorization was granted, at least six months before the marketing authorization ceases to be valid. Once renewed, the marketing authorization is valid for an unlimited period, unless the European Commission or the competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal. Any authorization which is not followed by the actual placing of the drug on the EU market (in case of centralized procedure) or on the market of the authorizing member state within three years after authorization ceases to be valid (the so-called sunset clause).

Regulatory Data Protection

EU legislation also provides for a system of regulatory data and market exclusivity. According to Article 14(11) of Regulation (EC) No 726/2004, as amended, and Article 10(1) of Directive 2001/83/EC, as amended, upon receiving marketing authorization, new chemical entities approved on the basis of complete independent data package benefit from eight years of data exclusivity and an additional two years of market exclusivity. Data exclusivity prevents regulatory authorities in the European Union from referencing the innovator's data to assess a generic (abbreviated) application. During the additional two-year period of market exclusivity, a generic marketing authorization can be submitted, and the innovator's data may be referenced, but no generic medicinal product can be marketed until the expiration of the market exclusivity. The overall ten-year period will be extended to a maximum of 11 years if, during the first eight years of those ten years, the marketing authorization holder, or MAH, obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. Even if a compound is considered to be a new chemical entity and the innovator is able to gain the period of data exclusivity, another company nevertheless could also market another version of the drug if such company obtained marketing authorization based on an MAA with a complete independent data package of pharmaceutical test, pre-clinical tests and clinical trials. However, products designated as orphan medicinal products enjoy, upon receiving marketing authorization, a period of ten years of orphan market exclusivity. Depending upon the timing and duration of the EU marketing authorization process, products may be eligible for up to five years' supplementary protection certificates, or SPCs, pursuant to Regulation (EC) No 469/2009. Such SPCs extend the rights under the basic patent for the drug.

Regulatory Requirements After a Marketing Authorization has been Obtained

If we obtain authorization for a medicinal product in the EU, we will be required to comply with a range of requirements applicable to the manufacturing, marketing, promotion and sale of medicinal products:

Pharmacovigilance and Other Requirements

We are required to comply with the EU's stringent pharmacovigilance or safety reporting rules, pursuant to which post-authorization studies and additional monitoring obligations can be imposed. Other requirements relate, for example, to the manufacturing of products and APIs in accordance with good manufacturing practice standards. EU regulators may conduct inspections to verify our compliance with applicable requirements, and we will have to continue to expend time, money and effort to remain compliant. Non-compliance with EU requirements regarding safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population, can also result in significant financial penalties in the European Union. Similarly, failure to comply with the EU's requirements regarding the protection of individual personal data can also lead to significant penalties and sanctions. Individual EU member states may also impose various sanctions and penalties in case we do not comply with locally applicable requirements.

Manufacturing

The manufacturing of authorized drugs, for which a separate manufacturer's license is mandatory, must be conducted in strict compliance with the EMA's Good Manufacturing Practices, or GMP, requirements and comparable requirements of other regulatory bodies in the European Union, which mandate the methods, facilities and controls used in manufacturing, processing and packing of drugs to assure their safety and identity. The EMA enforces its current GMP requirements through mandatory registration of facilities and inspections of those facilities. The EMA may have a coordinating role for these inspections while the responsibility for carrying them out rests with the member states competent authority under whose responsibility the manufacturer falls. Failure to comply with these requirements could interrupt supply and result in delays, unanticipated costs and lost revenues, and could subject the applicant to potential legal or regulatory action, including but not limited to warning letters, suspension of manufacturing, seizure of product, injunctive action or possible civil and criminal penalties.

Marketing and Promotion

The marketing and promotion of authorized drugs, including industry-sponsored continuing medical education and advertising directed toward the prescribers of drugs and/or the general public, are strictly regulated in the EU under Directive 2001/83/EC. The applicable regulations aim to ensure that information provided by holders of marketing authorizations regarding their products is truthful, balanced and accurately reflects the safety and efficacy claims authorized by the EMA or by the competent authority of the authorizing member state. Failure to comply with these requirements can result in adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties.

Patent Term Extension

In order to compensate the patentee for delays in obtaining a marketing authorization for a patented product, a supplementary certificate, or SPC, may be granted extending the exclusivity period for that specific product by up to five years. Applications for SPCs must be made to the relevant patent office in each EU member state and the granted certificates are valid only in the member state of grant. An application has to be made by the patent owner within six months of the first marketing authorization being granted in the EU (assuming the patent in question has not expired, lapsed or been revoked) or within six months of the grant of the patent (if the marketing authorization is granted first). In the context of SPCs, the term "product" means the active ingredient or combination of active ingredients for a medicinal product and the term "patent" means a patent protecting such a product or a new manufacturing process or application for it. The duration of an SPC is calculated as the difference between the patent's filing date and the date of the first marketing authorization, minus five years, subject to a maximum term of five years.

A six-month pediatric extension of an SPC may be obtained where the patentee has carried out an agreed pediatric investigation plan, the authorized product information includes information on the results of the studies and the product is authorized in all member states of the European Union.

Pharmaceutical Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of products approved by the FDA and other government authorities. Sales of products will depend, in part, on the extent to which the costs of the products will be covered by third-party payors, including government health programs in the U.S. such as Medicare and Medicaid, commercial health insurers and managed care organizations. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the approved products for a particular indication.

In order to secure coverage and reimbursement for any product that might be approved for sale, a company may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the costs required to obtain FDA or other comparable regulatory approvals. A payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Third-party reimbursement may not be sufficient to maintain price levels high enough to realize an appropriate return on investment in product development.

There has been an increased focus on drug pricing in recent years in the U.S. Although there are no direct government price controls over private sector purchases in the U.S., there are rebates and other financial requirements for federal and state health care programs. The Medicare Modernization Act, enacted in December 2003, established the Medicare Part D outpatient prescription drug benefit, which is provided primarily through private entities that attempt to negotiate price concessions from pharmaceutical manufacturers. The health care reform legislation enacted in 2010, known as the Affordable Care Act, requires drug manufacturers to pay 50% of the Medicare Part D coverage gap, also known as the "donut hole," on prescriptions for branded products filled when the beneficiary reaches this coverage. The Deficit Reduction Act of 2005 resulted in changes to the way drug prices are reported to the government and the formula using such information to calculate the required Medicaid rebates. The Affordable Care Act increased the minimum basic Medicaid rebate for branded prescription drugs from 15.1% to 23.1% and requires pharmaceutical manufacturers to pay states rebates on prescription drugs dispensed to Medicaid managed care enrollees. In addition, the Affordable Care Act increased the additional Medicaid rebate on "line extensions" (such as extended-release formulations) of solid oral dosage forms of branded products, revised the definition of average manufacturer price by changing the classes of purchasers included in the calculation, and expanded the entities eligible for discounted pricing under the federal 340B drug pricing program. Current orphan drugs are excluded from the expanded 340B hospitals eligible for discounts.

The Affordable Care Act imposes a significant annual fee on companies that manufacture or import branded prescription drug products. The fee (which is not deductible for federal income tax purposes) is based on the manufacturer's market share of sales of branded drugs and biologics (excluding orphan drugs) to, or pursuant to coverage under, specified U. S. government programs. The Affordable Care Act also contains a number of provisions, including provisions governing the way that health care is financed by both governmental and private insurers, enrollment in federal health care programs, reimbursement changes, the increased use of comparative effectiveness research in health care decision-making, and enhancements to fraud and abuse requirements and enforcement, that are affecting existing government health care programs and will result in the development of new programs. The Affordable Care Act also contains requirements for manufacturers to publicly report certain payments or other transfers of value made to physicians and teaching hospitals. We are unable to predict the future course of federal or state health care legislation and regulations, including regulations that will be issued to implement provisions of the Affordable Care Act. The Affordable Care Act and further changes in the law or regulatory framework that reduce our revenues or increase our costs could also have a material adverse effect on our business, financial condition and results of operations and cash flows.

Public and private health care payers control costs and influence drug pricing through a variety of mechanisms, including through negotiating discounts with the manufacturers and through the use of tiered formularies and other mechanisms that provide preferential access to certain drugs over others within a therapeutic class. Payers also set other criteria to govern the uses of a drug that will be deemed medically appropriate and therefore reimbursed or otherwise covered. Payers may require physicians to seek approval from them before a product will be reimbursed or covered, commonly referred to as prior authorization. In particular, many public and private health care payers limit reimbursement and coverage to the uses of a drug that are either approved by the FDA or appear in a recognized drug compendium. Drug compendia are publications that summarize the available medical evidence for particular drug products and identify which uses of a drug are supported or not supported by the available evidence, whether or not such uses have been approved by the FDA. For example, in the case of Medicare Part D coverage for oncology drugs, the Medicare Modernization Act, with certain exceptions, provides for Medicare coverage of unapproved uses of an FDA-approved drug if the unapproved use is reasonable and necessary and is supported by one or more citations in CMS-approved compendia, such as the National Comprehensive Cancer Network Drugs and Biologics Compendium. Different pricing and reimbursement schemes exist in other countries. For example, in the European Union, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of such products to consumers. The approach taken varies from member state to member state. Some jurisdictions operate positive or negative list systems under which products may only be marketed once a reimbursement price has been agreed. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits and may limit or restrict reimbursement. The downward pressure on health care costs in general, and prescription drugs in particular, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products, as exemplified by the actions of the National Institute for Clinical Excellence in the U.K., which evaluates the data supporting new medicines and passes reimbursement recommendations to the government. In addition, in some countries cross-border imports from low-priced markets (parallel imports) exert a commercial pressure on pricing within a country.

In the EU, pricing and reimbursement schemes vary widely from country to country. Some countries provide that drug products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of our drug candidate to currently available therapies (so called health technology assessment) in order to obtain reimbursement or pricing approval. For example, the EU provides options for its member states to restrict the range of drug products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. EU member states may approve a specific price for a drug product, or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the drug product on the market. Other member states allow companies to fix their own prices for drug products but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. The downward pressure on health care costs in general, particularly prescription drugs, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, there can be considerable pressure from governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various EU member states, and parallel distribution (arbitrage between low-priced and high-priced member states), can further reduce prices. Any country that has price controls or reimbursement limitations for drug products may not allow favorable reimbursement and pricing arrangements.

Healthcare Law and Regulation

Healthcare providers, physicians and third-party payors play a primary role in the recommendation and prescription of drug products that are granted marketing approval. Arrangements with third-party payors and customers are subject to broadly applicable fraud and abuse and other healthcare laws and regulations. Such restrictions under applicable federal and state healthcare laws and regulations, include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid;
- the federal False Claims Act imposes civil penalties, and provides for civil whistleblower or qui tam actions, against individuals or entities for 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, or HIPAA, imposes criminal and civil liability for executing 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 and its implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;
- the federal transparency requirements under the Health Care Reform Law requires manufacturers of drugs, devices, biologics and medical supplies to report to the Department of Health and Human Services information related to payments and other transfers of value to physicians and teaching hospitals and physician ownership and investment interests; 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.

An increasing number of states have enacted legislation requiring pharmaceutical and biotechnology companies to file periodic reports of expenses relating to the marketing and promotion of drug products and gifts and payments to individual healthcare practitioners in these states; to make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities; to report information pertaining to and justifying price increases; or to register their sales representatives. Other states prohibit various marketing-related activities, such as the provision of certain kinds of gifts or meals; price gouging; or pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical and biotechnology companies for use in sales and marketing. In addition, states such as California, Connecticut, Nevada, and Massachusetts require pharmaceutical companies to implement compliance programs and/or marketing codes. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Environmental, Health and Safety Matters

The manufacturing facilities of the third-parties that develop our product candidates are subject to extensive environmental, health and safety laws and regulations in a number of jurisdictions, governing, among other things: the use, storage, registration, handling, emission and disposal of chemicals, waste materials and sewage; chemicals, air, water and ground contamination; air emissions and the cleanup of contaminated sites, including any contamination that results from spills due to our failure to properly dispose of chemicals, waste materials and sewage.

These laws, regulations and permits could potentially require the expenditure by us of significant amounts for compliance or remediation if, among other things, our operations result in contamination of the environment or breach of regulatory obligations or expose individuals to harm. If the third-party manufacturers fail to comply with such laws, regulations or permits, we may be subject to fines and other civil, administrative or criminal sanctions, including the revocation of permits and licenses necessary to continue our business activities. In addition, we may be required to pay damages or civil judgments in respect of third-party claims, including those relating to personal injury (including exposure to hazardous substances we use, store, handle, transport, manufacture or dispose of), property damage or contribution claims. Some environmental, health and safety laws allow for strict, joint and several liability for remediation costs, regardless of comparative fault. We may be identified as a responsible party under such laws. Such developments could have a material adverse effect on our business, financial condition and results of operations.

In addition, laws and regulations relating to environmental, health and safety matters are often subject to change. In the event of any changes or new laws or regulations, we could be subject to new compliance measures or to penalties for activities that were previously permitted.

Competition

Our industry is subject to rapid and intense technological change. Competition is intense among manufacturers of nutritional, non-prescription, and prescription pharmaceuticals. We face, and will continue to face, competition from nutraceutical, pharmaceutical, biopharmaceutical, medical device and biotechnology companies developing similar products and technologies both in the United States and abroad, as well as numerous academic and research institutions, governmental agencies and private organizations engaged in drug funding or research and discovery activities both in the United States and abroad. Academic institutions, government agencies and other public and private research organizations may also conduct research, seek patent protection and establish collaborative arrangements for discovery, research and clinical development of technologies and products similar to ours. We also face competition from entities and healthcare providers using more traditional methods. We believe there are a substantial number of products under development by numerous nutraceutical, pharmaceutical, biopharmaceutical, medical device and biotechnology companies, and it is likely that other competitors will emerge.

Many of our existing and potential competitors are large, well-established pharmaceutical, chemical or healthcare companies with considerably greater research and product development capabilities and financial, scientific, marketing and human resources than we have. Large and established companies, such as Merck & Co., Inc., GlaxoSmithKline plc, CSL Ltd., Sanofi Pasteur, SA, Pfizer Inc., Johnson & Johnson, AstraZeneca, and Moderna, among others, compete in the same or similar markets. In particular, these companies have greater experience and expertise in securing government contracts and grants to support their research and development efforts, conducting testing and clinical trials, obtaining regulatory approvals to market products, manufacturing such products on a broad scale and marketing approved products. As a result, these competitors may succeed in developing competing products earlier than we do; obtain patents that block or otherwise inhibit our ability to further develop and commercialize our product candidates; obtain approvals from the FDA or other regulatory agencies for products more rapidly than we do; or develop treatments or cures that are safer or more effective than those we propose to develop. These competitors may also devote greater resources to marketing or selling their products and may be better able to withstand price competition. In addition, these competitors may introduce or adapt more quickly to new technologies or scientific advances, which could render our technologies obsolete, and may introduce products or technologies that make the continued development, production, or marketing of our product candidates uneconomical. These competitors may also be more successful in negotiating third-party licensing or collaborative arrangements and may be able to take advantage of acquisitions or other strategic opportunities more readily than we can. These actions by competitors or potential competitors could materially affect our business, financial condition and results of operations. We cannot assure you that we will be able to compete successfully.

Regardless of the disease, smaller or early-stage companies and research institutions also may prove to be significant competitors, particularly through collaborative arrangements with large and established pharmaceutical companies. As these companies develop their technologies, they may develop proprietary positions, which may prevent or limit our product development and commercialization efforts. We will also face competition from these parties in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and participant registration for clinical trials and in acquiring and in-licensing technologies and products complementary to our programs or potentially advantageous to our business. If any of our competitors succeed in obtaining approval from the FDA or other regulatory authorities for their products sooner than we do or for products that are more effective or less costly than ours, our commercial opportunity could be significantly reduced.

We have limited ability to predict how competitive our products and product candidates will be in the marketplace.

Our Intellectual Property

Our success will depend in part on our ability to obtain and maintain patent and other proprietary protection for our technology, inventions, improvements, and know-how related to the business; to defend and enforce proprietary rights, including any patents that we may own in the future; to preserve the confidentiality of our trade secrets and other intellectual property; to obtain and maintain licenses to use intellectual property owned by third parties; and to operate without infringing valid and enforceable patents and other proprietary rights of third parties. Our ability to stop third parties from making, using, selling, offering to sell, or importing our products may depend on the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities. With respect to both licensed and company-owned intellectual property, we cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed in the future, nor can we be sure that any of our existing patents or any patents that may be granted in the future will be commercially useful in protecting our commercial products and methods of manufacturing the same.

Patents

We attempt to protect our technology, innovations, and products through patents and patent applications. As part of the December 2023 acquisition of ONP-002 and related intellectual property, we acquired rights to numerous patent properties for ONP-002 which have been filed and/or issued and a rights to multiple patent applications that haves been filed worldwide on the novel Breadth-Powered Nasal Delivery Devices and Uses Thereof.

Patent applications that concern ONP-002 and the nasal delivery device have been filed as follows:

- New chemical entity patent filings concerning the C-20 Steroid compounds haves been filed with the USPTO and are pending in the U.S. To date, national patents in 9 different countries have been granted, including European countries and Canada. A bundle of patents under the European Patent Convention have also been granted.
    - C-20 steroid compounds, composition and uses thereof to treat traumatic brain injury (TBI), including concussion.
    - Inventions relate to, inter alia, ONP-002 compositions, methods of use to treat, minimize and/or prevent traumatic brain injury (TBI), including severe TBI, moderate TBI, and mild TBI, including concussions, methods of manufacture and/or synthesis, products by process, and intermediates.
    - An issued U.S. patent expiration with 5-year maximum patent term extension - 9/17/2040.
    - An issued U.S. patent expiration without patent term extension - 9/17/2035.

- Multiple nasal delivery device patent applications concerning the Breath-Powered Nasal Devices and Uses Thereof haves been filed in the U.S. with the USPTO as utility patent applications. In addition, multiple nationalized patent applications drawn to the Breath-Powered Nasal Devices and Uses Thereof have been filed in over 60 countries.
    - Breath-Powered Nasal Devices and Uses Thereof for Treatment of Traumatic Brain Injury (TBI), Including Concussion, and Methods.
    - Inventions relate to, inter alia, breath-powered nasal devices, single-directional breath-powered nasal devices for providing dual airflow for propelling a drug substance into a nasal cavity for targeted delivery to the olfactory region in high drug substance concentration for rapid diffusion into the brain for the treatment of local or systemic and/or central nervous system (CNS) injury, disease or disorder, and methods of treating local or systemic and/or CNS injury, disease or disorder with such devices.
    - An exemplary issued U.S. patent expiration - 10/19/2042.

The effect of issued patents is that they provide patent protection for the claims covered by the patents. While the expiration of a product patent normally results in a loss of market exclusivity for the covered product or product candidate, commercial benefits may continue to be derived from later-granted patents on, for example, (i) processes, (ii) methods, (iii) uses, (iv) dosage strengths, (v) dosage forms, (vi) compositions, (vii) formulations, (viii) treatment regimens, (ix) pharmacokinetic properties, (x) safety properties, (xi) stability properties, (xii) improvements, and (xii) intermediates related to the most economical method of manufacture of the active ingredients of such product in the United States and certain other countries. Market exclusivities may also be available under relevant regulatory law in the United States and certain other countries that can provide regulatory exclusivities in addition to patent protection. The effect of patent expiration on products or product candidates also depends upon many other factors such as the nature of the market and the position of the product in it, the growth of the market, the complexities and economics of the process for manufacture of the active ingredient of the product and the requirements of new drug provisions of the Federal Food, Drug and Cosmetic Act or similar laws and regulations in other countries.

We believe that the protection of discoveries in connection with our development activities, our proprietary products, technologies, processes and know-how and all of our intellectual property are important to our business. There can be no assurance that our patents, and any patents that may be issued, assigned, or licensed to us in the future, will afford protection against competitors with similar technology. In addition, no assurances can be given that any patents issued, assigned, or licensed to us will not be infringed upon or designed around by others or that others will not obtain patents that we would need to license or design around. If existing or future patents held by third parties and containing broad claims over technology used by us were upheld by a court or other authority of competent jurisdiction, the holders of such patents could require us to obtain licenses to use such technology.

Trademarks

Our trademarks are important to our business. We currently use the following unregistered trademarks: SMaRT Replacement Therapy™, MU1140™, and LPT3-04™. In March 2022, the USPTO issued a Notice of Allowance in connection with our application for registration of the mark of ORAGENICS™ (therapeutic products; anti-infectives and vaccine products). Registration of the mark of ORAGENICS™ is pending, subject to our filing of a Statement of Use and the subsequent acceptance thereof by the USPTO. We also have rights to use other names essential to our business. Federally registered trademarks have a perpetual life, as long as they are maintained and renewed on a timely basis and used properly as trademarks, subject to the rights of third parties to seek cancellation of the trademarks if they claim priority or confusion of usage. We regard our trademarks and other proprietary rights as valuable assets and believe they have significant value to us.

Protection of Trade Secrets

We attempt to protect and safeguard our trade secrets, including the processes, concepts, ideas and documentation associated with our technologies, through the use of internal policies and confidentiality agreements and non-competition agreements with our current employees and with other parties to whom we have divulged such trade secrets. There can be no assurance that these agreements will not be breached, that we will have adequate remedies for any breach, that others will not independently develop equivalent proprietary information or that other third parties will not otherwise gain access to our trade secrets and other intellectual property. If our employees or other parties breach our confidentiality agreements and non-competition agreements or if these agreements are not sufficient to protect our technology or are found to be unenforceable, our competitors could acquire and use information that we consider to be our trade secrets and we may not be able to compete effectively. Most of our competitors have substantially greater financial, marketing, technical and manufacturing resources than we have and we may not be profitable if our competitors are also able to take advantage of our trade secrets.

Human Capital

Employees

We have three full-time employees and two part-time employees. We enjoy good relations with our employees. None of our employees are a member of any labor union, and we are not a party to any collective bargaining agreement.

Consultants

We have consulting agreements with a number of scientists, clinicians and regulatory experts. They serve as important contacts for us throughout the broader scientific and clinical communities. They are distinguished individuals with expertise in numerous fields, including vaccine development and regulatory matters.

We retain each consultant according to the terms of the consulting agreement. Under such agreements, we pay them a consulting fee and reimburse them for out-of-pocket expenses incurred in performing their services for us. In addition, some consultants hold options to purchase our common stock, subject to the vesting requirements contained in separate award agreements. Our consultants may be employed by other entities and therefore may have commitments to their employer or may have other consulting or advisory agreements that may limit their availability to us.

Corporate Information

We were incorporated in November 1996 and commenced operations in 1999. We consummated our initial public offering in June 2003. Our corporate office is located at 1990 Main Street Suite 750 Sarasota, Florida 34236.

Available Information

Our website is www.oragenics.com. On our website we make available at no cost our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished as soon as reasonably practicable after we electronically file such material with, or furnish them to, the United States Securities and Exchange Commission ("SEC"). The information contained on our website or connected thereto is not a part of, or incorporated into, this annual report on Form 10-K.

ITEM 1A. RISK FACTORS.

An investment in our common stock involves a high degree of risk. You should carefully consider the risks described below before making an investment decision in our securities. These risk factors are effective as of the date of this Form 10-K and shall be deemed to be modified or superseded to the extent that a statement contained in our future filings modifies or replaces such statement. All of these risks may impair our business operations. The forward-looking statements in this Form 10-K involve risks and uncertainties and actual results may differ materially from the results we discuss in the forward-looking statements. If any of the following risks actually occur, our business, financial condition or results of operations could be materially adversely affected. In that case, the trading price of our stock could decline, and you may lose all or part of your investment.

Risk Factor Summary

The below summary of risk factors provides an overview of many of the risks we are exposed to in the normal course of our business activities. As a result, the below summary risks do not contain all of the information that may be important to you, and you should read the summary risks together with the more detailed discussion of risks set forth following this section as well as elsewhere in this Annual Report. Additional risks, beyond those summarized below or discussed elsewhere in this Annual Report, may apply to our activities or operations as currently conducted or as we may conduct them in the future or in the markets in which we operate or may in the future operate. Consistent with the foregoing, we are exposed to a variety of risks, including risks associated with the following:

- We have incurred significant losses since our inception, have limited financial resources, do not generate any revenues and will need to raise additional capital in the future.
- We may not be able to secure additional funding.
- Our auditor has expressed substantial doubt about our ability to continue as a going concern.
- We may not be able to satisfy the continued listing standards of the NYSE American and may be delisted from the NYSE American.

- We have limited neurology-specific research, development, manufacturing, testing, regulatory, commercialization, sales, distribution, and marketing experience, and we may need to invest significant financial and management resources to establish these capabilities.
- None of our product candidates have been approved for sale and if we are unable to successfully develop our product candidates, we may not be able to continue as a going concern.
- Our product candidates, if approved, will face significant competition; many of our competitors have significantly greater resources and experience.
- Our ONP-002 concussion candidate may face competition from biosimilars approved through an abbreviated regulatory pathway.
- The market opportunities for our neurology product candidates may be smaller than we believe them to be and we cannot assure you that the market and consumers will accept our products or product candidates.
- If our manufacturers and suppliers fail to meet our requirements and the requirements of regulatory authorities, our research and development may be materially adversely affected.
- We rely on the significant experience and specialized expertise of our senior management and scientific team and the loss of any of our key personnel or our inability to successfully hire their successors could harm our business.
- If any of our product candidates are shown to be ineffective or harmful in humans, we will be unable to generate revenues from these product candidates.
- We might not be successful at acquiring, investing in or integrating businesses, entering into joint ventures or divesting businesses.
- Our concussion and neurology related research and development efforts are to a large extent dependent upon our intellectual property and biologicals materials licenses.
- We may not be able to protect our intellectual property and if we are unable to protect our trademarks or other intellectual property from infringement, our business prospects may be harmed.
- We may be subject to claims challenging the inventorship of our patents and other intellectual property rights.
- If we are sued for infringing intellectual property rights of third parties, it will be costly and time-consuming and an unfavorable outcome in that litigation could have a material adverse effect on our business.
- Security breaches and other disruptions to our information technology systems or those of the vendors on whom we rely on could compromise our information and expose us to liability, reputational damage, or other costs.
- Our product candidates are subject to substantial government regulation.
- Clinical trials conducted outside of the United States, present additional risks.
- We may be unable to obtain regulatory approval for our product candidates under applicable regulatory requirements.
- Delays or difficulties in the enrollment of patients in clinical trials may result in additional costs and delays.
- Any product candidates that we commercialize will be subject to ongoing and continued regulatory review and we may also be subject to healthcare laws, regulation and enforcement.

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

- Even if our current product candidates or any future product candidates obtain regulatory approval, they may fail to achieve the broad degree of health care payers, physician and patient adoption and use necessary for commercial success.

- The issuance of additional equity securities by us in the future will result in dilution and the conversion of our outstanding preferred stock will result in significant dilution.

- Certain provisions of our articles of incorporation, bylaws, executive employment agreements and stock option plan may prevent a change of control of our company that a shareholder may consider favorable.

- The price and volume of our common stock has been volatile and fluctuates substantially.

- The requirements of being a public company may strain our resources, divert management's attention and affect our ability to attract and retain qualified members for our Board of Directors.

- If we fail to maintain an effective system of internal controls, we may not be able to accurately report our financial results or prevent fraud.

Risks Related to Our Business

We have incurred significant losses since our inception and expect to continue to experience losses for the foreseeable future and may not be able to continue as a going concern.

We have incurred significant net losses and negative cash flow in each year since our inception, including net losses of $10.6 million and $20.7 million for the years ended December 31, 2024, and 2023, respectively. As of December 31, 2024, our accumulated deficit was approximately $217 million. We have devoted a significant amount of our financial resources to research and development, including our nonclinical development activities and clinical trials. We expect that the costs associated with our plans to begin Phase 2 work on ONP-002 will be significant. Additionally, our License Agreements also require the payment of certain recurring and performance-based royalties that may negatively impact our financial capabilities. In addition, Ladenburg Thalmann has sent us an invoice and demand letter claiming it is owed $2,500,000 in connection with our purchase of the Neurology Assets (the "Ladenburg Claim"). We strongly disagree with such claim and have filed a confidential action for arbitration against Ladenburg through FINRA on March 12, 2024, seeking, among other things, a declaratory action ruling that no such fee is owed, the litigation expenses related thereto will put further strain on our limited resources. As a result, we expect to continue to incur substantial net losses and negative cash flow for the foreseeable future. These losses and negative cash flows have had, and will continue to have, an adverse effect on our shareholders' equity and working capital. Because of the numerous risks and uncertainties associated with product development and commercialization, we are unable to accurately predict the timing or amount of substantial expenses or when, or if, we will be able to generate the revenue necessary to achieve or maintain profitability.

We will need to raise additional capital in the future to complete the development and commercialization of our product candidates and operate our business.

Developing and commercializing biopharmaceutical products, including Phase 2 work for our ONP-002 product candidate and conducting nonclinical studies and clinical trials and establishing manufacturing capabilities, and the progress of our efforts to develop and commercialize our product candidates, is expensive, and can cause us to use our limited, available capital resources faster than we currently anticipate. We anticipate that our estimated cash resources of approximately $0.8 million as of December 31, 2024, will be sufficient to fund our operations as presently structured through the first quarter of 2025. On February 5, 2025 we sold approximately 7.8 million common shares through our ATM for gross proceeds of approximately $2.8 million before subtracting commission and legal expenses. In addition, on March 13, 2025, the Company entered into and consummated a note securities purchase agreement (the "**Purchase Agreement**") with a single investor pursuant to which the Company sold, in a private placement, to the purchaser a promissory note with an aggregate principal amount of $3,000,000 and 1,000,000 shares of Series G Mirroring Preferred Stock of the Company. The aggregate gross proceeds to the Company were $2,500,000 million, before deducting placement agent fees and expenses. After the February ATM cash proceeds and the purchase Agreement financing, we anticipate that our estimated cash resources will be sufficient to fund our operations as presently structured through the third quarter of 2025. We are currently evaluating cost-saving initiatives, including restructuring that could allow further cash runway through 2025 to the extent such initiatives are undertaken but there can be no assurances we will be able to implement them. Our auditor has previously expressed substantial doubt about our ability to continue as a going concern and absent additional financing we may be unable to remain a going concern. Our actual costs may ultimately vary from our current expectations, which could materially impact our use of capital and our forecast of the period of time through which our financial resources will be adequate to support our operations. Our current cash, cash equivalents and short-term investments are not sufficient to fully implement our business strategy and sustain our operations. Accordingly, we will need to seek additional sources of financing and such additional financing may not be available on favorable terms, if at all. Until we can generate a sufficient amount of product revenue, if ever, we expect to finance future cash needs through public or private equity offerings, debt financings or corporate or government collaboration and licensing arrangements. If we do not succeed in raising additional funds on acceptable terms, we may be unable to complete existing nonclinical and planned clinical trials or obtain approval of our product candidates from the FDA and other regulatory authorities. We expect capital outlays and operating expenditures to increase over the next several years as we expand our infrastructure, and research and development activities. Specifically, we need to raise additional capital to, among other things:

- conduct Phase 2 clinical trials for our ONP-002 product candidate;
- engage in GMP and non-GMP manufacturing for our product candidates at the preclinical research and clinical trial stages;
- fund our clinical validation study activities;
- expand our research and development activities; and
- finance our capital expenditures and general and administrative expenses.

Our present and future funding requirements will depend on many factors, including:

- the level of research and development investment budgeted to develop our current and future product candidates through each phase of development;
- the timing, scope, progress, results and cost of research and development, testing, screening, manufacturing, preclinical and non-clinical studies and clinical trials.
- costs of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights;
- our need or decision to acquire or license complementary technologies or acquire complementary businesses;
- changes in test development plans needed to address any difficulties in product candidate selection for commercialization;
- competing neurological, vaccine and technological and market developments;
- our interaction and relationship with the FDA, or other, regulatory agencies; and
- changes in regulatory policies or laws that affect our operations.

In addition, we have previously discontinued and could be forced to discontinue future product development and commercialization of one or more of our product candidates, curtail or forego sales and marketing efforts, and/or forego licensing attractive business opportunities.

Given our current cash position and significant uncertainties related to future funding opportunities and our 2024 financials, substantial doubt exists regarding our ability to continue as a going concern through one year from the date that the financial statements included in this Annual Report were issued.

Our ability to fund our operations is dependent upon funding from grants and/or equity financing. New financing may not be available to us on commercially acceptable terms, or at all. Ongoing litigation may make it more difficult to obtain financing. Also, any collaborations, strategic alliances, and marketing, distribution, or licensing arrangements may require us to give up some or all of our rights to a product candidate, which in some cases may be at less than the full potential value of such rights. In addition, the regulatory and commercial success of our product candidates remains uncertain. If we are unable to obtain additional capital, we will assess our capital resources and may be required to delay, pivot, reduce the scope of, or eliminate some or all of our operations, or downsize our organization, any of which may have a material adverse effect on our business, financial condition, results of operations, and ability to operate as a going concern.

Our management believes that, given the significance of these uncertainties, substantial doubt exists regarding our ability to continue as a going concern through one year from the date that these financials statements are issued.

Our auditor has expressed substantial doubt about our ability to continue as a going concern and absent additional financing we may be unable to remain a going concern.

In light of our recurring losses, accumulated deficit and negative cash flow as described in our notes to our audited consolidated financial statements, the report of our independent registered public accounting firm on our consolidated financial statements for the year ended December 31, 2024, contained an explanatory paragraph raising substantial doubt about our ability to continue as a going concern. Our financial statements did not include any adjustments that may have been necessary in the event we were unable to continue as a going concern. If we are unable to establish to the satisfaction of our independent registered public accounting firm that the net proceeds from our financing efforts will be sufficient to allow for the removal of this going concern qualification, we may need to significantly modify our operational plans for us to continue as a going concern. On February 5, 2025 we sold approximately 7.8 million common shares through our ATM for gross proceeds of approximately $2.8 million before subtracting commission and legal expenses. In addition, on March 13, 2025, the Company entered into and consummated a note securities purchase agreement (the "**Purchase Agreement**") with a single investor pursuant to which the Company sold, in a private placement, to the purchaser a promissory note with an aggregate principal amount of $3,000,000 and 1,000,000 shares of Series G Mirroring Preferred Stock of the Company. The aggregate gross proceeds to the Company were $2,500,000 million, before deducting placement agent fees and expenses. After the February ATM cash proceeds and the purchase Agreement financing, we anticipate that our estimated cash resources will be sufficient to fund our operations as presently structured through the third quarter of 2025. Absent sufficient additional financing, we may be unable to remain a going concern.

We require additional funding to be able to maintain our current level of operations and to fund the further development of our new ONP-002 product candidate; we may not be able to obtain additional funding.

To date, we have never developed any product candidate, and we cannot assure investors that we will be able to successfully develop any drug candidate, including without limitation a drug treatment for mild traumatic brain injury, with our current resources and capabilities. Because our new ONP-002 concussion drug product candidate is in early stages of development and contemplates nasal administration it will require extensive pre-clinical and clinical testing, and we will need significant additional funding to conduct such research and testing. We do not expect to generate revenue from product sales, licensing fees, royalties, milestones, contract research or other sources of funds in amounts sufficient to fully fund our operations for the foreseeable future, and we will therefore use our cash resources, and expect to require additional funds, to maintain our existing operations, continue our research and development programs, commence Phase 2 clinical studies and clinical trials for our ONP-002 product candidate, and to seek regulatory approvals. Additionally, we expect our operating expenses to increase, both due to additional employment costs and operating costs required to pursue the development of the Neurology Assets.

We anticipate seeking such additional funds through a combination of public or private equity or debt financings, as well as potential collaborations, strategic alliances and marketing, distribution or licensing arrangements and non-dilutive funding from government and nongovernment funding entities, as well as other sources to further the research, development, manufacturing, testing, and regulatory approval our concussion drug product. We are unable to provide any assurance or guarantee that additional capital will be available when needed by our company or that such capital will be available under terms acceptable to our company or on a timely basis. While we may continue to apply for contracts or grants from academic institutions, nonprofit organizations and governmental entities, we may not be successful. If adequate funds are not available, we may have to scale back our operations or limit our research and development activities, which may cause us to grow at a slower pace, or not at all, and our business could be adversely affected. With limited capital, we have put the research and development of our COVID vaccine program and our lantibiotics program on hold and have chosen instead to focus the limited capital on the development of ONP-002.

Adequate additional funding may not be available to us on acceptable terms, if at all. Our ability to raise additional financing depends on many factors beyond our control, including the state of capital markets, the market price of our common stock and the development or prospects for development of competitive products by others. If we cannot raise the additional funds required for our anticipated operations or to support our development efforts, we may be required to delay significantly, reduce the scope of or eliminate one or more of our research or development programs, downsize our organization, or seek alternative measures to avoid insolvency, including arrangements with collaborative partners or others that may require us to relinquish rights to certain of our technologies or our concussion drug candidate.

Furthermore, if we raise additional funds by issuing equity securities, dilution to our existing stockholders could result. Any equity securities issued also may provide for rights, preferences or privileges senior to those of holders of our common and preferred stock. If we raise additional funds by issuing debt securities, these debt securities would have rights, preferences and privileges senior to those of holders of our common stock, and the terms of the debt securities issued could impose significant restrictions on our operations. Additionally, future offerings also could have a material and adverse effect on the price of our common stock. If we raise additional funds through collaborations and licensing arrangements, we might be required to relinquish significant rights to our technologies or our products under development or grant licenses on terms that are not favorable to us, which could lower the economic value of those programs to us. If additional funds are raised through the issuance of equity, convertible debt or similar securities of our company, the percentage of ownership of our company by our company's stockholders will be reduced, our company's stockholders may experience additional dilution upon conversion, and such securities may have rights or preferences senior to those of our common stock. The preferential rights granted to the providers of such additional financing may include preferential rights to payments of dividends, super voting rights, a liquidation preference, protective provisions preventing certain corporate actions without the consent of the fund providers, or a combination thereof. We are unable to provide any assurance that additional financing will be available on terms favorable to us or at all.

We may rely on government funding and collaboration with government entities for our product development, which adds uncertainty to our research and development efforts and may impose requirements that increase the costs of development, commercialization and production of any programs developed under those government-funded programs.

Because we anticipate the resources necessary to develop our new ONP-002 concussion drug candidate will be substantial, we may explore funding and development collaboration opportunities with the U.S. or foreign governments and their agencies. We have no control or input over whether an application for grant funding or any other funding will be accepted or approved, in full or in part, and we cannot provide investors with any assurances that we will receive such funding.

Additionally, contracts and grants funded by the U.S. or foreign governments and their agencies, contain provisions that reflect the government's substantial rights and remedies, many of which are not typically found in commercial contracts, including powers of the government to:

- reduce or modify the government's obligations under such agreements without the consent of the other party;
- claim rights, including IP rights, in products and data developed under such agreements;
- audit contract-related costs and fees, including allocated indirect costs;
- suspend the contractor or grantee from receiving new contracts pending resolution of alleged violations of procurement laws or regulations;
- impose U.S. manufacturing requirements for products that embody inventions conceived or first reduced to practice under such agreements;

- suspend or debar the contractor or grantee from doing future business with the government;
- control and potentially prohibit the export of products;
- pursue criminal or civil remedies under the False Claims Act, False Statements Act, and similar remedy provisions specific to government agreements; and
- limit the government's financial liability to amounts appropriated by the U.S. Congress on a fiscal-year basis, thereby leaving some uncertainty about the future availability of funding for a program even after it has been funded for an initial period.

In addition, government contracts and grants, ordinarily contain additional requirements that may increase our costs of doing business, reduce our profits, and expose us to liability for failure to comply with these terms and conditions, including the following:

- specialized accounting systems unique to government contracts and grants;
- mandatory financial audits and potential liability for price adjustments or recoupment of government funds after such funds have been spent;
- public disclosures of certain contract and grant information, which may enable competitors to gain insights into our research program; and
- mandatory socioeconomic compliance requirements, including labor standards, non-discrimination, and affirmative action programs, and environmental compliance requirements.

If we received such grants or agreements, we may not have the right to prohibit the U.S. government from using certain technologies developed by us, and we may not be able to prohibit third-parties, including our competitors, from using those technologies in providing products and services to the U.S. government. Further, under such agreements we could be subject to obligations to and the rights of the U.S. government set forth in the Bayh-Dole Act of 1980, meaning the U.S. government may have rights in certain inventions developed under these government-funded agreements, including a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government could have the right to require us to grant exclusive, partially exclusive, or nonexclusive licenses to any of these inventions to a third party if it determines that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet public health or safety needs; or (iii) government action is necessary to meet requirements for public use under federal regulations, also referred to as "march-in rights." Although the U.S. government's historic restraint with respect to these rights indicates they are unlikely to be used, any exercise of the march-in rights could harm our competitive position, business, financial condition, results of operations, and prospects. In the event we would be subject to the U.S. government's exercise such march-in rights, we may receive compensation that is deemed reasonable by the U.S. government in its sole discretion, which may be less than what we might be able to obtain in the open market.

Additionally, the U.S. government requires that any products embodying any invention generated through the use of U.S. government funding be manufactured substantially in the United States. The manufacturing preference requirement can be waived if the owner 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. manufacturers may limit our ability to contract with non-U.S. manufacturers for products covered by such intellectual property.

Although we will need to comply with some of these obligations, not all of the aforementioned obligations may be applicable to us unless and only to the extent that we receive a government grant, contract or other agreement. However, as an organization, we are relatively new to government contracting and new to the regulatory compliance obligations that such contracting entails. If we were to fail to maintain compliance with those obligations, we may be subject to potential liability and to termination of our contracts.

We have limited concussion and neurology-specific research, development, manufacturing, testing, regulatory, commercialization, sales, distribution, and marketing experience, and we may need to invest significant financial and management resources to establish these capabilities. Despite such investments and our best efforts, our strategic acquisition of the ONP-002 and ONP-001 neurology drug assets may turn out to be unsuccessful.

As part of our business strategy, we monitor and analyze strategic acquisition opportunities that we believe will be strategic fits for the Company and beneficial to the Company's shareholders. As demonstrated by our acquisition of the Neurology Assets in December of 2023, we may acquire companies, businesses, products and technologies that complement, augment or transform our existing business. However, such acquisitions could involve numerous risks that may prevent us from fully realizing the benefits that we anticipated as a result of such transactions.

Prior to our acquisition of the Neurology Assets, we had little-to-no experience in the development and commercialization of neurology or concussion related drugs. Although, in connection with the acquisition, we added experienced neurology researchers and consultants, given our size and current pre-clinical stage of development, we still have limited neurology-specific research, development, manufacturing, testing, regulatory, commercialization, sales, distribution, and marketing experience. To successfully develop our neurology product candidate, we will need to dedicate significant amounts of our limited financial and management resources to bolster our expertise in this area. Our success depends significantly on the continued contributions of our executive officers, financial, scientific and technical personnel and consultants, and on our ability to attract additional personnel.

During our operating history, many essential responsibilities have been assigned to a relatively small number of individuals, and we currently depend heavily upon the efforts and abilities of our management team. However, as we advance into neurology development, the demands on our key employees will expand and we will need to recruit additional qualified employees or consultants for our Company. The competition for such qualified personnel is intense. The loss of services of any of our existing consultants or our inability to attract additional personnel to fill critical positions could adversely affect our ability to efficiently develop our neurology product candidates. The loss or unavailability of the services of any of these individuals could have a material adverse effect on our business, prospects, financial condition and results.

Alternatively, or in addition to the above, we may enter into strategic alliances or partnership with other industry entities to utilize their research, development, manufacturing, testing, regulatory or commercialization skills, but we may be unable to enter into such agreements on favorable terms, if at all. If our future strategic collaborators do not commit sufficient resources to our alliances or partnerships and the progress of our development, if any, and we are unable to develop the necessary capabilities on our own, we may be unable to advance the development of our neurology asset product candidates to the point of commercialization, even if we obtain regulatory approval. We will be competing with many companies that currently have existing, extensive and well-funded operations, and without a significant internal team or the support of a third party to perform essential functions related to neurology research, development, manufacturing, testing, regulatory approval, and commercialization, we may be unable to compete successfully against these more established companies and our neurology product candidates may fail.

Any failure by us to effectively limit such risks as we implement our strategic acquisition could have a material adverse effect on our business, financial condition or results of operations and cause the price of our securities to fall.

Our success with regard to the Neurology Assets depends on the viability of our business strategy with regard to those assets, which is unproven and may be unfeasible.

Our revenue and income potential with regard to the Neurology Assets, in particular the concussion asset, are unproven, and we continue to develop our strategy for such assets. Our anticipated business model is based on a variety of assumptions based on a growing trend in the healthcare systems in the United States and many other countries. These assumptions may not reflect the business and market conditions we actually face. As a result, our operating results could differ materially from those projected under our business model, and our business model may prove to be unprofitable. The product candidate ONP-002 (the concussion asset) being developed is in its early stages and will require extensive testing and clinical trials before it is commercialized. There is no guarantee that ONP-002 will be approved for commercial use. The product candidate ONP-001 (the potential treatment for Niemann Pick Disease Type C) is in its early stages and will require extensive testing and clinical trials before it is commercialized. There is no guarantee that ONP-001 will be approved for commercial use. Further, we own 50% of the rights to this product candidate, with the other 50% owner by a third party. We anticipate this product candidate will be developed through a joint venture with a third party. However, the joint venture with that third party has not been finalized. If we fail to obtain marketing authorization for these product candidates, our business, financial condition, and results of operations will be materially adversely affected.

There are substantial inherent risks in attempting to commercialize newly developed products, and, as a result, we may not be able to successfully develop any products.

We hope to conduct research and development of the purchased Neurology Assets. However, commercial feasibility and acceptance of such product candidates are unknown. Scientific research and development require significant amounts of capital and takes an extremely long time to reach commercial viability, if at all. During the research and development process, we may experience technological barriers that we may be unable to overcome. Because of these uncertainties, it is possible that some or all of our future product candidates will never be successfully developed. If we are unable to successfully develop new products, we may be unable to generate new revenue sources or build a sustainable or profitable business.

With limited resources we have paused our other product candidate research and development and now rely on the progress and success of ONP-002.

With limited capital, we have put the research and development of our COVID vaccine program and our lantibiotics program on hold and have chosen instead to focus the limited capital on the development of ONP-002. As such, our future success currently depends on the successful development of ONP-002, our concussion asset, of which there can be no assurances.

We will need to achieve commercial acceptance of our products, if cleared or approved, to generate revenues and achieve profitability.

Superior products may be introduced that compete with the Neurology Assets, which would diminish or extinguish the uses for those products candidates, if cleared or approved. We cannot predict when significant commercial market acceptance for such products, if cleared or approved, will develop, if at all, and we cannot reliably estimate the projected size of any such potential market. If markets fail to accept such products, then we may not be able to generate revenue from them. Our revenue growth and achievement of profitability will depend substantially on our ability to introduce new products that are accepted by customers. Our competitors in the industry are predominantly large companies with longer operating histories, with significantly easier access to capital and other resources and an established product pipeline than us. There can be no assurance that we will be able to establish ourselves in our targeted markets, or, if established, that we will be able to maintain our market position, if any. Our commercial opportunity may be reduced if our competitors develop new or improved products that are more convenient, more effective or less expensive than our product candidates are. Competitors also may obtain FDA or other regulatory marketing authorization for their products more rapidly or earlier than we may obtain marketing authorization for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. If we are unable to cost-effectively achieve acceptance of our products by customers, or if our products do not achieve wide market acceptance, then our business will be materially and adversely affected.

The product candidates included in the Neurology Assets are still in development and we have not obtained authorization from any regulatory agency to commercially distribute such products in any country and we may never obtain such authorizations.

We currently have no products authorized for commercial distribution in either the United States, Europe or any other country. All of our product candidates require regulatory clearance or approvals. We cannot begin marketing and selling product candidates until we obtain applicable authorizations from the applicable regulatory agencies. The process of obtaining regulatory authorization is expensive and time-consuming and can vary substantially based upon, among other things, the type, complexity and novelty of a product candidate. Changes in regulatory policy, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application may cause delays in the authorization of a product candidate or rejection of a regulatory application altogether.

The FDA has substantial discretion in the review process and may refuse to accept our application or may decide that data are insufficient to grant the request and require additional pre-clinical, clinical, or other studies. In addition, varying interpretations of the data obtained from pre-clinical and clinical testing could delay, limit, or prevent marketing authorization from the FDA or other regulatory authorities. Any marketing authorization from the FDA we ultimately obtain may be limited or subject to restrictions or post-market commitments that render the product candidate not commercially viable. If our attempts to obtain marketing authorization are unsuccessful, we may be unable to generate sufficient revenue to sustain and grow our business, and our business, financial condition, and results of operations will be materially adversely affected.

Our concussion drug product candidate is at the Phase 2 clinical stage and has not been approved for sale. We have not conducted substantial research and development for a concussion product candidate, and we may be unable to produce a concussion drug that successfully treats mild traumatic brain injury in a timely and economical manner, if at all.

Our Neurology Asset development program is in the early stages of research and development, and currently includes only one product candidate, which has completed Phase I clinical trials but has not commenced Phase 2 clinical trials. Limited data exist regarding the safety and efficacy of our concussion product candidate, and we must conduct a substantial amount of additional research, development and clinical testing before any regulatory authority will approve our concussion product candidate. The success of our efforts to develop and commercialize our product candidates could fail for a number of reasons. For example, we could experience delays in product development and clinical trials or unsatisfactory clinical trial results.

In addition, adverse events, or the perception of adverse events, relating to a concussion product candidate administered intranasally and delivery technologies may negatively impact our ability to develop commercially successful products. Regardless of the veracity of or the data supporting these claims, these and other claims may influence public perception of the use of intranasal delivery product candidates and could result in greater governmental regulation, stricter labeling requirements and potential regulatory delays in the testing or approval of our potential product candidate. Such greater government regulation could have a material effect on our ability to develop and market our concussion product candidate.

Only a small fraction of biotechnology development programs ultimately result in commercial products or even product candidates and a number of events could delay our development efforts and negatively impact our ability to obtain regulatory approval for, and to manufacture, market and sell, a nasally administered vaccine. Additionally, our ability to develop an effective concussion drug will depend on our ability to work on an accelerated timeline, with uncertain access to financial resources beyond those that we currently possess, and in competition with a significant number of better-funded and more experienced development companies. Even if a market exists, our concussion drug product candidate could be found to be ineffective or unsafe, or otherwise fail to receive necessary regulatory clearances. Our concussion drug product candidate, even if safe and effective, could be difficult to manufacture on a large scale or uneconomical to market, or our competitors could develop superior products more quickly and efficiently or more effectively market their competing products. Accordingly, our inability to develop a commercially successful concussion product will materially harm our business.

We are, and will continue to be, dependent in significant part on outside scientists and third-party research institutions for our research and development in order to be able to commercialize our product candidates.

We currently have a limited number of employees and resources available to perform the research and development necessary to commercialize our product candidates and potential future product candidates. We therefore rely, and will continue to rely, on third-party research institutions, collaborators and consultants for this capability. While the Company continues to seek additional funding, it is taking steps to reduce the use of its cash resources, which include the determination to terminate the Lease.

The third party upon whom we rely for the supply of ONP-002 is our sole source of supply, and the loss of this supplier could significantly harm our business.

We do not manufacture or have the capacity to manufacture any of our drug candidates and have one manufacturer as our current partner in the development of synthetic chemistry and manufacturing of the ONP-002 (Molecular Formula: C20H28O2, Molecular Weight: 300.14 g/mol). Our ability to successfully develop our ONP-002 product candidates, and to ultimately supply our commercial products in quantities sufficient to meet the market demand, depends in part on our ability to obtain the drug product and drug substance for our product candidates in accordance with regulatory requirements and in sufficient quantities for commercialization and clinical testing. We do not currently have arrangements in place for a redundant or second-source supply of any products or substances in the event our current supplier ceases their operations or stops offering us sufficient quantities of these materials for any reason.

We are not certain that our single-source supplier will be able to meet our demand, either because of the nature of our agreement with the supplier, our limited experience with the supplier or our relative importance as a customer to the supplier. It may be difficult for us to assess its ability to timely meet our demand in the future based on past performance. While our supplier has generally met our demand on a timely basis in the past, they may subordinate our needs in the future to their other customers.

Moreover, if there is a disruption to our third-party manufacturers' or suppliers' relevant operations the supply of ONP-002 and its components will be delayed until such manufacturer or supplier restores the affected facilities or we or they procure alternative manufacturing facilities or sources of supply. Our ability to progress our pre-clinical and clinical programs could be materially and adversely impacted if any of the third-party suppliers upon which we rely were to experience a significant business challenge, disruption or failure due to issues such as financial difficulties or bankruptcy, issues relating to other customers such as regulatory or quality compliance issues, or other financial, legal, regulatory or reputational issues. Additionally, any damage to or destruction of our third-party manufacturers' or suppliers' facilities or equipment may significantly impair our ability to manufacture our product candidates on a timely basis.

Establishing additional or replacement suppliers for drug products and drug substance used in our product candidates, if required, may not be accomplished quickly and can take several years, if at all. Furthermore, despite our efforts, we may be unable to procure a replacement supplier or do so on commercially reasonable terms, which could have a material adverse impact upon our business. If we are able to find a replacement supplier, such replacement supplier would need to be qualified and may require additional regulatory approval, which could result in further delay. While we seek to maintain adequate inventory of the drug product and drug substance used in our product candidates, any interruption or delay in the supply of components or materials, or our inability to obtain such drug product and drug substance from alternate sources at acceptable prices in a timely manner could impede, delay, limit or prevent our development efforts, which could harm our business, results of operations, financial condition and prospects.

Certain raw materials required in the manufacture and the formulation of our product candidates are derived from biological sources. Such raw materials are difficult to procure and may be subject to contamination or recall. Access to and supply of sufficient quantities of raw materials which meet the technical specifications for the production process is challenging, and often limited to single-source suppliers. Finding an alternative supplier could take a significant amount of time and involve significant expense due to the nature of the products and the need to obtain regulatory approvals. If we or our manufacturers are unable to purchase the raw materials necessary for the manufacture of our product candidates on acceptable terms in a timely manner, at sufficient quality levels, or in adequate quantities, if at all, our ability to produce sufficient quantities of our products for clinical or commercial requirements would be negatively impacted. A material shortage, contamination, recall or restriction on the use of certain biologically derived substances or any raw material used in the manufacture of our products could adversely impact or disrupt manufacturing, which would impair our ability to generate revenues from the sale of such product candidates, if approved or cleared.

If Odyssey were to convert all of its Series F Convertible Preferred Stock, they would own more than a majority of our outstanding shares of common stock.

At the closing of the Odyssey transaction, we issued 8,000,000 shares of Series F Convertible Preferred Stock to Odyssey, which are convertible into our common stock on a one-for-one basis. The Series F Convertible Preferred Stock is non-voting, but if Odyssey were to convert all of its shares of Series F Convertible Preferred Stock into our common stock, they would control the vote of more than a majority of our outstanding common stock. Such a conversion would likely be considered a change of control under the rules of the NYSE American, requiring us to apply for and meet the NYSE Americans initial listing standards. We do not currently meet those standards. Accordingly, our Certificate of Designation creating the Series F Preferred Stock specifies that the remainder of the Series F Convertible Preferred shares are not convertible until the occurrence of all of the following: (i) Oragenics' shall have applied for and been approved for initial listing on the NYSE American or another national securities exchange or shall have been delisted from the NYSE American, which Oragenics' does not anticipate undertaking until it meets the NYSE American's initial listing standards, and (ii) if required by the rules of the NYSE American, Oragenics' shareholders shall have approved any change of control that could be deemed to occur upon the conversion of the Series F Preferred Stock into common stock, based on the fact and circumstances existing at such time.

The market opportunities for our concussion drug product candidate may be smaller than we believe them to be, or alternative drugs or technologies may be adopted, before our concussion drug achieve regulatory approval.

The primary area of focus for our future research and product development activities is the development of a nasally administered treatment of moderate-to-severe concussion ("mTBI") in the acute through subacute phases, ONP-002. Our current projections of both the number of people who are or will be affected by this disease, as well as the subset of people who may be affected by this disease and who have the potential to benefit from treatment through our ONP-002 product candidate are based on estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations, or market research, and may prove to be incorrect. The number of clinical trial participants in the United States, Australia, and elsewhere may turn out to be lower than expected, potential clinical trial participants may not be otherwise amenable to treatment with our products, or new clinical trial participants may become increasingly difficult to identify or gain access to, all of which would adversely affect our ability to conduct the research and development necessary to complete the concussion product candidate.

If we are unable to successfully develop our product candidates, our operating results and competitive position could be harmed. Research and development involves a lengthy and complex process, and we may not be successful in our efforts to develop and commercialize our product candidates. The further development and ultimate commercialization of our Neurology Assets, as well as our other product candidates, are keys to our strategy.

A key element of our business strategy is to discover, develop, validate, and commercialize a treatment product candidate for mTBI, which we aim to market globally to both public and private payers. We cannot assure you that we will be able to successfully complete development of or commercialize any or all of our planned future product candidates, or that they will be clinically usable. The product development process involves a high degree of risk and may take up to several years or more. Our new product development efforts may fail for many reasons, including:

- our recent entry into the neurology research and development industry;
- failure of future tests at the research or development stages;
- lack of clinical validation data to support effectiveness;
- delays resulting from the failure of third-party suppliers or contractors to meet their obligations in a timely and cost-effective manner;
- regulatory delays at the FDA or from other independent oversight authorities, particularly in light of the demands placed on public health resources during and following the COVID-19 pandemic;
- failure to obtain or maintain necessary certifications, licenses, clearances or approvals to market or perform the test; or
- lack of commercial acceptance by the health care marketplace.

Few research and development projects result in commercial products, and success in early clinical trials often is not replicated in later trials. At any point, we may abandon development of products in favor of the development or acquisition of new products, or we may be required to expend considerable resources repeating clinical studies or trials, which would adversely impact the timing for generating potential revenues from those new products. In addition, as we advance the development of new products through to the commercialization stage, we will have to make additional investments in our sales and marketing operations, which may be prematurely or unnecessarily incurred if the commercial launch of a product is abandoned or delayed.

If we are successful in producing a treatment for mTBI (concussion), we may need to devote significant resources to its scale-up and development, including for use by the U.S. government or other foreign authorities. Moreover, government involvement may limit the commercial success of our concussion product candidate.

We have not manufactured a concussion treatment to date, but if we were to do so, the economic value of such a treatment to us could be limited by such government action or inaction. Various government entities, including the U.S. government, offer, but may not continue to offer, incentives, grants and contracts to encourage the research and development of new drug technologies, which may have the effect of increasing the number of competitors and/or providing advantages to known competitors. Accordingly, there can be no assurance that we will be able to successfully establish a competitive market share for our concussion treatment product candidate.

In the event that any of the pre-clinical research or, if an IND is accepted by the FDA, the Phase 2 clinical trials for our concussion treatment product candidate are perceived to be successful, we may need to work toward the large-scale technical development, manufacturing scale-up and larger scale deployment of this potential treatment through a variety of U.S. government-sponsored mechanisms, such as an Expanded Access Program or an Emergency Use Authorization program. In this case we may need to divert significant resources to this program, which would require diversion of resources from our other existing product candidate programs. In addition, since the path to licensure of any concussion drug treatment is unclear there could be a negative impact on our receipt of marketing approval. Unexpected safety issues in these circumstances could lead to significant reputational damage for us and our technology platform going forward and other issues, including delays in our other programs, the need for re-design of our clinical trials and the need for significant additional financial resources.

Our product candidates, if approved, will face significant competition and our failure to compete effectively may prevent us from achieving significant market penetration.

The pharmaceutical industry is characterized by rapidly advancing technologies, intense competition, and a strong emphasis on developing proprietary therapeutics. Numerous companies are engaged in the development, patenting, manufacturing and marketing of healthcare products competitive with those that we are developing. We face competition from a number of sources, such as pharmaceutical companies, including generic drug companies, biotechnology companies and academic and research institutions, many of which have greater financial resources, marketing capabilities, sales forces, manufacturing capabilities, research and development capabilities, clinical trial expertise, intellectual property portfolios, experience in obtaining patents and regulatory approvals for product candidates and other resources than us. Some of the companies that offer competing products also have a broad range of other product offerings, large direct sales forces and long-term customer relationships with our target physicians, which could inhibit our market penetration efforts. In addition, certain of our product candidates, if approved, may compete with other products, for a share of some patients' discretionary budgets and for physicians' attention within their clinical practices.

We anticipate that, if we obtain regulatory approval of our product candidates, we will face significant competition from other approved therapies and may need to compete with unregulated, unapproved, and off-label treatments. Certain of our product candidates, if approved, will present novel therapeutic approaches for the approved indications, and will have to compete with existing therapies, some of which are widely known and accepted by physicians and patients. To compete successfully in this market, we will have to demonstrate that the relative cost, safety, and efficacy of our approved products, if any, provide an attractive alternative to existing and other new therapies. Such competition could lead to a reduced market share for our product candidates and contribute to downward pressure on the pricing of our product candidates, which could harm our business, financial condition, operating results, and prospects.

Due to less stringent regulatory requirements in certain foreign countries, there are many more products and procedures available for use in those international markets than are approved for use in the United States. In certain international markets, there are also fewer limitations on the claims that our competitors can make about the effectiveness of their products and the manner in which they can market them. As a result, we expect to face more competition in these markets than in the United States.

Many of our competitors have significantly greater resources and experience, which may negatively impact our commercial opportunities.

The biotechnology and pharmaceutical industries are subject to intense competition and rapid and significant technological change. We have many potential competitors, including major pharmaceutical companies, specialized biotechnology firms, academic institutions, government agencies and private and public research institutions. Many of our competitors have significantly greater financial and technical resources, experience and expertise in:

- research and development;
- pre-clinical testing;
- designing and implementing clinical trials;
- regulatory processes and approvals;
- production and manufacturing; and
- sales and marketing of approved products.

Principal competitive factors in our industry include:

- the quality and breadth of an organization's technology;
- management of the organization and the execution of the organization's strategy;
- the skill and experience of an organization's employees and its ability to recruit and retain skilled and experienced employees;
- an organization's intellectual property portfolio;
- the range of capabilities, from target identification and validation to drug discovery and development to manufacturing and marketing; and
- the availability of substantial capital resources to fund discovery, development and commercialization activities.

Large and established companies, such as Merck & Co., Inc., GlaxoSmithKline plc, CSL Ltd., Sanofi Pasteur, SA, Pfizer Inc., Johnson & Johnson, AstraZeneca, and Moderna, among others, compete in the market. In particular, these companies have greater experience and expertise in securing government contracts and grants to support their research and development efforts, conducting testing and clinical trials, obtaining regulatory approvals to market products, manufacturing such products on a broad scale and marketing approved products.

Regardless of the disease, smaller or early-stage companies and research institutions also may prove to be significant competitors, particularly through collaborative arrangements with large and established pharmaceutical companies. As these companies develop their technologies, they may develop proprietary positions, which may prevent or limit our product development and commercialization efforts. If any of our competitors succeed in obtaining approval from the FDA or other regulatory authorities for their products sooner than we do or for products that are more effective or less costly than ours, our commercial opportunity could be significantly reduced.

In order to effectively compete, we will have to make substantial investments in development, testing, manufacturing and sales and marketing or partner with one or more established companies. We may not be successful in gaining any market share. Our technologies and neurology product candidates also may be rendered obsolete or non-competitive as a result of products introduced by our competitors to the marketplace more rapidly and at a lower cost.

We may choose not to continue developing or commercializing any of our product candidates at any time during development or after approval, which would reduce or eliminate our potential return on investment for those product candidates.

At any time, we may decide to discontinue the development or commercialization of any of our products or product candidates for a variety of reasons, including inadequate financial resources the appearance of new technologies that render our product obsolete, competition from a competing product or changes in or failure to comply with applicable regulatory requirements. If we terminate a program in which we have invested significant resources, we will not receive any return on our investment and we will have missed the opportunity to allocate those resources to potentially more productive uses.

If any of our product candidates are shown to be ineffective or harmful in humans, we will be unable to generate revenues from these product candidates.

Before obtaining regulatory approvals for the commercial sale of our product candidates, we must demonstrate through nonclinical testing and clinical trials that our products are safe and effective for use in humans. To date ONP-002 has successfully completed Phase I clinical trials but has not yet completed Phase 2 clinical trials. It is possible that when and if future clinical trials are conducted in humans, they will show that our ONP-002 is ineffective or harmful in humans. If ONP-002 is shown to be ineffective or harmful to humans, we will be unable to commercialize and generate revenues from sales of such product candidate.

We intend to seek licensing partners to cover a portion of the costs associated with obtaining regulatory approval for, and manufacturing and marketing of, our product candidates. If we are unable to obtain agreements with third parties to fund these costs, we will have to fund such costs ourselves or we may be unable to extract any value from these technologies.

As we continue our development of product candidates, we intend to either license these product candidates to, or partner with, one or more major pharmaceutical companies at the earliest possible time in their product development. If we do so, we intend for these licensees or partners to pay the costs associated with any remaining development work, regulatory submissions, clinical trials and the manufacturing and marketing of our product candidates. If we are unable to license our product candidates or otherwise partner with third parties, we will have to fund the costs of our clinical trials ourselves or we will be unable to extract any value from these technologies. We may also have to establish our own manufacturing facilities and find our own distribution channels. This would greatly increase our future capital requirements and we cannot assure you that we will be able to obtain the necessary financing to pay these costs. If we are unable to cover the associated costs or we cannot obtain financing on acceptable terms or at all, our business, financial condition and results of operations will be materially adversely affected.

Our dependence on collaborative arrangements with third parties subjects us to a number of risks. These collaborative arrangements may not be on terms favorable to us. Agreements with collaborative partners typically allow partners significant discretion in electing whether or not to pursue any of the planned activities. We cannot control the amount and timing of resources our collaborative partners may devote to products based on the collaboration, and our partners may choose to pursue alternative products. Our partners may not perform their obligations as expected. Business combinations or significant changes in a collaborative partner's business strategy may adversely affect a partner's willingness or ability to complete its obligations under the arrangement. Moreover, we could become involved in disputes with our partners, which could lead to delays or termination of the collaborations and time-consuming and expensive litigation or arbitration. Even if we fulfill our obligations under a collaborative agreement, our partner may be able to terminate the agreement under certain circumstances. If any collaborative partner were to terminate or breach our agreement with it, or otherwise fail to complete its obligations in a timely manner, our chances of successfully commercializing our product candidates would be materially and adversely affected.

We are heavily dependent upon the ability and expertise of our management team and a very limited number of employees, and the loss of such individuals could have a material adverse effect on our business, operating results or financial condition.

We currently have a very small management team. Our success is dependent upon the ability, expertise and judgment of our senior management. While employment agreements are customarily used as a primary method of retaining the services of key employees, these agreements cannot assure the continued services of such employees. Any loss of the services of such individuals could have a material adverse effect on our business, operating results or financial condition.

We believe that our future success with regard to the Neurology Assets will depend significantly on the skills and efforts of key personnel, including Jacob VanLandingham, Ph.D., one of the Company's independent contractors. The loss of the services of any of these individuals could harm our ability to successfully pursue the development of the Neurology Assets. If any of our executive officers or key personnel left or was otherwise unable to work and we were unable to find a qualified replacement and/or to obtain adequate compensation for such loss, we may be unable to manage our business, which could harm our operating results and financial condition.

On December 5, 2022, the Mississippi Department of Human Services ("MDHS") filed an Amended Complaint in the Circuit Court of Hinds County, Mississippi First Judicial District against Mississippi Community Education Center, Inc., a non-profit corporation, Nancy New, its director, Prevacus, Inc., Dr. VanLandingham its founder, and several other defendants, alleging, among other things, a conspiracy to defraud the MDHS. Prevacus, Inc., is the Company from whom Odyssey purchased the Neurology Assets in 2021. The MDHS is designated by Mississippi law as the State agency exclusively responsible for administering the federally-authorized and federally-funded anti-poverty (or "welfare") program known as the Temporary Assistance for Needy Families program, or "TANF." With regard to Prevacus and Dr. VanLandingham, the complaint alleges that $2.1 million was funneled through the Mississippi Community Education Center, a nonprofit run by Nancy New, to Prevacus and PresolMD, another company founded by Dr. VanLandingham. The MDHS, among other things, is seeking to recover $2.1 million it alleges went to Prevacus and PresolMD. On or about July 2024, Dr. VanLandingham pled guilty to a single federal charge of wire fraud related to these proceedings. The Company does not believe it has any financial exposure related to the reimbursement of the funds paid to Prevacus and does not believe there are any grounds on which the Company could become embroiled in the foregoing legal proceedings. Dr. VanLandingham is not an Officer or Director of Oragenics but is instead an independent contractor. Nevertheless, any negative media related to foregoing legal proceedings, and in particular any negative media related to the concussion assets or Dr. VanLandingham, may negatively impact the Company's ability to raise capital and otherwise continue the development of the Neurology Assets. Furthermore, Dr. VanLandingham's ability to continue to assist in the development of the Neurology Assets may be negatively impacted by his need to respond to, and participate in, the foregoing legal proceedings.

We need to hire and retain additional qualified scientists and other highly skilled personnel to maintain and grow our business.

Our future success depends on our ability to identify, attract, hire, train, retain and motivate highly skilled technical, managerial and research personnel in all areas within our organization. We plan to continue to execute on our business strategy and expect to hire additional personnel to support our product development efforts. We believe that there are only a limited number of individuals with the requisite skills to serve in many of our key positions, and we compete for key personnel with other more established biotechnology companies, as well as universities and research institutions. It is often difficult to hire and retain these persons, and we may be unable to replace key persons if they leave or be unable to fill new positions requiring key persons with appropriate experience. If we fail to attract, integrate and retain the necessary personnel, our ability to maintain and grow our business could suffer significantly.

We might not be successful at acquiring, investing in or integrating businesses, entering into joint ventures or divesting businesses.

We expect to continue pursuing strategic acquisitions, investments and joint ventures to enhance or add to our skills and capabilities or offerings of services and solutions, or to enable us to expand in certain geographic and other markets. Depending on the opportunities available, we may increase the amount of capital invested in such opportunities. We may not succeed in completing targeted transactions, including as a result of the market becoming increasingly competitive, or achieve desired results of operations. Furthermore, we face risks in successfully integrating any businesses we might acquire or create through a joint venture. Ongoing business may be disrupted, and our management's attention may be diverted by acquisition, investment, transition or integration activities. In addition, we might need to dedicate additional management and other resources, and our organizational structure could make it difficult for us to efficiently integrate acquired businesses into our ongoing operations and assimilate and retain employees of those businesses into our culture and operations. The loss of key executives, employees, customers, suppliers, vendors and other business partners of businesses we acquire may adversely impact the value of the assets, operations or businesses. Furthermore, acquisitions or joint ventures may result in significant costs and expenses, including those related to retention payments, equity compensation, severance pay, early retirement costs, intangible asset amortization and asset impairment charges, assumed litigation and other liabilities, and legal, accounting and financial advisory fees, which could negatively affect our profitability. We may have difficulties as a result of entering into new markets where we have limited or no direct prior experience or where competitors may have stronger market positions. We might fail to realize the expected benefits or strategic objectives of any acquisition, investment or joint venture we undertake. We might not achieve our expected return on investment or may lose money. We may be adversely impacted by liabilities that we assume from a company we acquire or in which we invest, including from that company's known and unknown obligations, intellectual property or other assets, terminated employees, current or former clients or other third parties. In addition, we may fail to identify or adequately assess the magnitude of certain liabilities, shortcomings or other circumstances prior to acquiring, investing in or partnering with a company, including potential exposure to regulatory sanctions or liabilities resulting from an acquisition target's previous activities, internal controls and security environment. If any of these circumstances occurs, they could result in unexpected legal or regulatory exposure, unfavorable accounting treatment, unexpected increases in taxes or other adverse effects on our business. In addition, we have a lesser degree of control over the business operations of the joint ventures and businesses in which we have made minority investments or in which we have acquired less than 100% of the equity. This lesser degree of control may expose us to additional reputational, financial, legal, compliance or operational risks. Litigation, indemnification claims and other unforeseen claims and liabilities may arise from the acquisition or operation of acquired businesses. For example, we may face litigation or other claims as a result of certain terms and conditions of the acquisition agreement, such as earnout payments or closing net asset adjustments. Alternatively, shareholder litigation may arise as a result of proposed acquisitions. If we are unable to complete the number and kind of investments for which we plan, or if we are inefficient or unsuccessful at integrating any acquired businesses into our operations, we may not be able to achieve our planned rates of growth or improve our market share, profitability or competitive position in specific markets or services. We also periodically evaluate, and have engaged in, the disposition of assets and businesses. Divestitures could involve difficulties in the separation of operations, services, products and personnel, the diversion of management's attention, the disruption of our business and the potential loss of key employees. After reaching an agreement with a buyer for the disposition of a business, the transaction may be subject to the satisfaction of pre-closing conditions, including obtaining necessary regulatory and government approvals, which, if not satisfied or obtained, may prevent us from completing the transaction. Divestitures may also involve continued financial involvement in or liability with respect to the divested assets and businesses, such as indemnities or other financial obligations, in which the performance of the divested assets or businesses could impact our results of operations. Any divestiture we undertake could adversely affect our results of operations.

We may face product liability exposure, and if successful claims are brought against us, we may incur substantial liability if our insurance coverage for those claims is inadequate.

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any products. This risk exists even if a product is approved for commercial sale by the FDA and manufactured in facilities regulated by the FDA or an applicable foreign regulatory authority. Our products and product candidates are designed to affect bodily functions and processes. Any side effects, manufacturing defects, misuse or abuse associated with our product candidates could result in injury and possibly death to a patient. An inability to obtain sufficient insurance coverage on commercially reasonable terms or otherwise to protect against potential product liability claims could inhibit our business.

In addition, a liability claim may be brought against us even if our product candidates merely appear to have caused an injury. Product liability claims may be brought against us by consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our product candidates, among others. If we cannot successfully defend ourselves against product liability claims we will incur substantial liabilities and reputational harm. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- withdrawal of clinical trial participants;
- termination of clinical trial sites or entire trial programs;
- the inability to commercialize our product candidates;
- decreased demand for our product candidates;
- impairment of our brand and/or reputation;
- product recall or withdrawal from the market or labeling, marketing or promotional restrictions;
- substantial costs of any related litigation or similar disputes;
- distraction of management's attention and other resources from our primary business;
- substantial monetary awards to patients or other claimants against us that may not be covered by insurance; or
- loss of potential revenue.

Although we may maintain product liability insurance coverage for clinical trials, our insurance coverage may not be sufficient to cover all of our product liability-related expenses or losses and may not cover us for any expenses or losses we suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost, in sufficient amounts or upon adequate terms to protect us against losses due to product liability, particularly if any of our product candidates receive regulatory approval. Further, a successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could decrease our cash and harm our business, financial condition, operating results and prospects.

We may be adversely affected by natural disasters, pandemics and other catastrophic events, and by man-made problems such as terrorism, that could disrupt our business operations and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our corporate headquarters is located in Sarasota, Florida, a hurricane zone. If a disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as enterprise financial systems, manufacturing resource planning or enterprise quality systems, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. Our contract manufacturers' and suppliers' facilities are located in multiple locations, where other natural disasters or similar events, such as blizzards, tornadoes, fires, explosions or large-scale accidents or power outages, and other public health emergencies could severely disrupt our operations and have a material adverse effect on our business, financial condition, operating results and prospects. For example, the recent COVID-19 pandemic may cause significant disruption to our business operations, the operations of our third-party contractors and suppliers and the operations of our clinical trials, including as a result of significant restrictions or bans on travel into and within the geographic areas in which our manufacturers product our product candidates or where we conduct our clinical trials. A public health emergency could also affect the operations of the FDA and other regulatory or public health authorities, resulting in delays to meetings related to planned or completed clinical trials and ultimately of reviews and approvals of our product candidates. Such disruption could impede, delay, limit or prevent our employees and third-party contractors from beginning or continuing research and development or clinical trial-related activities, which may impede, delay, limit or prevent initiation or completion of our ongoing clinical trials and pre-clinical research and ultimately lead to the delay or denial of regulatory approval of our product candidates, which could seriously harm our operations and financial condition.

In addition, acts of terrorism and other geo-political unrest could cause disruptions in our business or the businesses of our partners, manufacturers or the economy as a whole. All of the aforementioned risks may be further increased if we do not implement a disaster recovery plan or our partners' or manufacturers' disaster recovery plans prove to be inadequate. To the extent that any of the above should result in delays in the regulatory approval, manufacture, distribution or commercialization of our product candidates, our business, financial condition, operating results and prospects would suffer.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited, each of which could harm our business.

As of December 31, 2024, we had U.S. federal and state net operating loss carryforwards of approximately $159,358,319 and $142,594,207, respectively. We also accumulated U.S. federal and state research tax credits of approximately $4,041,694 as of December 31, 2024. Under Sections 382 and 383 of the Internal Revenue Code (the "Code"), if a corporation undergoes an "ownership change," the corporation's ability to use its pre-ownership change net operating loss carryforwards and other pre-ownership change tax attributes, such as research tax credits, to offset its post-ownership change income and taxes may be limited. In general, an ownership change will occur when the percentage of the Corporation's ownership (by value) of one or more "5-percent shareholders" (as defined in the Code) has increased by more than 50 percent over the lowest percentage owned by such shareholders at any time during the prior three years (calculated on a rolling basis). Similar rules may apply under state tax laws. An entity that experiences an ownership change generally will be subject to an annual limitation on its pre-ownership change tax loss and credit carryforwards equal to the equity value of the corporation immediately before the ownership change, multiplied by the long-term, tax-exempt rate posted monthly by the IRS (subject to certain adjustments). The annual limitation would be increased each year to the extent that there is an unused limitation in a prior year. In the event that it is determined that we have in the past experienced an ownership change as a result of transactions in our stock, or if we experience one or more ownership changes as a result of future transactions in our stock, then we may be limited in our ability to use our net operating loss carryforwards and other tax assets to reduce taxes owed on the net taxable income that we earn. Any limitations on the ability to use our net operating loss carryforwards and other tax assets could harm our business.

If we fail to maintain an effective system of internal controls, we may not be able to accurately report our financial results or prevent fraud.

Because of its inherent limitations, internal controls over financial reporting may not prevent or detect misstatements. All internal control systems, no matter how well designed, have inherent limitations, including the possibility of human error and the circumvention of overriding controls. Accordingly, effective internal control over financial reporting can provide only reasonable assurance with respect to financial statement preparation. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

If we are unable to produce accurate consolidated financial statements in the future, our stock price, liquidity and access to the capital markets may be adversely affected and we may be unable to maintain compliance with applicable stock exchange listing requirements. Further, because of its inherent limitations, even our remediated and effective internal control over financial reporting may not prevent or detect all misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in our conditions, or that the degree of compliance with our policies or procedures may deteriorate.

Risks Related to Our Intellectual Property and Data Security and Privacy

Our limited resources and decision to pause the development of our COVID-19 vaccine candidate to focus on the development of ONP-002 may result in our breach of certain contracts.

We previously began the research and development stage for our Terra CoV-2 and NT-CoV2-1 vaccine product candidates. In connection therewith, we hold a non-exclusive, worldwide intellectual property license agreement for certain research, patent applications and biological materials relating to the use of pre-fusion coronavirus spike proteins for the development and commercialization of a vaccine against SARS-CoV-2. We also hold a non-exclusive license with the NRC that enables us to pursue the rapid development of next-generation vaccines against SARS-CoV-2 (the "NIH License") and its variants (the "NRC License") and an exclusive global license with Inspirevax (the "Inspirevax License" and, together with the NIH License and NRC License, the "License Agreements").

Under the License Agreements we must use reasonable commercial efforts to bring to market a vaccine product candidate covered by our licenses, which means we must adhere to an existing commercial development plan and existing performance benchmarks. Additionally, we are obliged to pay to the licensors certain minimum annual royalties, certain benchmark-related royalties and royalties based upon a share of any net sales of our vaccine product candidate, following regulatory approval and the first commercial sale. Additionally, among other obligations, we must provide regular written reports to the licensors on the development status of our vaccine product candidate and pay for our pro rata share of the NIH's patent prosecution-related expenses and fees. Moreover, we must use reasonable commercial efforts to develop, manufacture, and commercialize the vaccine product candidate, to manufacture the vaccine product candidate substantially within the United States and or Canada and provide the United States and Canadian public with reasonable access to the vaccine, if approved for commercialization by the FDA and Canadian regulatory agencies.

Due to our limited resources and recent acquisition of the Neurology Assets, which we believe hold great promise, we have chosen to pause our vaccine product candidates. It is uncertain when, if ever, we will recommence the research and development of our vaccine product candidates as it will require significant additional financing. We may not be able to obtain the additional financing on terms acceptable to us, or at all. As a result, we may be unable to meet our obligations under the License Agreements, which may be terminated, and we may be unable to proceed with the development of our vaccine product candidates in the future.

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

We or the Licensors may be subject to claims that former employees, collaborators or other third parties have an interest in the licensed patents or other intellectual property as an inventor or co-inventor. For example, we or the Licensors may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing the intellectual property covered by the License Agreements or our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or our license or the Licensors' ownership, as applicable, of the licensed patents, trade secrets or other intellectual property. If we or our licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as our right to use intellectual property that is important to our product candidate development and commercialization. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

The United States has recently enacted and is currently implementing wide-ranging patent reform legislation. Further, recent United States Supreme Court rulings have either narrowed the scope of patent protection available in certain circumstances or weakened the rights of patent owners in certain situations. Moreover, patent law and protection in foreign countries, particularly developing countries, may be insufficient or otherwise unclear in its efficacy to protect our intellectual property. 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 scope and value of patents, once obtained.

For our U.S. patent applications containing a priority claim after March 16, 2013, there is a greater level of uncertainty in the patent law. In September 2011, the Leahy-Smith America Invents Act, also known as the America Invents Act, or AIA, was signed into law. The AIA includes a number of significant changes to U.S. patent law, including provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The USPTO is currently developing regulations and procedures to govern the administration of the AIA, and many of the substantive changes to patent law associated with the AIA. It is not clear what other, if any, impact(s) the AIA will have on the operation of our business. Moreover, the AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have an adverse effect on our business. One important change introduced by the AIA is that, as of March 16, 2013, the United States transitioned to a "first-to-file" system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. A third party who files a patent application with the USPTO after such date but prior to us may therefore be awarded a patent covering an invention of ours even if we were the first to invent. This "first-inventor-to-file" system will require us both to remain cognizant, going forward, of the timing between invention and filing of a patent application.

Among some of the other changes introduced by the AIA are those that (i) limit where a patentee may file a patent infringement suit and (ii) provide opportunities for third parties to challenge any issued patent in the USPTO. Such changes apply to all of our U.S. patents, even those issued prior to March 16, 2013. Because of a lower evidentiary standard in USPTO proceedings, as compared to the evidentiary standard applied in U.S. federal courts, necessary to invalidate a patent claim, a third party could potentially present evidence in a USPTO proceeding sufficient for the USPTO to find a claim invalid, notwithstanding that the same evidence would be insufficient to invalidate a claim first presented in a district court action. Accordingly, a third party may attempt opportunistically to use USPTO procedures to invalidate our patent claims.

Depending on decisions by the United States 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 may weaken our and our licensors' abilities to obtain new patents or to enforce existing patents we and our licensors or partners may obtain in the future.

If we are unable to protect our trademarks or other intellectual property from infringement, our business prospects may be harmed.

We have applied for trademark protection for trademarks in the United States, the European Union and China. Although we take steps to monitor the possible infringement or misuse of our trademarks, it is possible that third parties may infringe, dilute or otherwise violate our trademark rights. Any unauthorized use of our trademarks or other intellectual property rights could harm our reputation or commercial interests. Moreover, our License Agreements do not commit to defend any declaratory judgment action alleging the invalidity of any of the licensed patent rights covered by the license, nor does the NIAID commit to commence legal actions against third parties alleged to infringe upon those licensed patent rights. Our enforcement against third-party infringers or violators may be unduly expensive and time-consuming, and any remedy obtained may constitute insufficient redress relative to the damages we may suffer.

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

Filing, prosecuting, and defending patents on our product candidates in all countries throughout the world would be prohibitively expensive. The requirements for patentability may differ in certain countries, particularly developing countries. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as 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. 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 insufficient to guard against such infringement. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to pharmaceuticals. In such instances, we may be unable to enjoin or otherwise prevent infringement of our patents or marketing of competing products in violation of our proprietary rights, generally. Proceedings to enforce our patent rights in foreign jurisdictions could (i) result in substantial costs and divert our efforts and attention from other aspects of our business, (ii) put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and (iii) 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. In addition, certain countries in Europe and certain developing countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we may be unable to seek adequate remedies to address infringement and/or material diminishment of the value of our patents, which could limit our potential revenue opportunities in such jurisdictions. Accordingly, our efforts to establish or enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from our intellectual property. Finally, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws.

If we are sued for infringing intellectual property rights of third parties, it will be costly and time-consuming and an unfavorable outcome in that litigation could have a material adverse effect on our business.

Our commercial success depends upon our ability to develop, manufacture, market, and sell our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. We cannot guarantee that engaging in such actions and using such technologies will not infringe existing or future patents. Numerous U.S. and foreign issued patents and pending patent applications owned by third parties exist in the fields relating to our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that others may assert that our product candidates, technologies or methods of delivery or use infringe their patent rights. Moreover, it is not always clear to industry participants, including us, which patents cover various drugs, biologics, drug delivery systems or their methods of use, and which of these patents may be valid and enforceable. Thus, due to the large number of patents issued and patent applications filed in our fields, third parties may allege they have patent rights encompassing our product candidates, technologies or methods.

In addition, our product candidates or proprietary technologies may infringe patents owned and/or filed by third parties, or third parties may allege such infringement. Because (i) some patent applications in the United States may be maintained in secrecy until the patents are issued, (ii) patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing and (iii) publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our own and in-licensed issued patents or our pending applications. Our competitors may have filed, and may in the future file, patent applications covering our product candidates or technology similar to ours. Any such patent application may have priority over our own and in-licensed patent applications or patents, which could further require us to obtain rights to issued patents covering such technologies. If another party has filed a U.S. patent application on inventions similar to those owned or in-licensed to us, we or, in the case of in-licensed technology, the licensor may have to participate, in the United States, in an interference proceeding to determine priority of invention.

We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that our product candidates or proprietary technologies infringe such third parties' intellectual property rights, including litigation resulting from filing under Paragraph IV of the Hatch-Waxman Act. Such lawsuits can be costly and could adversely affect our operating results and divert the attention of managerial and technical personnel, even if we do not infringe such patents or the patents asserted against us are later invalidated. A court may, however, decide that we are infringing the third party's patents and order us to cease the activities covered by the patents. In addition, there is a risk that a court will order us to pay for such third-party damages for having violated the other party's patents.

As a result of patent infringement claims, or to avoid potential claims, we may choose or be required to seek licenses from third parties. These licenses may not be available on commercially acceptable terms, or at all. Even if we are able to obtain a license, the license would likely obligate us to pay license fees or royalties or both, and the rights granted to us might be nonexclusive, which could result in our competitors gaining access to the same intellectual property, or such rights might be restrictive and limit our present and future activities. Ultimately, we or a licensee could be prevented from commercializing a product or forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on acceptable terms.

In addition to possible infringement claims against us, we may become a party to other patent litigation and other proceedings, including interference, derivation, re-examination or other post-grant proceedings declared or granted by the USPTO, and similar proceedings in foreign countries, regarding intellectual property rights with respect to our current or future products.

There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, generally. To date, no litigation asserting infringement claims has ever been brought against us. If a third-party claims that we infringe its intellectual property rights, we may face a number of issues, including:

- infringement and other intellectual property claims which, regardless of merit, may be expensive and time-consuming to litigate and may divert our management's attention from our core business;
- substantial damages for infringement, which we may have to pay if a court decides that the product or technology at issue infringes or violates the third party's rights, and if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner's attorneys' fees;
- a court prohibiting us from selling or licensing the product or using the technology unless the third party licenses its intellectual property rights to us, which it is not required to do;
- if a license is available from a third party, we may have to pay substantial royalties or upfront fees or grant cross-licenses to intellectual property rights for our products or technologies; and

- redesigning our products or processes so they do not infringe, which may not be possible or may require substantial monetary expenditures and time.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could harm our ability to raise additional funds or otherwise adversely affect our business, financial condition, operating results and prospects.

Because we rely on certain third-party licensors and partners, and will continue to do so in the future, if one of our licensors or partners is sued for infringing a third party's intellectual property rights, our business, financial condition, operating results and prospects could suffer in the same manner as if we were sued directly. In addition to facing litigation risks, we have agreed to indemnify certain third-party licensors and partners against claims of infringement caused by our proprietary technologies, and we have entered or may enter into cost-sharing agreements with some our licensors and partners that could require us to pay some of the costs of patent litigation brought against those third parties whether or not the alleged infringement is caused by our proprietary technologies. In certain instances, these cost-sharing agreements could also require us to assume greater responsibility for infringement damages than our technology alone would otherwise suggest.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property or the patents of our licensors, which could be expensive and time-consuming.

Competitors may infringe upon our intellectual property, including our patent applications or the patents of our licensors. As a result, we may be required to file infringement claims to stop third-party infringement or unauthorized use. Such proceedings and/or litigation can be expensive – particularly for a company of our size – and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable or may refuse to enjoin the other party from using the technology at issue on the grounds that our patent claims do not cover its technology or that the factors necessary to grant an injunction are not satisfied. An adverse determination in such a case could put one or more of our patents at risk of being invalidated, interpreted narrowly or amended such that they fail to cover or otherwise protect our product candidates. Moreover, such adverse determinations could subject our patent applications to the risk that they will not issue, or issue with limited and potentially inadequate scope to cover our product candidates.

Interference, derivation, or other proceedings brought at the USPTO may be necessary to determine the priority or patentability of inventions with respect to our patent applications or those of our licensors or potential partners. Litigation or USPTO proceedings brought by us may fail or may be invoked against us by third parties. Even if we are successful, domestic or foreign litigation, or USPTO or foreign patent office proceedings may result in substantial costs and distraction to our management. We may not be able, alone or with our licensors or potential partners, to prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other proceedings, there is a risk that we may, intentionally or incidentally, disclose some of our confidential results of hearings, motions or other interim proceedings or developments or public access to related documents. If investors perceive these results to be negative, the market price for our common stock could be significantly harmed.

If our intellectual property rights do not adequately protect our products or product candidates, or if third parties claim we are infringing their intellectual property rights, others could compete against us more directly or we could be subject to significant litigation. Such results could prevent us from marketing our products or product candidates and hurt our profitability.

Our product candidates are protected by patents and patent applications. Our success depends in part on our ability to obtain patents or rights to patents, protect trade secrets, operate without infringing upon the proprietary rights of others, and prevent others from infringing on our patents, trademarks and other intellectual property rights. We will be able to protect our intellectual property from unauthorized use by third parties only to the extent that it is covered by valid and enforceable patents, trademarks and licenses. Patent protection generally involves complex legal and factual questions and, therefore, enforceability of patent rights cannot be predicted with certainty. Patents, if issued, may be challenged, invalidated or circumvented. Thus, any patents that we own or license from others may not provide adequate protection against competitors. In addition, any future patent applications may fail to result in patents being issued. Also, those patents that are issued may not provide us with adequate proprietary protection or competitive advantages against competitors with similar product candidates. Moreover, the laws of certain foreign countries do not protect intellectual property rights to the same extent as do the laws of the United States.

In addition to patents and trademarks, we rely on trade secrets and proprietary know-how. We seek protection of these rights, in part, through confidentiality and proprietary information agreements. These agreements may not provide meaningful protection or adequate remedies for violation of our rights in the event of unauthorized use or disclosure of confidential and proprietary information. Failure to protect our proprietary rights could seriously impair our competitive position.

In the event of an infringement or violation, we may face litigation and may be prevented from pursuing product development or commercialization. We may receive in the future notice of claims of infringement of other parties' proprietary rights. We may not have the financial resources to defend against claims of infringement by other parties or to prosecute third parties for infringement of our intellectual property. Infringement or other claims could be asserted or prosecuted against us in the future, and it is possible that past or future assertions or prosecutions could harm our business.

Our business and operations would suffer in the event of cybersecurity/information systems risk.

Despite the implementation of security measures, our internal computer systems, and those of our manufacturers and other third parties on which we rely, are vulnerable to damage from computer viruses, malware, ransomware, unauthorized access, natural disasters, fire, explosions or large-scale accidents, power outages or surges, terrorism, successful breaches, employee malfeasance, or human or technological error, war and telecommunication and electrical failures. In addition, our systems safeguard important confidential personal data regarding our subjects. If a disruption event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs. For example, the loss of clinical trial data from completed, ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our product candidates could be delayed.

Security breaches and other disruptions to our information technology systems or those of the vendors on whom we rely could compromise our information and expose us to liability, reputational damage, or other costs.

In the ordinary course of our business, we and our current and future strategic partners, vendors, contractors, and consultants collect and store sensitive data, including intellectual property, our proprietary business information and data about our clinical participants, suppliers and business partners and personally identifiable information. The secure maintenance of this information is critical to our operations and business strategy. Some of this information represents an attractive target of criminal attack by malicious third parties with a wide range of motives and expertise, including nation-states, organized criminal groups, "hacktivists," patient groups, disgruntled current or former employees and others. Our ongoing operating activities also depend on functioning information technology systems. Cyberattacks are of ever-increasing levels of sophistication, and, despite our security measures, our information technology systems and infrastructure and those of our vendors and partners are not immune to such attacks or breaches.

Any such attack could result in a material compromise of our networks, and the information stored there could be accessed, publicly disclosed, lost, rendered, permanently or temporarily, inaccessible. Furthermore, we may not promptly discover a system intrusion. Attacks could have a material impact on our business, operations or financial results. Any access, disclosure or other loss of information, whether stored by us or our partners, or other cyberattack causing disruption to our business, including ransomware, could result in reputational, business, and competitive harms, significant costs related to remediation and strengthening our cyber defenses, legal claims or proceedings, government investigations, liability including under laws that protect the privacy of personal information, and increased insurance premium, all of which could adversely affect our business. We also may need to pay a ransom if a "ransomware" infection prevents access or use of our systems and we may face reputational and other harms in addition to the cost of the ransom if an attacker steals certain critical data in the course of such an attack.

We may incur costs of addressing a cybersecurity incident.

Cybersecurity incidents have increased in number and severity recently and it is expected that these trends will continue. Should we be affected by such an incident, we may incur substantial costs and suffer other negative consequences, which may include:

- investigation costs and costs to engage specialized consultants or costs of ransom demands;
- remediation costs, such as liability for stolen assets or information, repairs of system damage, and incentives to customers or business partners in an effort to maintain relationships after an attack; and
- litigation and legal risks, including regulatory actions by state and federal regulators.

Risks Related to Government Regulations

Our product candidates are subject to substantial government regulation, including the regulation of nonclinical testing and clinical trials. If we are unable to obtain regulatory approval for our product candidates, we will be unable to generate revenues.

The production and marketing of products which may be developed from our Neurology Assets, or otherwise, and our research and development, nonclinical testing and clinical trial activities are subject to extensive regulation and review by numerous governmental authorities. Most of the product candidates we are developing must undergo rigorous nonclinical testing and clinical trials and an extensive regulatory approval process before they can be marketed in the United States or internationally.

If we fail to obtain regulatory approval for our product candidates, we may have to cease further development. Clinical trials on our product candidates are expected to take several years to fully complete. The commencement or completion of nonclinical studies or clinical trials can be delayed or prevented for a number of reasons, including:

- an inability to raise sufficient capital to commence, conduct, or complete pre-clinical testing and clinical trials;
- insufficient or inadequate supply or quality of a product candidate or other materials necessary to conduct our clinical trials;
- difficulties in finding a partner with the resources to support large and expensive clinical development and commercialization costs;
- findings in nonclinical trials;
- difficulties obtaining regulatory approval to commence a clinical trial or complying with conditions imposed by a regulatory authority regarding the scope or term of a clinical trial;
- delays in reaching or failing to reach agreement on acceptable terms with prospective contract research organizations, or CROs, and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- difficulties obtaining institutional review board, or IRB, approval to conduct a clinical trial at a prospective site;
- challenges recruiting and enrolling patients to participate in clinical trials for a variety of reasons, including the size and nature of patient population, proximity of patients to clinical sites, eligibility criteria for the trial, nature of the trial protocol, the availability of approved effective treatments for the relevant condition and competition from other clinical trial programs for similar indications;

- severe or unexpected drug or biologic-related side effects experienced by patients in a clinical trial; and
- difficulties retaining patients who have enrolled in a clinical trial but may be prone to withdraw due to rigors of the trial, lack of efficacy, side effects, or personal issues, or who are lost to further follow up.

Clinical trials also may be delayed or terminated as a result of ambiguous or negative interim results. In addition, a clinical trial may be suspended or terminated by us, the FDA, the IRBs at the sites where the IRBs are overseeing a trial, or a data safety monitoring board, or DSMB, overseeing the clinical trial at issue, or other regulatory authorities due to a number of factors, including:

- failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;
- inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities;
- inspection of manufacturing and drug packaging operations by regulatory authorities;
- unforeseen safety issues or lack of effectiveness; and
- lack of adequate funding to continue the clinical trial.

We cannot assure you that clinical trials will demonstrate the safety or effectiveness of any of our product candidates or will otherwise satisfy regulatory requirements. Our nonclinical studies or clinical trials may produce negative or inconclusive results, there may be inconsistencies between early clinical trial results and results obtained in later clinical trials, and we may decide, or regulators may require us, to conduct additional nonclinical studies or clinical trials. Moreover, nonclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in nonclinical studies and clinical trials have nonetheless failed to obtain FDA approval for their products. If we are unable to resolve the FDA's concerns, we will not be able to obtain regulatory approval for these product candidates.

The pre-marketing approval process can be particularly expensive, uncertain and lengthy, and a number of products for which FDA or other governmental regulatory approval has been sought by other companies have never been approved for marketing. In addition to testing and approval procedures, extensive regulations also govern marketing, manufacturing, distribution, labeling, and record-keeping procedures. If we do not comply with applicable regulatory requirements, such violations could result in warning letters, non-approval, suspensions of regulatory approvals or ongoing clinical trials, civil penalties and criminal fines, product seizures and recalls, operating restrictions, injunctions, and criminal prosecution.

We may encounter such delays and rejection of our product candidates by the FDA or other regulatory authority may also adversely affect our business. Such delays or rejection may be encountered due to, among other reasons, government or regulatory delays, lack of efficacy during clinical trials, unforeseen safety issues, or changes in regulatory policy during the period of product development. More stringent regulatory approval processes in product clearance and enforcement activities could result in our experiencing longer approval cycles, more uncertainty, greater risk, and higher expenses. Even if regulatory approval of a product is granted, this approval may entail limitations on uses for which the product may be labeled and promoted. It is possible, for example, that we may not receive FDA approval to market products based on our licensed, patented product candidates for different indications or to market updated products that represent extensions of our basic product candidates. In addition, we may not receive FDA approval to export our products based on our licensed, patented product candidates in the future, and countries to which products are to be exported may not approve them for import.

From time to time, legislative or regulatory proposals are introduced that could alter the review and approval process relating to our product candidates. It is possible that the applicable regulatory authority will issue additional regulations further restricting the sale of our product candidates. Any change in legislation or regulations that govern the review and approval process relating to our future product candidates could make it more difficult and costlier to obtain approval for new products based on our product candidates, or to produce, market, and distribute such products if approved.

Clinical trials conducted outside of the United States, present additional risks.

Conducting clinical trials in foreign countries, such as Australia, for our product candidate presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, as well as political and economic risks relevant to such foreign countries. Moreover, 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.

Delays in the completion of any preclinical studies or clinical trials of our product candidates will increase our costs, slow down our product candidate development and approval process and delay or potentially jeopardize our ability to commence product sales and generate product revenue. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Any delays to our preclinical studies or clinical trials that occur as a result could shorten any period during which we may have the exclusive right to commercialize our product candidates. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, the FDA's and other regulatory authorities' policies with respect to clinical trials may change.

We may be unable to obtain regulatory approval for our concussion candidate, or other early-stage product candidates under applicable regulatory requirements. The FDA and foreign regulatory bodies have substantial discretion in the approval process, including the ability to delay, limit or deny approval of product candidates. The delay, limitation or denial of any regulatory approval would adversely impact commercialization, our potential to generate revenue, our business and our operating results.

We are not permitted to market any of our current product candidates in the United States until we receive approval of an NDA or BLA from the FDA. We are also not permitted to market any of our current product candidates in any foreign countries until we receive the requisite approval from the applicable regulatory authorities of such countries. Failure to obtain such regulatory approvals will delay or prevent us from commercializing any of our current or future product candidates.

To gain approval to market a new product such as ONP-002, we must provide the FDA and/or foreign regulatory authorities with, among other things, extensive pre-clinical and clinical data that adequately demonstrates the safety and efficacy of the drug in its intended indication and information to demonstrate the adequacy of the manufacturing methods to assure the drug's identity, strength, quality and purity. The development and approval of new drug product candidates involves a long, expensive and uncertain process, and delay or failure can occur at any stage. A number of companies in the pharmaceutical and biopharmaceutical industries have suffered significant setbacks in clinical trials, including in Phase 3 clinical development, even after promising results in earlier pre-clinical studies or clinical trials. These setbacks have been caused by, among other things, observations during clinical trials regarding safety or efficacy, such as previously unreported adverse events. Success in pre-clinical testing and early clinical trials does not ensure success in later clinical trials, and the results of clinical trials by other parties may not be indicative of the results in trials we may conduct. Further, different results may be achieved depending upon whether the "per protocol", or PP, analysis is used to report data results or whether the "modified intent-to-treat," or MITT, approach is used. Accordingly, regardless of the outcome of any Phase 2 trials, any Phase 3 trials we may conduct may not be successful.

The FDA and foreign regulatory bodies have substantial discretion in the drug approval process, including the ability to delay, limit or deny approval of product candidates for many reasons. The FDA or the applicable foreign regulatory body may:

- disagree with the design or implementation of one or more clinical trials;
- decline to deem a product candidate safe and effective for its proposed indication, or deem a product candidate's safety or other perceived risks to outweigh its clinical or other benefits;
- find the data from pre-clinical studies and clinical trials does not sufficiently support approval, or the results of clinical trials may not meet the level of statistical or clinical significance required for approval;
- disagree with our interpretation of data from pre-clinical studies or clinical trials performed by us or third parties;
- determine the data collected from clinical trials are insufficient to support the submission or approval of an NDA or other applicable regulatory filing;
- require additional pre-clinical studies or clinical trials;
- identify deficiencies in the formulation, quality control, labeling or specifications of our current or future product candidates;
- grant approval contingent on the performance of costly additional post-approval clinical trials;
- approve our current or any future product candidates for a more limited indication or a narrower patient population than we originally requested or with strong warnings that may affect marketability;
- decline to approve the labeling that we believe is necessary or desirable for the successful commercialization of our product candidates;

- require a Risk Evaluation and Mitigation Strategy, or REMS, with monitoring requirements or distribution limitations. For example, it is possible that the FDA could require distribution controls in the approval, if any, of our product candidates to prevent inadvertent exposure to pregnant women;

- decline to approve of the manufacturing processes, controls or facilities of third-party manufacturers or testing labs with whom we contract; or

- change its approval policies or adopt new regulations in a manner rendering our clinical data or regulatory filings insufficient for approval.

Any delay, limitation or denial of any regulatory approval would adversely impact commercialization, our potential to generate revenue, our business, and our operating results.

Delays or difficulties in the enrollment of patients in clinical trials may result in additional costs and delays in our ability to generate significant revenues and may delay or prevent our receipt of any regulatory approvals necessary to commercialize our planned and future products.

We may not be able to initiate, or continue, or complete in a timely fashion clinical trials for ONP-002 or our other product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States.

Patient enrollment is affected by other factors including:

- the severity of the disease under investigation;

- the eligibility criteria for the study in question;

- the perceived risks and benefits of the product candidate under study;

- the efforts to facilitate timely enrollment in clinical trials;

- the patient referral practices of physicians;

- the ability to monitor patients adequately during and after treatment; and

- the proximity and availability of clinical trial sites for prospective patients.

Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays, could require us to abandon one or more clinical trials altogether and could delay or prevent our receipt of necessary regulatory approvals. Enrollment delays in our clinical trials may result in increased development costs for our product candidates, which would cause the value of our company to decline and impede our ability to obtain additional financing.

Any product candidates that we commercialize will be subject to ongoing and continued regulatory review.

Even after we achieve U.S. regulatory approval for a product candidate, if any, we will be subject to continued regulatory review and compliance obligations. For example, the FDA may impose significant restrictions on the approved indicated uses for which our product candidates may be marketed or on the conditions of approval. A product candidate's approval may contain requirements for potentially costly post-approval studies and surveillance, including Phase 4 clinical trials or a REMS to monitor the safety and efficacy of the product. We will also be subject to ongoing FDA obligations and continued regulatory review with respect to, among other things, the manufacturing, processing, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for our product candidates. These requirements include submissions of safety and other post-marketing information and reports, registration, continued compliance with the FDA's good clinical practice, or GCP, requirements and good laboratory practice requirements, which are regulations and guidelines the FDA would apply to all of our product candidates in clinical and pre-clinical development, along with any clinical trials that we conduct post-approval, and continued compliance with the FDA's cGMP requirements pursuant to which manufacturing facilities are subject to continual review and periodic inspections by the FDA. To the extent that a product candidate is approved for sale in other countries, we may be subject to similar restrictions and requirements imposed by laws and government regulators in those countries.

If we, our product candidates, or the manufacturing facilities for our product candidates fail to comply with applicable regulatory requirements, a regulatory agency may:

- impose restrictions on the marketing or manufacturing of the product, suspend or withdraw product approvals or revoke necessary licenses;
- issue warning letters, show cause notices or untitled letters describing alleged violations, which may be publicly available;
- mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners;
- require us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance; commence criminal investigations and prosecutions;
- impose injunctions;
- impose other civil or criminal penalties;
- suspend any ongoing clinical trials;
- delay or refuse to approve pending applications or supplements to approved applications filed by us;
- refuse to permit drugs or active ingredients to be imported or exported to or from the United States;
- suspend or impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products or require us to initiate a product recall.

The regulations, policies or guidance of the FDA and other applicable government agencies may change and new or additional statutes or government regulations may prevent or delay regulatory approval of our product candidates or further restrict or regulate post-approval activities. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are not able to achieve and maintain regulatory compliance, we may not be permitted to market our product candidates, which would materially and adversely affect our ability to generate revenue and achieve or maintain profitability.

Our product candidates may cause serious or undesirable side effects or possess other unexpected properties that could delay or prevent their regulatory approval, limit the commercial profile of approved labeling or result in post-approval regulatory action.

Unforeseen side effects from any of our product candidates could arise either during clinical development or, if approved, after marketing such product. Undesirable side effects caused by product candidates could cause us or regulatory authorities to interrupt, modify, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign authorities. Results of clinical trials could reveal a high and unacceptable severity and prevalence of side effects. In such an event, trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of product candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in product liability claims. Any of these occurrences may harm our business, financial condition, operating results and prospects.

Additionally, if we or others identify undesirable side effects, or other previously unknown problems, caused by our product candidates after obtaining U.S. or foreign regulatory approval or other products with the same or related active ingredients, a number of potentially negative consequences could result, including:

- regulatory authorities may withdraw their approval of the product;
- regulatory authorities may require a recall of the product or we may voluntarily recall a product;
- regulatory authorities may require the addition of warnings or contraindications in the product labeling, narrowing of the indication in the product label or issuance of field alerts to physicians and pharmacies;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients or institute a risk evaluation and mitigation strategy, or REMS;
- we may be subject to limitations as to how we promote the product;
- we may be required to change the way the product is administered or modify the product in some other way;
- the FDA or applicable foreign regulatory authority may require additional clinical trials or costly post-marketing testing and surveillance to monitor the safety or efficacy of the product;
- sales of the product may decrease significantly;
- we could be sued and held liable for harm caused to patients; and
- our brand and reputation may suffer.

Any of the above events could prevent us from achieving or maintaining market acceptance of the affected product candidate and could substantially increase the costs of commercializing our product candidates.

We may also be subject to healthcare laws, regulation and enforcement and our failure to comply with those laws could adversely affect our business, operations and financial condition.

Certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. We are subject to regulation by both the federal government and the states in which we conduct our business. The laws and regulations that may affect our ability to operate include:

- the federal healthcare program anti-kickback statute, which prohibits, among other things, any person or entity from knowingly and willfully offering, soliciting, receiving or providing any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce either the referral of an individual or in return for the purchase, lease, or order of any good, facility item or service, for which payment may be made, in whole or in part, under federal healthcare programs such as the Medicare and Medicaid programs;
- federal civil and criminal false claims laws and civil monetary penalty laws, including, for example, the United States False Claims Act, which impose criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, 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, as amended by the Health Information Technology for Economic and Clinical Health Act, or HIPAA, which prohibits knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (i.e., public or private), knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a health care offense and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;

- HIPAA and related implementing regulations, which impose obligations on covered entities, including healthcare providers, health plans, and healthcare clearinghouses, as well as their respective business associates that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- the federal physician sunshine requirements under the Patient Protection and Affordable Care Act, or ACA, which require manufacturers of drugs, devices, biologics and medical supplies to report annually to the Centers for Medicare & Medicaid Services information related to payments and other transfers of value provided to physicians and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members, with such information published on a searchable website on an annual basis; and

- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, which may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government, or otherwise restrict payments that may be provided to healthcare providers and other potential referral sources; state laws that require drug manufacturers to report information related to payments and other transfers of value to healthcare providers or marketing expenditures; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. In addition, recent health care reform legislation has strengthened these laws. For example, the recently enacted ACA, among other things, amended the intent requirement of the federal anti-kickback statute and certain criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it. In addition, the ACA provides that the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.

Achieving and sustaining compliance with these laws may prove costly. In addition, any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of the laws described above or any other governmental laws or regulations that apply to us, we may be subject to penalties, including administrative, civil and criminal penalties, damages, fines, disgorgement, the exclusion from participation in federal and state healthcare programs, individual imprisonment or the curtailment or restructuring of our operations, any of which could materially and adversely affect our ability to operate our business and our financial results.

Our employees, independent contractors, principal investigators, consultants, vendors and CROs 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, principal investigators, consultants, vendors and CROs may engage in fraudulent or other illegal activity. Misconduct by these persons could include intentional, reckless or negligent conduct or unauthorized activity that violates laws or regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA or foreign regulatory authorities; manufacturing standards; federal, state and foreign healthcare fraud and abuse laws and data privacy; or laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and other business arrangements in the healthcare industry are subject to extensive laws intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws may restrict or prohibit a wide range of business activities, including research, manufacturing, distribution, pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials, or illegal misappropriation of drug product, which could result in regulatory sanctions or other actions or lawsuits stemming from a failure to comply with such laws or regulations, and serious harm to our reputation. In addition, federal procurement laws impose substantial penalties for misconduct in connection with government contracts and require certain contractors to maintain a code of business ethics and conduct. If any such actions are instituted against us, we may have to terminate employees or others involved and the impact of such termination can result in our experiencing delays and additional costs associated with replacing the services being provided. If 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 civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, FDA debarment, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our operating results.

Even if our current product candidates or any future product candidates obtain regulatory approval, they may fail to achieve the broad degree of health care payers, physician and patient adoption and use necessary for commercial success.

The commercial success of any of our current or future product candidates, if approved, will depend significantly on the broad adoption and use of the resulting product by health care payers, physicians and patients for approved indications, and may not be commercially successful. The degree and rate of physician and patient adoption of our current or future product candidates, if approved, will depend on a number of factors, including:

- the clinical indications for which the product is approved and patient demand for approved products that treat those indications;
- the effectiveness of our product as compared to other available therapies;
- the availability of coverage and adequate reimbursement from managed care plans and other healthcare payors for any of our product candidates that may be approved;
- the cost of treatment with our product candidates in relation to alternative treatments and willingness to pay for the product, if approved, on the part of patients;
- acceptance by physicians, major operators of clinics and patients of the product as a safe and effective treatment;
- physician and patient willingness to adopt a new therapy over other available therapies to treat approved indications;
- overcoming any biases physicians or patients may have toward particular therapies for the treatment of approved indications;
- proper training and administration of our product candidates by physicians and medical staff;
- patient satisfaction with the results and administration of our product candidates and overall treatment experience;
- the willingness of patients to pay for certain of our product candidates relative to other discretionary items, especially during economically challenging times;
- the revenue and profitability that our product candidate may offer a physician as compared to alternative therapies;

- the prevalence and severity of side effects;
- limitations or warnings contained in the FDA-approved labeling for our product candidates;
- any FDA requirement to undertake a REMS;
- the effectiveness of our sales, marketing and distribution efforts;
- adverse publicity about our product candidates or favorable publicity about competitive products; and
- potential product liability claims.

If any of our current or future product candidates are approved for use but fail to achieve the broad degree of physician and patient adoption necessary for commercial success, our operating results and financial condition will be adversely affected, which may delay, prevent or limit our ability to generate revenue and continue our operations.

If we are unable to achieve and maintain coverage and adequate levels of reimbursement for any of our product candidates for which we receive regulatory approval, or any future products we may seek to commercialize, their commercial success may be severely hindered.

As to any of our product candidates that become available by prescription only, our success will depend on the availability of coverage and adequate reimbursement for our product from third-party payors. Patients who are prescribed medicine for the treatment of their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. The availability of coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and private third-party payors is critical to new product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. If any of our product candidates fail to demonstrate attractive efficacy profiles, they may not qualify for coverage and reimbursement. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate or may require co-payments that patients find unacceptably high. Patients are unlikely to use our prescription-only products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products.

In addition, the market for certain of our product candidates will depend significantly on access to third-party payors' drug formularies or lists of medications for which third-party payors provide coverage and reimbursement. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical companies. Also, third-party payors may refuse to include a particular branded drug in their formularies or otherwise restrict patient access to a branded drug when a less costly generic equivalent or another alternative is available.

Moreover, third-party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, in the United States, although private third-party payors tend to follow Medicare, no uniform policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained.

Further, we believe that future coverage and reimbursement will likely be subject to increased restrictions in both the United States and in international markets. Third-party coverage and reimbursement for any of our product candidates for which we may receive regulatory approval may not be available or adequate in either the United States or international markets, which could harm our business, financial condition, operating results and prospects.

Risks Related to Our Common Stock

We cannot assure you that we will continue to be listed on the NYSE American.

Our Common Stock commenced trading on the NYSE American (formerly the NYSE MKT) on April 10, 2013, and we are subject to certain NYSE American continued listing requirements and standards. On April 18, 2024, we received notification (the "Notice") from the NYSE American that we were no longer in compliance with NYSE American's continued listing standards. Specifically, the letter stated that the Company was not in compliance with the continued listing standards set forth in Sections 1003(a)(ii) and 1003(a)(iii) of the NYSE American Company Guide (the "Company Guide"). Section 1003(a)(ii) requires a listed company to have stockholders' equity of $4 million or more if the listed company has reported losses from continuing operations and/or net losses in three of its four most recent fiscal years. Section 1003(a)(iii) requires a listed company to have stockholders' equity of $6 million or more if the listed company has reported losses from continuing operations and/or net losses in our five most recent fiscal years. We reported shareholders' equity of $3.2 million as of December 31, 2023, and losses from continuing operations and/or net losses in its five most recent fiscal years ended December 31, 2023. On May 17, 2024, we submitted a plan of compliance (the "Plan") to the NYSE American. On June 18, 2024, the NYSE American accepted our Plan; the Company will be able to continue its listing during the Plan period and will be subject to continued periodic review by the NYSE American staff. If we are not in compliance with the continued listing standards by October 18, 2025 or if the Company does not make progress consistent with the Plan during the Plan period, the Company will be subject to delisting procedures as set forth in the NYSE American Company Guide. The Company is committed to undertaking a transaction or transactions in the future to achieve compliance with the NYSE American's requirements. However, there can be no assurance that the Company will be able to achieve compliance with the NYSE American's continued listing standards within the required timeframe. If the Common Stock ultimately were to be delisted for any reason, it could negatively impact the Company by (i) reducing the liquidity and market price of the Company's Common Stock; (ii) reducing the number of investors willing to hold or acquire the Common Stock, which could negatively impact the Company's ability to raise equity financing; (iii) limiting the Company's ability to use a registration statement to offer and sell freely tradable securities, thereby preventing the Company from accessing the public capital markets; and (iv) impairing the Company's ability to provide equity incentives to its employees.

The issuance of additional equity securities by us in the future would result in dilution to our existing common shareholders.

Our Board of Directors has authority, without action or vote of our shareholders, to issue all or a part of our authorized but unissued shares, except where shareholder approval is required by law or the rules of any exchange on which our shares are listed. Any issuance of additional equity securities by us in the future could result in dilution to our existing common shareholders. Such issuances could be made at a price that reflects a discount or a premium to the then-current trading price of our common stock. In addition, our business strategy may include expansion through internal growth by acquiring complementary businesses, acquiring or licensing additional products or brands, or establishing strategic relationships with targeted customers and suppliers. In order to do so, or to finance the cost of our other activities, we may issue additional equity securities that could result in further dilution to our existing common shareholders. These issuances would dilute the percentage ownership interest of our existing common shareholders, which would have the effect of reducing their influence on matters on which our shareholders vote and might dilute the book value of our common stock. For example, our outstanding shares of common stock at December 31, 2023 was 3,080,693, due to additional common stock issuances related to capital raises, incentive compensation, and the conversion of our Preferred Shares Series A and B our outstanding shares of common stock was 12,570,100 at December 31, 2024. Furthermore, if Odyssey converts their preferred shares into common stock an additional 7,488,197 shares of common stock could be issued resulting in dilution to our existing common shareholders.

Our financial results could vary significantly from quarter to quarter and are difficult to predict.

Our operating results could vary significantly from quarter to quarter due to a variety of factors, many of which are outside of our control. As a result, comparing our operating results on a period-to-period basis may not be meaningful. In addition, we may not be able to predict our future revenues or results of operations. We base our current and future expense levels on our internal research and development plans and forecasts, and our operating costs vary to the extent of our research and development and the planning for and conduct of clinical trials. As a result, we may incur significant or unanticipated expenses associated with our research and development efforts of our product candidates under development. In addition to other risk factors discussed in this section, factors that may contribute to the variability of our quarterly results include:

- Our use of available cash resources;
- decisions by us to continue to pursue research and development and incur additional expenses, such as commencing a clinical trial or increases in research and development with our current product candidate;
- the timing of release of pre-clinical and clinical trial results and new products and services by our competitors, particularly those that may represent a significant portion of revenues in any given period;
- changes by our competitors;
- the level of expenses associated with our regulatory applications or compliance and clinical trials; and
- the timing of compensation expense associated with equity compensation grants.

As a result of these and other factors, our quarterly and annual operating results could be materially adversely affected. Moreover, our operating results may not meet the expectations of research analysts or investors, in which case the price of our common stock could decrease significantly.

The conversion of our Series F Preferred Stock, and the exercise of currently outstanding warrants could result in significant dilution to the holders of our common stock.

The holders of our Series F Preferred Stock may convert their shares of preferred stock into shares of common stock. As of December 31, 2024, we had outstanding 7,488,692 shares of Series F Preferred Stock, which are convertible into common stock on a one-to-one basis. In addition to our outstanding shares of preferred stock, as of December 31, 2024, there were currently outstanding warrants to purchase 736,574 shares of our common stock. The conversion of our Series F Preferred Stock; as well as the exercise of our outstanding warrants will result in significant dilution to existing common shareholders and could adversely affect the market price of our common stock and impair our ability to raise capital through the sale of additional equity securities.

Certain provisions of our articles of incorporation, bylaws, executive employment agreements and stock option plan may prevent a change of control of our company that a shareholder may consider favorable.

Provisions of our articles of incorporation, bylaws, executive employment agreements and stock option plan may discourage, delay or prevent a change of control of our company that a shareholder may consider favorable. These provisions include:

- authorization of the issuance of "blank check" preferred stock that could be issued by our Board of Directors without shareholder approval and that may be substantially dilutive or contain preferences or rights objectionable to an acquirer;
- the ability of our Board of Directors to amend the bylaws without shareholder approval;
- vacancies on our Board may only be filled by the remaining Directors and not our shareholders;
- requirements that only our Board, our President or holders of more than 10% of our shares can call a special meeting of shareholders;
- obligations to make certain payments under executive employment agreements in the event of a change of control and termination of employment; and
- immediate vesting of all outstanding stock options.

As a result, these provisions could discourage bids for our common stock at a premium and limit the price that investors are willing to pay in the future for shares of our common stock. However, in our articles of incorporation we expressly elected not to be governed by Sections 607.0901 and 607.0902 of the Florida Business Corporation Act, which are statutory anti-takeover provisions relating to affiliated transactions and control share acquisitions, respectively. As such, we do not have the protection of these statutes in connection with any unwanted takeover attempts which could have the effect of encouraging an attempted change of control without first negotiating with our Board of Directors.

The market price of our common stock has been, and may continue to be volatile and fluctuate significantly, which could result in substantial losses for shareholders.

The trading price of our common stock has historically been, and we expect it to continue to be, volatile. The price at which our common stock trades depends upon a number of factors, including our historical and anticipated operating results, our financial situation, announcements by us or our competitors, our ability or inability to raise the additional capital we may need and the terms on which we raise it, and general market and economic conditions. Some of these factors are beyond our control. Broad market fluctuations may lower the market price of our common stock and affect the volume of trading in our stock, regardless of our financial condition, results of operations, business or prospects. The closing price of our common stock as reported on the NYSE American had a high price of $6.84 and a low price of $0.27 in the 52-week period ended December 31, 2024. Furthermore, our stock traded within a range of a high volume of 15,238,600 and a low volume of 4,400 per share for the period of January 1, 2024, through December 31, 2024. As a result of this volatility, our stockholders could incur substantial losses. Factors that impact our trading price include:

- results of preclinical and clinical studies of our product candidates or those of our competition, including information related to our development, manufacturing, and distribution efforts with respect to ONP-002, or information regarding such efforts by competitors with respect to their products, may also impact our stock price;

- regulatory or legal developments in the U.S. and other countries, especially changes in laws and regulations applicable to our product candidates;
- actions taken by regulatory agencies with respect to our product candidates, clinical studies, manufacturing process or sales and marketing terms;
- introductions and announcements of new products by us or our competitors, and the timing of these introductions or announcements;
- announcements by us or our competitors of significant acquisitions or other strategic transactions or capital commitments;
- fluctuations in our quarterly operating results or the operating results of our competitors;
- variance in our financial performance from the expectations of investors;
- changes in the estimation of the future size and growth rate of our markets;
- changes in accounting principles or changes in interpretations of existing principles, which could affect our financial results;
- failure of our products to achieve or maintain market acceptance or commercial success;
- conditions and trends in the markets we serve;
- changes in general economic, industry and market conditions;
- changes in legislation or regulatory policies, practices or actions;
- the commencement or outcome of litigation involving our company, our general industry or both;
- recruitment or departure of key personnel;
- changes in our capital structure, such as future issuances of securities, redemption or conversion of preferred stock or the incurrence of additional debt;
- actual or expected sales of our common stock by our stockholders;
- acquisitions and financings; and
- the trading volume of our common stock;

The stock markets, in general, NYSE American and the market for biotech companies in particular, may experience a loss of investor confidence. Such loss of investor confidence may result in extreme price and volume fluctuations in our common stock that are unrelated or disproportionate to the operating performance of our business, financial condition or results of operations.

If our quarterly or annual results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly or annual fluctuations in our results may, in turn, cause the price of our stock to fluctuate substantially. We believe that period-to-period comparisons of our results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

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

In the past, other publicly traded companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of securities law-related litigation in the future, and such litigation against us, even if unsuccessful, could result in substantial costs and divert management's attention from other business concerns, which could seriously harm our business, financial condition and results of operations and prospects.

Future sales or issuances of our common stock in the public markets, or the perception of such sales, could depress the trading price of our common stock.

Sales of a substantial number of shares of our common stock and/or securities convertible into shares of common stock, or the perception by the market that those sales could occur, could cause the market price of our common stock to decline or could make it more difficult for us to raise funds through the sale of equity in the future.

Future issuances of common stock could further depress the market for our common stock. We expect to continue to incur drug development and selling, general and administrative costs, and to satisfy our funding requirements, we will need to sell additional equity securities, which may include sales of significant amounts of common stock to strategic investors, and which common stock may be subject to registration rights and warrants with anti-dilutive protective provisions. The sale or the proposed sale of substantial amounts of our common stock or other equity securities in the public markets or in private transactions may adversely affect the market price of our common stock and our stock price may decline substantially. Our stockholders may experience substantial dilution and a reduction in the price that they are able to obtain upon the sale of their shares. Also, new equity securities issued may have greater rights, preferences, or privileges than our existing common stock. In addition, we have a significant number of shares of restricted stock, stock options and warrants outstanding. To the extent that outstanding stock options or warrants have been or may be exercised or other shares issued, stockholders may experience further dilution.

If we make one or more significant acquisitions in which the consideration includes stock or other securities, our stockholders' holdings may be significantly diluted. In addition, stockholders' holdings may also be diluted if we enter into arrangements with third parties permitting us to issue shares of common stock in lieu of certain cash payments upon the achievement of milestones.

The issuance of shares of our common stock under our 2021 Equity Incentive Plan is covered by Form S-8 registration statements we filed with the Securities and Exchange Commission, or SEC, and upon exercise of the options, such shares may be resold into the market. We have also issued shares of common stock and warrants in connection with previous private placements. Such shares are available for resale as well as certain shares of common stock issuable upon exercise of the warrants. We have also issued shares of our common stock in the private placement and financing transaction, which are deemed to be "restricted securities," as that term is defined in Rule 144 promulgated under the Securities Act of 1933, as amended, or Securities Act, and such shares may be resold pursuant to the provisions of Rule 144. The resale of shares acquired from us in private transactions could cause our stock price to decline significantly. In addition, the conversion of outstanding shares preferred stock into common stock and the subsequent sale of shares of common stock could also cause our stock price to decline significantly.

In addition, from time to time, certain of our shareholders may be eligible to sell all or some of their restricted shares of common stock by means of ordinary brokerage transactions on the open market pursuant to Rule 144, subject to certain limitations. In general, pursuant to Rule 144, after satisfying a six-month holding period: (i) affiliated shareholders, or shareholders whose shares are aggregated, may, under certain circumstances, sell within any three-month period a number of securities which does not exceed the greater of 1% of the then-outstanding shares of common stock or the average weekly trading volume of the class during the four calendar weeks prior to such sale and (ii) non-affiliated shareholders may sell without such limitations, in each case provided we are current in our public reporting obligations.

We are unable to estimate the number of shares that may be sold because this will depend on the market price for our common stock, the personal or business circumstances of sellers and other factors.

The requirements of being a public company may strain our resources, divert management's attention and affect our ability to attract and retain qualified members for our Board of Directors.

As a public company, we are already subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and the Sarbanes-Oxley Act. The requirements of these rules and regulations may increase our legal, accounting and financial compliance costs; may make some activities more difficult, time-consuming and costly; and may also place undue strain on our personnel, systems and resources. Our management and other personnel need to devote a substantial amount of time to comply with these requirements. Moreover, these rules and regulations increase our legal and financial compliance costs and make some activities more time-consuming and costlier. These rules and regulations could also make it more difficult for us to attract and retain qualified persons to serve on our Board of Directors and Board committees or as executive officers.

As a public company we are also required to assess our internal control over financial reporting under Section 404 of the Sarbanes-Oxley Act and file periodic reports with the SEC. If we are unable to comply with these requirements in a timely manner, or if material weaknesses or significant deficiencies persist, the market price of our stock could decline and we could be subject to sanctions or regulatory investigations, which could harm our business. We must perform an assessment 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. Our compliance with Section 404 of the Sarbanes-Oxley Act requires that we incur a substantial accounting expense and expend significant management efforts. If we are unable to comply with the requirements of Section 404 of the Sarbanes-Oxley Act or the SEC reporting requirements in a timely manner, or if we note or identify deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our stock 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. As a smaller reporting company, we do not have to have our independent registered public accounting firm report on the effectiveness of our internal control over financial reporting. If in the future we no longer meet the requirements of a smaller reporting company, our independent registered public accounting firm will have to report on our internal controls over financial reporting. There can be no assurance that our independent registered public accounting firm will not identify material weaknesses which could have an adverse effect on our stock price.

If we fail to maintain an effective system of internal controls, we may not be able to accurately report our financial results or prevent fraud which could subject us to regulatory sanctions, harm our business and operating results and cause the trading price of our stock to decline.

Effective internal controls required under Section 404 of the Sarbanes-Oxley Act of 2002, or Sarbanes-Oxley Act, are necessary for us to provide reliable financial reports and effectively prevent fraud. If we cannot provide reliable financial reports or prevent fraud, our business, reputation and operating results could be harmed. We have discovered, and may in the future discover, areas of our internal controls that need improvement. We cannot be certain that the measures we have taken or intend to take will ensure that we maintain adequate controls over our financial processes and reporting in the future. Any failure to implement required new or improved controls or difficulties encountered in their implementation could subject us to regulatory sanctions, harm our business and operating results or cause us to fail to meet our reporting obligations. Inferior internal controls could also harm our reputation and cause investors to lose confidence in our reported financial information, which could have a negative impact on the trading price of our stock.

We will continue to incur significant costs as a result of and devote substantial management time to operating as a public company listed on the NYSE American.

As a public company listed on the NYSE American, we incur and will continue to incur significant legal, accounting and other expenses that we did not incur before when trading on the OTCQB Marketplace. For example, we are subject to the rules and regulations required by the NYSE American, including changes in corporate governance practices and minimum listing requirements. These requirements have increased our legal and financial compliance costs and have and will continue to render some activities more time-consuming and costlier. In addition, our management and other personnel have diverted and will continue to divert attention from operational and other business matters to devote substantial time to these listing requirements and failure to meet these requirements could lead to an adverse effect on the listing of our common stock on the NYSE American.

If securities or industry analysts publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock depends in part upon the research and reports that securities or industry analysts publish about us or our business from time to time. If one or more of the analysts who seek to cover us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts ceases coverage, once commenced, or fails to publish reports on us regularly, demand for our stock could decrease, which could cause our stock price and trading volume to decline.

We may issue debt or debt securities convertible into equity securities, any of which may be senior to our common stock as to distributions and in liquidation, which could negatively affect the value of our common stock.

In the future, we may attempt to increase our capital resources by entering into debt or debt-like financing that is unsecured or secured by up to all of our assets, or by issuing additional debt or equity securities, which could include issuances of secured or unsecured commercial paper, medium-term notes, senior notes, subordinated notes, guarantees, preferred stock, hybrid securities, or securities convertible into or exchangeable for equity securities. In the event of our liquidation, our lenders and holders of our debt and securities would receive distributions of our available assets before distributions to the holders of our common stock. Because our decision to incur debt and issue securities in future offerings may be influenced by market conditions and other factors beyond our control, we cannot predict or estimate the amount, timing or nature of our future offerings or debt financings. Further, market conditions could require us to accept less favorable terms for the issuance of our securities in the future.

We are a "smaller reporting company" and, as a result of the reduced disclosure and governance requirements applicable to smaller reporting companies, our common stock may be less attractive to investors.

We are a "smaller reporting company," meaning that we are not an investment company, an asset-backed issuer, or a majority-owned subsidiary of a parent company that is not a "smaller reporting company," have a public float of less than $250 million and have annual revenues of less than $100 million during the most recently completed fiscal year. As a "smaller reporting company," we are subject to lesser disclosure obligations in our SEC filings compared to other issuers. Specifically, "smaller reporting companies" are able to provide simplified executive compensation disclosures in their filings, are exempt from the provisions of Section 404(b) of the Sarbanes-Oxley Act requiring that independent registered public accounting firms provide an attestation report on the effectiveness of internal control over financial reporting and have certain other decreased disclosure obligations in their SEC filings, including, among other things, only being required to provide two years of audited financial statements in annual reports. Decreased disclosures in our SEC filings due to our status as a "smaller reporting company" may make it harder for investors to analyze our operating results and financial prospects.

We do not intend to pay cash dividends.

We have not declared or paid any cash dividends on our capital stock, and we do not anticipate declaring or paying cash dividends in the foreseeable future. Any future determination as to the payment of cash dividends on our capital stock will be at our Board of Directors' discretion and will depend on our financial condition, operating results, capital requirements and other factors that our Board of Directors considers to be relevant.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

None.

ITEM 1C. CYBERSECURITY

Cybersecurity Risk Management and Strategy

Our management recognizes the impact that cybersecurity threats could have on our business operations, our compliance with regulations and our reputation. We have identified cybersecurity as a critical business risk as part of our overall risk management strategy, which our board of directors oversees.

We have implemented an information security management system in accordance with our risk profile and business that is designed to protect us, our employees, and our shareholders from cybersecurity threats. We have also developed an incident response policy and procedure designed to facilitate the handling of cybersecurity incidents.

Our cybersecurity risk management program aims to identify risks from cybersecurity threats. Our cybersecurity risk management program includes a number of components, including informal self-assessments. Our managed security services provider helps us implement additional security controls, including malware protection and network security tools. We take a risk-based approach to the evaluation of third-party vendors.

We have not identified any cybersecurity incidents or threats that have materially affected us or are reasonably likely to materially affect us, including our business strategy, results of operations, or financial condition. However, like other companies in our industry, we and our third-party vendors have from time-to-time experienced threats and cybersecurity incidents that could affect our information or systems. For more information, see Item 1A. Risk Factors.

Governance Related to Cybersecurity Risks

The Board of Directors and Audit Committee oversee the management of risks by our management. The Audit Committee is responsible for reviewing our cybersecurity program and risks, as identified by our management, and the steps our management has taken to protect against threats to our assets, including information systems and data security. The Audit Committee provides updates to the Board approximately annually.

ITEM 2. PROPERTIES.

We do not currently lease or own any properties. The lease for our Tampa facility expired in February 2024.

ITEM 3. LEGAL PROCEEDINGS.

On December 7, 2022, we entered into an investment banking engagement letter with Ladenburg Thalmann, ("Ladenburg"). The engagement letter was subsequently amended at various times (together with amendments to the "Engagement Letter"). We terminated the Engagement Letter as of August 15, 2023. Ladenburg sent us an invoice in the amount of $2,500,000, and a demand letter from Ladenburg's general counsel demanding payment thereof followed shortly thereafter. Ladenburg is of the view that a fee is owed based on our purchase of assets from Odyssey Health, Inc. We strongly disagrees that any such fee is due to Ladenburg and initiated a confidential action for arbitration against Ladenburg with the Financial Industry Regulatory Authority ("FINRA") on March 12, 2024, seeking, among other things, a declaratory judgment that no such fee is owed. On April 17, 2024 Ladenburg filed a Complaint in federal court in the Southern District of Florida and also filed motion for a temporary restraining order ("TRO") and preliminary injunction seeking to move the venue from FINRA to the federal court in Miami-Dade County. On May 3, 2024, the Magistrate Judge assigned to the case issued a Report and Recommendation denying the motion; although Ladenburg objected to the Report and Recommendation, Magistrate Judge's Report and Recommendation, the District Court Judge adopted the Report and Recommendation, finalizing the Court's denial of the requested injunctive relief. On May 9, 2024, we filed a motion to dismiss in the federal court action, which is still pending. Meanwhile, the FINRA action continues and is set to be heard in August 2025. We believe Ladenburg's claims are unlikely to prevail and intend to defend vigorously against such claims. It is possible, however, that there could be an unfavorable outcome or resolution of the claims asserted, which could negatively and materially impact our business, consolidated financial position and results of operations. Litigation is inherently uncertain and there can be no assurance that we will prevail. We do not include an estimate of legal fees and other related defense costs in our estimate of loss contingencies.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

PART II

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

Our common stock is quoted on the NYSE American under the ticker symbol OGEN. The last price of our common stock as reported on the NYSE American on March 10, 2025 was $XXX per share. As of March 10, 2025, there were approximately 40 stockholders of record of our common stock. This number does not include beneficial owners whose shares are held by nominees in street name such as banks and brokerage firms.

Dividends

To date, we have neither declared nor paid any dividends on our common stock nor do we anticipate that such dividends will be paid in the foreseeable future. Rather, we intend to retain any earnings to finance the growth and development of our business. Any payment of cash dividends on our common stock in the future will be dependent, among other things, upon our earnings, financial condition, capital requirements and other factors which the Board of Directors deems relevant. In addition, restrictive covenants contained in any financing agreements entered into in the future may preclude us from paying any dividends.

Unregistered Sale of Equity Securities and Use of Proceeds

None.

Stock Repurchases in the Fourth Quarter

There were no purchases of our common stock during the three months ended December 31, 2024.

ITEM 6. [RESERVED.]

Not applicable.

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

The following information should be read in conjunction with the Consolidated Financial Statements, including the notes thereto, included elsewhere in this Form 10-K. This discussion contains certain forward-looking statements that involve risks and uncertainties. Our actual results and the timing of certain events could differ materially from those discussed in these forward-looking statements as a result of certain factors, including, but not limited to, those set forth herein and elsewhere in this Form 10-K.

Overview

We are a development-stage company dedicated to the research and development of nasal delivery pharmaceutical medications in neurology and fighting infectious diseases. Our lead product ONP-002 is a fully synthetic, non-naturally occurring neurosteroid, is lipophilic, and is designed to can cross the blood-brain barrier with the goal of rapidly reducing swelling, oxidative stress and inflammation while restoring proper blood flow through gene amplification.

Our ONP-002 Neurology Asset for Brain Related Illness and Injury

Following our December 2023 acquisition of the assets of Odyssey Health, Inc. ("Odyssey") related to the segment of its business focused on developing medical products that treat brain related illnesses and diseases (the "Neurology Assets") our lead product and focus is on the development and commercialization of ONP-002 for the treatment of mild traumatic brain injury ("mTBI" or "Concussion").

ONP-002 to date has been shown to be stable up to 104 degrees for 18-months. The drug candidate is spray-dry manufactured into a powder and filled into the novel intranasal device. The drug is then administered through the nasal passage from the device. The novel intranasal device is lightweight and easy to use in the field.

The proprietary powder formulation and intranasal administration allows for rapid and direct accessibility to the brain. The device is breath propelled and allows patients to blow into the device which closes the soft palate in the back of the nasopharynx, preventing the flow of drug to the lungs or esophagus, minimizes system exposure and side effects, and easily crosses the blood brain barrier. This mechanism is designed to trap ONP-002 in the nasal cavity allowing for more abundant and faster drug availability in the traumatized brain.

Expected ONP-002 Product Development Timeline:

Pre-clinical Animal Studies	Phase 1	Phase 2a Australia	Phase 2b	Phase 3
Complete	Complete	Estimated Q1/Q2 2025 start	Estimated Q1 2026 start	Estimated Q1 2027 start

This product development plan is an estimate and is subject to change based on funding, technical risks and regulatory approvals.

For a discussion of the related intellectual property and clinical trials, refer to Item 1. Business.

Business Development Strategy

Success in the biopharmaceutical and product development industry relies on the continuous development of novel product candidates. Most product candidates do not make it past the clinical development stage, which forces companies to look externally for innovation. Accordingly, we expect, from time to time, to seek strategic opportunities through various forms of business development, which can include strategic alliances, licensing deals, joint ventures, collaborations, equity or debt-based investments, dispositions, mergers, and acquisitions. We view these business development activities as a necessary component of our strategies, and we seek to enhance shareholder value by evaluating business development opportunities both within and complementary to our current business, as well as opportunities that may be new and separate from the development of our existing product candidates.

Recent Funding

In February 2025, we sold 7.8 million shares of our common stock pursuant to our ATM agreement with Dawson James for gross proceeds of $2.75 million before deducting commission and legal expenses. See Note 7 of Notes to Consolidated Financial Statements for additional information.

On March 13, 2025, the Company entered into and consummated a note securities purchase agreement (the "**Purchase Agreement**") with a single investor (the "**Purchaser**") pursuant to which the Company sold, in a private placement (the "**Offering**"), to the Purchaser a promissory note with an aggregate principal amount of $3,000,000 (the "**Note**") and 1,000,000 shares of Series G Mirroring Preferred Stock of the Company (the "**Series G Preferred Stock**"). The aggregate gross proceeds to the Company are expected to be $2,500,000 million, before deducting placement agent fees and expenses. The Company intends to use the net proceeds from the Offering for working capital and other general corporate purposes. Dawson James Securities, Inc. served as the placement agent in the Offering, pursuant to the terms of a placement agent agreement dated February 26, 2024 and received 6% of the gross proceeds of the Offering and reimbursement of the legal fees of its counsel. The Note and Series G Preferred Stock sold in the Offering were issued in a private placement under Section 4(a)(2) of the Securities Act of 1933, as amended (the "**Act**"), and Regulation D promulgated thereunder and, have not been registered under the Act, or applicable state securities laws. Accordingly, the Note and Series G Preferred Stock may not be offered or sold in the United States except pursuant to an effective registration statement or an applicable exemption from the registration requirements of the Act and such applicable state securities laws.

Going Concern

We have incurred significant net losses and negative cash flow in each year since our inception, including net losses of $10.6 million and $20.7 million for the years ended December 31, 2024 and 2023 respectively. As of December 31, 2024, our accumulated deficit was $216.8 million.

We have devoted a significant amount of our financial resources to research and development, including our nonclinical development activities and clinical trials. We expect that the costs associated with our plans to begin Phase 2 work on ONP-002 will be significant. Additionally, our License Agreements also require the payment of certain recurring and performance-based royalties that may negatively impact our financial capabilities.

In addition, Ladenburg Thalmann has sent us an invoice and demand letter claiming we owe them $2.5 million in connection with our purchase of the Neurology Assets (the "Ladenburg Claim"). See Item 3. Legal Proceedings for additional information.

We expect to continue to incur substantial net losses and negative cash flows for the foreseeable future. These losses and negative cash flows have had, and will continue to have, an adverse effect on our shareholders' equity and working capital. Because of the numerous risks and uncertainties associated with product development and commercialization, we may not be able to continue as a going concern and are unable to accurately predict the timing or amount of substantial expenses or when, or if, we will be able to generate the revenue necessary to achieve or maintain profitability.

Future Capital Requirements

Our capital requirements for 2025 will depend on numerous factors, including the success of our commercialization efforts and of our research and development, the resources we devote to develop and support our technologies and our success in pursuing strategic licensing and funded product development relationships with external partners.

Subject to our ability to raise additional capital including through possible joint ventures and/or partnerships, we expect to incur substantial expenditures to further commercialize or develop our Neurology Assets, including continued increases in costs related to research, nonclinical testing and clinical trials, as well as costs associated with our capital raising efforts and being a public company.

Our plans include seeking both equity and debt financing, alliances or other partnership agreements with entities interested in our technologies, or other business transactions that would generate sufficient resources to ensure continuation of our operations and research and development programs.

Our current available cash and cash equivalents provide us with limited liquidity. We believe our existing cash and cash equivalents of $0.8 million at December 31, 2024 will allow us to fund our operating plan through the first quarter of 2025. Subsequent to December 31, 2024, in February 2025, we sold 7.8 million shares of common stock from our ATM program. The gross proceeds before commission and expenses from the February 2025 ATM sales were $2.75 million. Additionally, on March 13, 2025, the Company entered into and consummated a note securities purchase agreement (the "**Purchase Agreement**") with a single investor (the "**Purchaser**") pursuant to which the Company sold, in a private placement (the "**Offering**"), to the Purchaser a promissory note with an aggregate principal amount of $3,000,000 (the "**Note**") and 1,000,000 shares of Series G Mirroring Preferred Stock of the Company (the "**Series G Preferred Stock**"). The aggregate gross proceeds to the Company were $2,500,000 million, before deducting placement agent fees and expenses. The Company intends to use the net proceeds from the Offering for working capital and other general corporate purposes. We believe that these additional cash resources will allow us to fund our operating plan through the third quarter of 2025.

Required additional capital may not be available on reasonable terms, if at all. If we were unable to obtain additional financing, we may be required to reduce the scope of, delay or eliminate some or all of our planned clinical testing, research and development and commercialization activities, which could harm our business.

The sale of additional equity or debt securities may result in dilution to our shareholders. If we raise additional funds through the issuance of debt securities or preferred stock, these securities could have rights senior to those of our common stock and could contain covenants that would restrict our operations.

Because of the numerous risks and uncertainties associated with research, development, and commercialization of our product candidates, we are unable to estimate the exact amounts of our working capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- conducting Phase 2 clinical trials for our ONP-002 product candidate, filing an IND with the FDA and, if approved, engage in Phase 3 clinical trials; identifying and securing clinical sites for the conduct of human trials for our product candidates;
- the number and characteristics of the product candidates we pursue;
- the scope, progress, results, and costs of researching and developing our product candidates, and conducting nonclinical and clinical trials including the research and development expenditures we expect to make in connection with agreements with third parties we put in place to advance our research and development efforts;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates;
- our ability to maintain current research and development licensing agreements and to establish new strategic partnerships, licensing or other arrangements and the financial terms of such agreements;
- our ability to achieve our milestones under our ECC agreement and licensing arrangements and the payment obligations we may have;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation; and
- the timing, receipt and amount of sales of, or royalties on, our products and future products, if any.

We have based our estimates on assumptions that may prove to be wrong. We may need to obtain additional funds sooner or in greater amounts than we currently anticipate.

Research and Development

Research and development consist of expenses incurred in connection with the discovery and development of our product candidates and are divided into (i) clinical research and (ii) nonclinical research and development activities.

Clinical research activities consist of clinical trials, manufacturing services and regulatory activities, all of which are largely provided by third parties. Nonclinical research and development activities consist of our own research activities, research activities provided by third parties, our own nonclinical studies, nonclinical studies provided by third parties and the acquisition of in process research and development.

We do not manufacture or have the capacity to manufacture any of our drug candidates and have one manufacturer as our current partner in the development of synthetic chemistry and manufacturing of the ONP-002 (Molecular Formula: C20H28O2, Molecular Weight: 300.14 g/mol). Our ability to successfully develop our ONP-002 product candidates, and to ultimately supply our commercial products in quantities sufficient to meet the market demand, depends in part on our ability to obtain the drug product and drug substance for our product candidates in accordance with regulatory requirements and in sufficient quantities for commercialization and clinical testing. We do not currently have arrangements in place for a redundant or second-source supply of any products or substances in the event our current supplier ceases their operations or stops offering us sufficient quantities of these materials for any reason.

We are not certain that our single-source supplier will be able to meet our demand, either because of the nature of our agreement with the supplier, our limited experience with the supplier or our relative importance as a customer to the supplier. It may be difficult for us to assess its ability to timely meet our demand in the future based on past performance. While our supplier has generally met our demand on a timely basis in the past, they may subordinate our needs in the future to their other customers.

Research and development expenses consist primarily of:

- employee-related expenses, which include salaries and benefits, including stock-based compensation, and attending science conferences;
- expenses incurred under our License Agreements with third parties and under other agreements with contract research organizations, investigative sites and consultants that conduct our clinical trials and a substantial portion of our nonclinical studies;
- the cost of acquiring and manufacturing clinical trial materials;
- facilities, depreciation and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities and equipment and depreciation of fixed assets;
- license fees for, and milestone payments related to, in-licensed products and technology; and
- costs associated with nonclinical activities and regulatory approvals.

We expense research and development costs as incurred.

Our current product development strategy contemplates (i) an expected increase in our research and development expenses in the future as we continue the advancement of our product development program for our ONP-002 and (ii) a continued attempt to decrease expenses related to our other product candidates, as we have paused our lantibiotics program and COVID-19 vaccine program pending additional financing and other developments. Our research and development projects focused on ONP-002 are currently expected to be taken to the point where they can be licensed or partnered with larger pharmaceutical companies.

The lengthy process of completing pre-clinical studies and clinical trials, seeking regulatory approval for our product candidates and expanding the potential claims we are able to make requires expenditure of substantial resources. Any failure or delay in completing pre-clinical studies, clinical trials, or in obtaining regulatory approvals, could cause a delay in generating product revenues and cause our research and development expenses to increase and, in turn, have a material adverse effect on our operations and financial position.

Our current product candidates are not expected to be commercially available until we are able to obtain regulatory approval from the FDA or the regulatory authority in other jurisdictions where we may seek approval.

General and Administrative

General and administrative expenses consist principally of salaries and related costs for personnel in executive, finance, business development, marketing, information technology, legal and human resources functions. Other general and administrative expenses include facility costs not otherwise included in research and development expenses, patent filing, and professional fees for legal, consulting, auditing, and tax services.

We anticipate that our general and administrative expenses to increase, but be subject to variability for, among others, the following reasons:

- to support our research and development activities, which, subject to available capital, we expect to expand as we continue the development of our product candidates; with a focus on ONP-002;

- the efforts we undertake from time to time to raise additional capital;
- the increased payroll, stock-based compensation, expanded infrastructure and consulting, legal, accounting and investor relations costs associated with being a public company; and
- The additional staff we anticipate hiring or retaining to develop our Neurology Assets.

Other Income (Expense)

Other income (expense) includes local business taxes, as well as interest income and expense, and realized gains and losses related to foreign currency exchange rates with our vendors. Interest income consists of interest earned on our cash and cash equivalents. The primary objective of our investment policy is capital preservation. Interest expense consists primarily of interest and costs associated with our indebtedness.

Income Taxes

At December 31, 2024, the Company has federal and state tax net operating loss carry forwards of $159,358,389 and $142,594,207, respectively. The State of Pennsylvania tax net operating loss carryforwards will expire through 2036. Federal and Florida tax net operating loss carryforwards generated prior to December 31, 2017 will expire through 2037 and are not subject to taxable income limitations. Federal and Florida tax net operating loss carryforwards generated subsequent to December 31, 2017, do not expire but may be subject to taxable income limitation pursuant to the Tax Cuts and Jobs Act that was enacted on December 22, 2017. The Company also has federal research and development tax credit carryforwards of $4,041,694 of which are included as an uncertain tax position. The federal tax credit carryforward will expire beginning in 2021 and continuing through 2043 unless utilized.

Utilization of net operating loss carryforwards and research and development credit carryforwards may be subject to a substantial annual limitation due to ownership change limitations that may have occurred or, could occur in the future in accordance with Section 382 of the Internal Revenue Code of 1986 ("IRC Section 382") and with Section 383 of the Internal Revenue Code of 1986, as well as similar state provisions. These ownership changes may limit the amount of net operating loss carryforwards and research and development credit carryforwards that can be utilized annually to offset future taxable income and taxes, respectively. In general, an ownership change, as defined by IRC Section 382, results from transactions increasing the ownership of certain stockholders or public groups in the stock of a corporation by more than 50 percentage points over a three-year period. The Company has completed several financings since its inception, which may result in a change in ownership as defined by IRC Section 382, or could result in a change in control in the future. In each period since our inception, we have recorded a 100% valuation allowance for the full amount of our deferred tax asset, as the realization of the deferred tax asset is uncertain. As a result, we have not recorded any federal tax benefit in our statements of operations.

At December 31, 2024 and 2023, we included a full valuation allowance against our deferred tax assets of approximately $46,958,449 and $41,166,891, respectively, as our management believes it is uncertain that they will be fully realized. If we determine in the future that we will be able to realize all or a portion of our net operating loss carryforwards, an adjustment to our net operating loss carryforwards would increase net income in the period in which we make such a determination.

Critical Accounting Estimates and Policies

Our discussion and analysis of our financial condition and results of operations are based upon our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States ("US GAAP"). The preparation of financial statements in accordance with US GAAP requires us to make estimates and assumptions that affect reported amounts and related disclosures. There are certain critical estimates that we believe require significant judgment in the preparation of our financial statements. We consider an accounting estimate to be critical if:

- It requires us to make an assumption because information was not available at the time or it included matters that were highly uncertain at the time, we were making the estimate; and
- Changes in the estimate or different estimates that we could have selected may have had a material impact on our financial condition or results of operations.

Stock-Based Compensation

U.S. Generally Accepted Accounting Principles ("US GAAP") requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair values as of the grant date. Stock-based compensation expense is recorded over the requisite service period in which the grantee provides services to us, to the extent the options do not vest at the grant date and are subject to forfeiture. For performance-based awards that do not include market-based conditions, we record share-based compensation expense only when the performance-based milestone is deemed probable of achievement. We utilize both quantitative and qualitative criteria to judge whether milestones are probable of achievement. For awards with market-based performance conditions, we recognize the grant-date fair value of the award over the derived service period regardless of whether the underlying performance condition is met. We account for forfeitures of stock-based awards as a component of compensation expense as the forfeitures occur.

Stock-Based Payment Arrangements

Generally, all forms of stock-based payments, including stock option grants and warrants are measured at their fair value on the awards' grant date typically using a Black-Scholes Pricing Option Pricing Model. Stock-based compensation awards issued to non-employees for services rendered are recorded at the fair value of the stock-based payment. The expense resulting from stock-based payments are recorded in research and development expense or general and administrative expense in the statement of operations, depending on the nature of the services provided. Stock-based payment expense is recorded over the requisite service period in which the grantee provides services to us. To the extent the stock option grants or warrants do not vest at the grant date they are subject to forfeiture.

New Accounting Pronouncements

Income Taxes

In December 2023, the FASB issued ASU 2023-09, "Income Taxes (Topic 740): Improvements to Income Tax Disclosures," which requires public entities to disclose consistent categories and greater disaggregation of information in the rate reconciliation and for income taxes paid. It also includes certain other amendments to improve the effectiveness of income tax disclosures. The guidance is effective for financial statements issued for annual periods beginning after December 15, 2024, with early adoption permitted. The accounting pronouncement is not expected to have a material impact on the Company's related disclosures.

Effective January 1, 2023, repurchases are subject to a non-deductible excise tax under the Inflation Reduction Act of 2022 equal to 1.0% of the fair market value of the shares repurchased, subject to certain limitations. The Company did not have an impact to the financial condition or results of operations in 2023 as a result of the excise tax.

See Note 2 of Notes to Consolidated Financial Statements for additional information.

Results of Operations

	Year Ended December 31,		Increase	Percentage
	2024	2023	(Decrease)	Change
Grant revenue	$ -	$ 37,653	$ (37,653)	-100%
Operating expenses:				
Research and development	4,114,434	15,490,604	(11,376,170)	-73%
General and administrative	6,444,381	5,451,952	992,429	18%
Total operating expenses	10,558,815	20,942,556	(10,383,741)	-50%
Loss from operations	(10,504,437)	(20,904,903)	10,346,0888	-49%
Other income (expense):				
Interest income	45,897	210,394	(164,497)	-78%
Interest expense	(29,828)	(30,591)	763	-2%
Miscellaneous income	—	69,363	(69,363)	-100%
Foreign Currency Exchange Net	(25,172)	—	(25,172)	100%
Total other income (expense), net	(9,103)	249,166	(258,269)	-104%
Loss before income taxes	(10,567,918)	(20,655,737)	10,087,819	-49%
Income tax benefit	-	-	-	0%
Net loss	$ (10,567,918)	$ (20,655,737)	$ 10,087,819	-49%

Grant revenue

The decrease in Grant revenue in 2024 compared to 2023 was attributable to awards received for a small business innovation research grant that expired September 30, 2023.

Research and Development

The decrease in research and development in 2024 compared to 2023 was mainly attributed to In process research and development expensed in connection with the acquisition of our concussion asset in 2023 of $10.3 million and decreased development costs. Development costs associated with the development of our ONP-002 concussion drug in 2024 were $2.8 million compared to development costs associated with our vaccine product and our lantibiotics program of $1.3 million. Research and development expense in 2024 related to our vaccine product and lantibiotics program are associated with contract terminations.

General and Administrative

The increase in General and administrative in 2024 compared to 2023 was primarily due to the following:

	Increase (Decrease) 2024 compared to 2023
Travel expense	5,293
Board compensation	91,145
Stock-based compensation	(485,550)
Employee related expenses	661,206
Legal and professional fees	(36,834)
Patent expense	365,195
Insurance	(30,325)
Investor relations	866,083
Public company expense	(130,950)
All other overhead	(312,834)
Total increase	992,429

Other Income (Expense)

The decrease in other income (expense) in 2024 compared to 2023 was attributed to decreased interest income generated from cash balances held in our money market account, the sale of fixed assets in 2023 related to the closing of our laboratory in Alachua Florida and foreign currency exchange in 2024 related to payments made to foreign vendors.

Liquidity and Capital Resources

Since our inception, we have funded our operations primarily through the sale of equity securities in our initial public offering, the sale of equity securities and warrants in private and public offerings, debt financing, warrant exercises and grants. As of December 31, 2024, we had an accumulated deficit of $216.8 million and we have yet to achieve profitability. We incurred net losses of $10.6 million and $20.7 million for the years ended December 31, 2024 and 2023 respectively. We expect to incur significant and increasing operating losses for the foreseeable future as we seek to advance our Neurology Assets through nonclinical testing and clinical trials to ultimately obtain regulatory approval and eventual commercialization.

The following table sets forth the primary sources and uses of cash for each of the periods indicated:

	Year Ended December 31,	
	2024	2023
Net cash used in operating activities	$ (8,597,382)	$ (7,290,880)
Net cash used in investing activities	-	(936,285)
Net cash provided by financing activities	5,978,721	283,880
Net decrease in cash and cash equivalents	$ (2,618,661)	$ (7,943,285)

Operating Activities

Cash used in operating activities in 2024 resulted from our net loss adjusted for non-cash items and changes in operating assets and liabilities. Significant items included a non-cash charge of $0.5 million for stock-based compensation and a $1.1 million decrease in Prepaid research and development.

Significant items affecting cash used in operations in 2023 included non-cash charges of $10.3 million for In process research and development and $1.0 million for stock-based compensation and a $2.0 million decrease in Prepaid expenses and other current assets.

We had a working capital deficit of $211,885 at December 31, 2024 compared to a working capital surplus of $2,067,593 at December 31, 2023.

Investing Activities

There were no investing activities in 2024.

Investing activities in 2023 primarily related to $1.0 million used for the purchase of In process research and development as part of the Neurology Assets purchase in December 2023.

Financing Activities

Cash provided by financing activities in 2024 was primarily related to $6.7 million received from sales of our common stock, this was offset by $0.7 million in payments on our short-term note payable for financed insurance premiums.

Cash provided by financing activities in 2023 was primarily related to $0.8 million received in sales of our common stock partially offset by $0.6 million used for payments on our short-term notes payable.

Short-Term Notes Payable

We had the following short-term notes payable outstanding:

	December 31, 2024	December 31, 2023
Directors' and officers' liability insurance and other business financing of $636,972 and $611,109 due in monthly installments of $67,277 and $54,366 including principal and interest at 9.55% through May 24, 2025 and May 24, 2024, respectively.	$ 328,528	$ 312,703

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements.

Inflation

Inflation affects the cost of raw materials, goods, and services that we use. In recent years, inflation has been modest but has recently increased. High energy costs and fluctuations in commodity prices can affect the cost of all raw materials and components. Although we cannot precisely determine the effects of inflation on our business, it is management's belief that the effects on operating results will not be significant. We do not believe that inflation has had a material impact on our results of operations for the periods presented, except with respect to payroll-related costs and other costs arising from or related to government-imposed regulations.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

Not applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

The Financial Statements are incorporated herein by reference to pages F-1 to F-18 at the end of this report and the supplementary data is not applicable.

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

Not Applicable.

ITEM 9A. CONTROLS AND PROCEDURES.

Disclosure Controls and Procedures

Management's evaluation of the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act was performed under the supervision and participation of our senior management, including our Interim Chief Executive Officer and Chief Financial Officer. The purpose of disclosure controls and procedures is to ensure that information required to be disclosed in the reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to management, including our Interim Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosures.

Changes in Internal Controls over Financial Reporting

Our management, with the participation of our Interim Chief Executive Officer and Chief Financial Officer, has concluded that there were no significant changes in our internal controls over financial reporting that occurred during our last fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Limitations on the Effectiveness of Controls

Our management, including our Interim Chief Executive Officer and Chief Financial Officer, does not expect that our Disclosure Controls and internal controls will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management or board override of the control.

The design of any system of controls also is based in part upon 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; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Management's Report on Internal Control over Financial Reporting

The management of Oragenics, Inc is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in the Securities Exchange Act Rule 13a-15(f). The Company's internal control over financial reporting is a process designed to provide reasonable assurance to the Company's management and Board of Directors regarding the reliability of financial reporting and the preparation of the financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America.

The Company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with accounting principles generally accepted in the United States of America, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and Directors of the Company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the Company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal controls over financial reporting may not prevent or detect misstatements. All internal control systems, no matter how well designed, have inherent limitations, including the possibility of human error and the circumvention of overriding controls. Accordingly, effective internal control over financial reporting can provide only reasonable assurance with respect to financial statement preparation. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management, under the supervision of the Interim Chief Executive Officer and Chief Financial Officer, conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2024 based on the framework in Internal Control-Integrated Framework 2013 issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on that evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2024.

This annual report does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our registered public accounting firm pursuant to temporary rules of the Securities and Exchange Commission that permit us to provide only Management's report in this annual report.

ITEM 9B. OTHER INFORMATION.

(a) Entry into a Material Definitive Agreement

On March 13, 2025, the Company entered into and consummated a note securities purchase agreement (the "**Purchase Agreement**") with a single investor (the "**Purchaser**") pursuant to which the Company sold, in a private placement (the "**Offering**"), to the Purchaser a promissory note with an aggregate principal amount of $3,000,000 (the "**Note**") and 1,000,000 shares of Series G Mirroring Preferred Stock of the Company (the "**Series G Preferred Stock**").

The aggregate gross proceeds to the Company were $2,500,000 million, before deducting placement agent fees and expenses. The Company intends to use the net proceeds from the Offering for working capital and other general corporate purposes.

Dawson James Securities, Inc. served as the placement agent in the Offering, pursuant to the terms of a placement agent agreement dated February 26, 2024 (the "**Placement Agency Agreement**") and received 6% of the gross proceeds of the Offering and reimbursement of the legal fees of its counsel.

The Note and Series G Preferred Stock sold in the Offering were issued in a private placement under Section 4(a)(2) of the Securities Act of 1933, as amended (the "**Act**"), and Regulation D promulgated thereunder and, have not been registered under the Act, or applicable state securities laws. Accordingly, the Note and Series G Preferred Stock may not be offered or sold in the United States except pursuant to an effective registration statement or an applicable exemption from the registration requirements of the Act and such applicable state securities laws.

The Purchase Agreement

The Purchase Agreement contains customary representations, warranties and agreements by the Company, customary conditions to closing, indemnification obligations of the Company, other obligations of the parties and termination provisions.

Original Issue Discount Senior Note

The Note was issued with an original issue discount of 20%. No interest accrues on the Note unless and until an Event of Default (as defined in the Note) has occurred, upon which interest shall accrue at a rate of twenty percent (20.0%) per annum and shall be computed on the basis of a three hundred sixty (360)-day year and twelve (12) thirty (30)-day months and shall be payable on the maturity date. The Note matures upon the earlier of 120 days from the issuance date or the closing of any subsequent offering by the Company with net proceeds equal to or in excess of all amounts due under the Note. The Note contain certain Events of Default, including (i) the Company's failure to pay any amount of principal, interest, redemption price or other amounts due under the Notes or any other transaction document, (ii) any default under, redemption of, or acceleration prior to maturity of any indebtedness of the Company, as such term is defined in the transaction documents, (iii) bankruptcy of the Company or its subsidiaries, (iv) a final judgement or judgements for the payment of money in excess of $250,000, which is not discharged or stayed pending appeal within 60 days, and (v) any breach or failure to comply with any provision of the Note or any other transaction document. Upon the occurrence of any Event of Default and at any time thereafter, the Purchaser shall have the right to exercise all of the remedies under the Note. The Note also provide for redemption upon a change of control, as such term is defined under the Notes and mandatory redemption upon the receipt of net proceeds from any offering of equity or debt by the Company.

Lock-Up Agreements

Concurrently with the execution of the Purchase Agreement, the directors and executive officers of the Company entered into lock-up agreements (the "**Lock-Up Agreements**"), pursuant to which they accepted certain restrictions on transfers of shares of Company Common Stock held, or to be held, by them for the 90-day period following the execution of the Purchase Agreement.

The Certificate of Designation

In connection with the Offering, the Company filed a Certificate of Designation with the Secretary of State for the State of Florida (the "**Certificate of Designation**") designating 1,000,000 shares out of the authorized but unissued shares of its preferred stock as Series G Preferred Stock. The following is a summary of the principal terms of the Series G Preferred Stock.

Dividends

No dividends shall be paid on shares of the Series G Preferred Stock.

Voting Rights

The rights and preferences of the Series G Preferred Stock are set forth in the Certificate of Designation filed with Secretary of State for the State of Florida, a copy of which is attached hereto as Exhibit 3.9. The Series G Preferred Stock has no voting rights, except as required by applicable law and except that each share of Series G Preferred Stock shall entitle the holder thereof to 1,000 votes per each share of Series G Preferred Stock solely and exclusively with respect to the Reverse Split Proposal, the Amendment Proposal and any Adjournment Proposal (as defined below), voting together with the Common Stock as a single class. The Purchaser has agreed to vote all of Purchaser's shares of Series G Mirroring Preferred Stock on any proposal presented to the shareholders of the Corporation for purposes of approving the Reverse Split Proposal, the Amendment Proposal and the Adjournment Proposal and has agreed that such shares of Series G Mirroring Preferred Stock, shall, to the extent voted in favor of such proposals, be automatically and without further action of the Purchaser voted in the same proportions as shares of Common Stock (excluding any shares of Common Stock that are not voted) are voted on the Reverse Split Proposal, the Amendment Proposal and the Adjournment Proposal, as applicable. For the avoidance of doubt, and for illustrative purposes only, if 30% of the aggregate votes cast by Common Stock in connection with the Reverse Split Proposal are voted against such proposal and 70% of the aggregate votes cast by Common Stock are voted in favor thereof, then 30% of the votes cast by the shares of Series G Mirroring Preferred Stock voting in connection with the Reverse Split Proposal shall vote against the approval of the Reverse Split Proposal and 70% of such votes shall be cast in favor.

In connection with the Company's annual meeting schedule for April 30, 2025, the Company anticipates seeking its shareholders' approval for:

1. a proposal authorizing the Company's Board of Directors, in its discretion at any time within one year after shareholder approval is obtained, to effect a reverse stock split of then-outstanding shares of the Company's common stock, at a ratio of not less than one-for-five (1:5) and not greater than one-for-sixty (1:60), with the exact ratio to be determined by the Company's Board and included in a public announcement (the "**Reverse Split Proposal**"); and

2. an amendment to the Company's Articles of Incorporation, as amended, to increase the Company's authorized shares of common stock to 3,500,000,000 in the event a reverse stock split of our common stock is effectuated prior to approval of the Reverse Split Proposal (the "**Proposal to Increase Authorized Shares**").

Liquidation

The Series G Preferred Stock shall rank junior to the Series F Preferred Stock. Upon any liquidation, dissolution or winding-up of the Corporation, whether voluntary or involuntary (a "**Liquidation**"), the Holders shall be entitled to receive out of the assets, whether capital or surplus, of the Corporation an amount equal to the Stated Value for each share of Series G Mirroring Preferred Stock before any distribution or payment shall be made to the holders of Common Stock but after any other class of stock than ranks senior to the Series G Mirroring Preferred Stock, including the Series F Preferred Stock, and if the assets of the Corporation shall be insufficient to pay in full such amounts, then the entire assets to be distributed to the Holders shall be ratably distributed among the Holders in accordance with the respective amounts that would be payable on such shares if all amounts payable thereon were paid in full. Each share of Series G Mirroring Preferred Stock shall have no par value and a stated value equal to $0.10.

Cancellation

Upon effectiveness of either the Reverse Split Proposal or the Proposal to Increase Authorized Shares, each share of Series G Preferred Stock shall be automatically transferred to the Company and cancelled for no consideration with no action on behalf of the holders of Series G Preferred Stock. Such shares shall resume the status of authorized but unissued preferred stock and will no longer be designated as Series G Mirroring Preferred Stock.

Preemptive Rights

No holders of Series G Preferred Stock will, as holders of Series G Preferred Stock, have any preemptive rights to purchase or subscribe for our Common Stock or any of our other securities.

Redemption

The Series G Preferred Stock are not redeemable by the Company.

Trading Market

There is no established trading market for any of the Series G Preferred Stock, and we do not expect a market to develop. We do not intend to apply for a listing for any of the Series G Preferred Stock on any securities exchange or other nationally recognized trading system. Without an active trading market, the liquidity of the Series G Preferred Stock will be limited.

The foregoing descriptions of the Certificate of Designation, the Purchase Agreement, the Note, the Lock-Up Agreements and the Placement Agency Agreement do not purport to be complete and are qualified in their entirety by reference to the full text of the Purchase Agreement, Notes, the Lock-Up Agreement and the Placement Agency Agreement, forms of which are attached hereto as Exhibits 3.9, 10.25, 10.26, 10.27, and 10.28, respectively and are each incorporated by reference herein.

(b) During the quarter ended December 31, 2024, no officer or director adopted or terminated a Rule 10b5-1 or non-Rule 10b5-1 trading arrangement.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS.

Not Applicable

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS, AND CORPORATE GOVERNANCE.

Directors and Executive Officers

The following table sets forth the names, ages and titles of our Directors and executive officers:

Name	Age	Position
Charles L. Pope*	72	Executive Chairman and Director
Robert C. Koski	65	Director
Dr. Frederick W. Telling, Ph.D.	72	Director
Dr. Alan W. Dunton, M.D.	69	Director
Bruce Cassidy*	74	Director
John Gandolfo	64	Director
Kimberly M. Murphy*	61	President, Chief Executive Officer, and Director
Janet Huffman	52	Chief Financial Officer, Secretary and Treasurer, Interim Chief Executive Officer
Joseph Michael Redmond*	64	Interim Principal Executive Officer, President

* Ms. Murphy resigned from her role as President and Chief Executive Officer in February of 2024, and, as a result, effective February 2024, Mr. Redmond began serving as the Company's Interim Principal Executive Officer and President and Mr. Pope began serving, on an interim basis, as Executive Chairman. The Company elected not to renew Mr. Redmond's Employment Agreement dated December 28, 2023 and, on December 16, 2024, we terminated the employment of Mr. Redmond and appointed the Company's Chief Financial Officer, Janet Huffman, to serve as the new Interim Principal Executive Officer and President until such time as the Company retain a new Chief Executive Officer and president. Effective December 11, 2024 Ms. Murphy no longer serves as a director of the Company and effective January 15, 2025 Mr. Cassidy resigned as director of the Company.

Directors of the Company

Charles L. Pope. Mr. Pope was elected Chairman on December 16, 2022, and has served as a Director since June 2010. Mr. Pope served as the Chief Financial Officer of Palm Bancorp, Inc. from June 2009 to June 2012 when he retired. From September 2007 through June 2009, Mr. Pope served as the Chief Financial Officer of Aerosonic Inc., a manufacturer of aviation products. Mr. Pope served as the Chief Financial Officer of Reptron Inc., a manufacturer of electronic products, from March 2005 through June 2007. From March 2002 to March 2005, Mr. Pope served as Chief Financial Officer of SRI/Surgical Express, Inc. From February 2001 to March 2002, Mr. Pope served as Chief Financial Officer of Innovaro, Inc. (formerly UTEK Corporation NYSE American: INV) a public company. Mr. Pope served as a Director for Trxade Health, Inc. (NASDAQ: MEDS). Mr. Pope served as a Director of Innovaro, Inc. from March 2010 to August 2012. Mr. Pope also served as a director of Inuvo, Inc. from July 2008 through July 2018. Prior to this time, Mr. Pope served as a Partner in the Audit and Financial Advisory Consulting Divisions of PricewaterhouseCoopers LLP, and he was also a Partner in the Accounting and SEC Directorate in PricewaterhouseCoopers LLP's New York City office. Mr. Pope holds a B.S. degree in Economics and Accounting from Auburn University and is a Certified Public Accountant in Florida.

Mr. Pope brings to our Board over three decades of experience in the finance and accounting fields. In addition, Mr. Pope also has experience serving as a Director of public companies.

Dr. Frederick W. Telling. Dr. Telling has served as a Director since June 2010. Dr. Telling served as Chairman of the Board of Directors from February 4, 2011 through December 16, 2022 and as Executive Chairman from May 2, 2021 through December 16, 2022. Dr. Telling retired from Pfizer Inc., a pharmaceutical company, in June 2007 after 30 years of service. At Pfizer, Dr. Telling served as its Corporate Vice President and Vice President of Corporate Strategic Planning and Policy. Dr. Telling also serves on the boards of various civic and non-profit organizations. Dr. Telling holds a B.A. degree in History and Economics from Hamilton College and an M.A. degree in Industrial and Labor Relations and a Ph.D. in Economics and Public Policy from Cornell University.

Dr. Telling brings to our Board an extensive array of business and industry experience as well as experience as a director of public companies.

Dr. Alan W. Dunton. Dr. Dunton has served as a Director of Oragenics, Inc. since April 2011. He is the principal owner of Danerius, LLC, a biotechnology consulting company which he founded in 2006. In addition to Oragenics, he is currently a Director of the public biotechnology company Palatin, Inc. (AMEX: PTN), CorMedix (NASDAQ: CRMD) and Recce Pharmaceuticals (ASX: RCE). Dr. Dunton has held significant senior positions in major pharmaceutical companies. Most recent was from November 2015 through March 2018 as the Senior Vice President of Research, Development and Regulatory Affairs of Purdue Pharma L.P., a private pharmaceutical company. From January 2007 until March 2009, Dr. Dunton served as President and Chief Executive Officer of Panacos Pharmaceuticals, Inc. In 2005, Dr. Dunton served as the Non-Executive Chairman of the Board of Directors of ActivBiotics, Inc., a private biopharmaceutical company. Previously, he was the President and Chief Executive Officer of Metaphore Pharmaceuticals, Inc. from 2003 until 2006, when it merged with ActivBiotics. From 2004 until 2005, Dr. Dunton served as a member of the Board of Directors of Vicuron Pharmaceuticals until it was acquired by Pfizer, Inc. In 2002, Dr. Dunton served as President, Chief Operating Officer and a Director of Emisphere Technologies, Inc., a biopharmaceutical company. From 1994 to 2001, Dr. Dunton was a senior executive in various capacities in the Pharmaceuticals Group of Johnson & Johnson. From 1999 to 2001, Dr. Dunton was President and Managing Director of The Janssen Research Foundation, a Johnson & Johnson company. From 1998 to 1999, he served as Group Vice President of Global Clinical Research and Development of Janssen. Prior to joining Janssen, Dr. Dunton was Vice President of Global Clinical Research and Development at the R.W. Johnson Pharmaceutical Research Institute, also a Johnson & Johnson company. Prior to joining Johnson & Johnson, Dr. Dunton held positions in clinical research and development at Syntex Corporation, CIBA-GEIGY Corporation and Hoffmann La Roche Inc. Dr. Dunton holds an M.D. degree from New York University School of Medicine, where he completed his residency in internal medicine. He was also a Fellow in Clinical Pharmacology at the New York Hospital/Cornell University Medical Center.

Dr. Dunton brings to our Board a significant depth of experience in the pharmaceutical industry that will be invaluable to us as we continue to develop biotechnology assets.

Robert C. Koski. Mr. Koski has served as a Director since June 2009. Mr. Koski has practiced as an attorney with the Koski Firm, a sole proprietorship located in Atlanta, Georgia since 1992, where his practice includes litigation and tax law. Mr. Koski has also served as a partner in the Koski Family Limited Partnership, which beneficially owns an interest in the Company, and as a Director of the Koski Family Foundation since December 1996. Mr. Koski holds a B.A. degree in Philosophy and English from Colgate University, a J.D. from Emory School of Law and an L.L.M. degree in Taxation and Litigation from Emory University.

Mr. Koski brings to our Board over two decades of experience in the legal field as a practicing attorney. In addition to his legal experience, Mr. Koski's educational background provides a foundation for leadership and consensus-building.

John Gandolfo. Mr. Gandolfo has more than 30 years of experience as a Chief Financial Officer (CFO) of multiple rapidly growing private and publicly held companies with a primary focus in the life sciences, healthcare, and medical device areas. Mr. Gandolfo has had direct responsibility over all financial and treasury functions including capital raising and mergers and acquisitions. Mr. Gandolfo previously served as CFO of Eyenovia, Inc., (EYEN) a late-stage ophthalmic biopharmaceutical company since January 2018. Prior to this, Mr. Gandolfo was CFO of Xtant Medical Holdings, Inc., a biologics company, from July 2010 through September 2017. Prior to this, he served as the CFO for Progenitor Cell Therapy LLC from January 2009 to June 2010 and, before that, as CFO of Power Medical Interventions, Inc. from January 2007 to January 2009. Mr. Gandolfo currently serves on the Board of Directors of Electrocore, Inc. (ECOR) and previously served on the Board of Directors and was chair of the Audit Committee of Odyssey Health, Inc. f/k/a Odyssey Group International, Inc., (ODDY) from 2019 until 2023. Oragenics announced the signing of an asset purchase agreement with Odyssey Health on October 6, 2023.

Mr. Gandolfo is currently a member of the Board of Directors of Electrocore, Inc. (ECOR) and is chair of the Compensation Committee and sits on their audit committee. Mr. Gandolfo received his B.A. degree in Business Administration from Rutgers University.

Executive Management

Janet Huffman. Ms. Huffman has served as our Chief Financial Officer since March 8, 2023. On January 21, 2025, Ms. Huffman was also appointed as Interim Chief Executive Officer. Most recently, Ms. Huffman served as Chief Financial Officer for TRxADE HEALTH, Inc., a Nasdaq-listed company focused on health services IT for retail pharmacies. In 2019, Ms. Huffman was a founding member of Banyan Pediatric Care Centers and served as its Chief Financial Officer. After leading Banyan's merger with Assisted 4 Living, Inc., an OTC-listed company later renamed Arboreta Healthcare Inc. and a provider of skilled nursing, rehabilitation and assisted living services, she continued as Chief Financial Officer until February 2022. Prior to Arboreta Healthcare, Ms. Huffman was the Chief Financial Officer for Signature HomeNow, a home healthcare services company. Earlier in her career, she served as Director of Finance and Regional Director of Operations for Infinity Homecare and was Vice President of Finance for Family Home Health Services. Ms. Huffman obtained a B.S.in accounting from the University of South Florida.

Family Relationships

No family relationship exists among any of our directors or executive officer. No arrangement or understanding exists between any director or executive officer and any other person pursuant to which any director was selected as a director or executive officer.

Board of Directors and Committees

Our property, affairs and business are under the general management of our Board of Directors as provided by the laws of the State of Florida and our Bylaws.

The Board of Directors conducts its business through meetings of the full Board and through committees of the Board. The Board of Directors has appointed standing Audit, Compensation and Nominating and Governance Committees of the Board of Directors.

The Board periodically reviews the size of the Board and recommends any changes it determines to be appropriate given our needs. Under our Bylaws, the number of members on the Board may be increased or decreased by resolution of the Board.

During 2024, all members of the Board of Directors attended at least 75% of the meetings of the Board and committee meetings to which he is a member. We do not have a policy requiring our Board member to attend the annual shareholders' meeting. However, all members of the Board attended our 2024 annual shareholders' meeting.

Independence of Directors

Our common stock is listed on a national securities exchange, the NYSE American. Accordingly, in determining whether our Directors are independent, we are required to comply with the rules of the NYSE American. We also expect to continue to comply with securities and other laws and regulations regarding the independence of Directors, including those adopted under Section 301 of the Sarbanes-Oxley Act and Rule 10A-3 under the Securities and Exchange Act of 1934 with respect to the independence of Audit Committee members. The NYSE American listing standards define an "independent director" generally as a person, other than an officer of a company, who does not, in the view of the company's Board of Directors, have a relationship with the company that would interfere with the Director's exercise of independent judgment. The Board has affirmatively determined that each of the following Directors, constituting a majority of the Board, is independent within the meaning of the NYSE American listing standards:

Charles L. Pope
Dr. Frederick W. Telling
Dr. Alan Dunton
Robert Koski
John Gandolfo

Such independence definition includes a series of objective tests, including that the Director is not an executive officer employee of the company and has not engaged in various types of business dealings with the company. In addition, as further required by the NYSE American listing standards, the Board has made a subjective determination as to each independent director that no relationships exist which, in the opinion of the Board, would interfere with the exercise of independent judgment in carrying out the responsibilities of a Director.

Audit Committee and Audit Committee Financial Expert

The Audit Committee members currently consist of Mr. Charles Pope (Chairman), Dr. Frederick Telling and Dr. Alan Dunton. The Board has affirmatively determined that each such person met the independence requirements for audit committee purposes based on the more stringent independence standards imposed by applicable NYSE American and SEC rules. In addition, the Board of Directors has determined that Mr. Pope is an "audit committee financial expert" as that term is defined in Item 407(d)(5) of Regulation S-K promulgated under the Securities and Exchange Act of 1934. We believe that our Audit Committee Charter complies with the requirements related to Sarbanes-Oxley and a current copy of the Audit Committee Charter is available on our website http://ir.oragenics.com/governance-docs.

Code of Ethics

We have adopted a code of ethics known as the Company Operating Principles, which is applicable to all of our Directors and employees, including our principal executive officer and our principal financial officer. A copy of the Company Operating Principles can be found on our website at www.oragenics.com. Any future amendments to, or waivers from, the Company Operating Principles will be posted on our website.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934 requires the Company's officers and Directors and any persons who beneficially own more than ten percent of the Company's Common Stock to file reports of ownership and changes in ownership of such securities with the Securities and Exchange Commission Officers, Directors and beneficial owners of more than ten percent of the Common Stock are required by applicable regulations to furnish the Company with copies of all Section 16(a) forms they file. Based solely on its review of copies of forms furnished to the Company and written representations from the executive officers and Directors, the Company believes, all persons subject to the reporting requirements with regard to the Common Stock complied with the applicable filing requirements during 2024.

ITEM 11. EXECUTIVE COMPENSATION.

Compensation Discussion and Analysis

This section explains the objectives of our named executive officer compensation program, the compensation decisions we made with respect to compensation for our fiscal year ended December 31, 2024, and the factors we considered in making those decisions, and focuses on the compensation of officers who are listed below as our "named executive officers" and Key Employees:

- Kimberly Murphy, our former Chief Executive Officer,
- Janet Huffman, Chief Financial Officer, Interim Chief Executive Officer and
- Michael Redmond, our former President

The Compensation Committee of our Board of Directors is responsible for establishing and evaluating our policies governing the compensation of our executive officers, including our named executive officers. The Compensation Committee reviews and proposes recommendations to the Board of Directors regarding the compensation to be paid to the Chief Executive Officer. In addition, the Compensation Committee reviews and approves the compensation to be paid to all other executive officers. The Compensation Committee ensures that the total compensation paid to our executive officers is fair, reasonable, and competitive. The Compensation Committee has, in the past, at times included the other members of our Board of Directors in its deliberations regarding the salaries of our named executive officers.

At our 2023 Annual Meeting of Shareholders, on an advisory basis, a majority of the shareholders who voted on this matter, approved the compensation of our named executive officers as disclosed in our Proxy Statement. The Compensation Committee believes the views of our shareholders are an important consideration when making decisions regarding our compensation program and will continue to take the views of our shareholders into consideration when assessing our compensation program and making decisions related to the structure and amount of pay.

Business Highlights

During 2024, we paused the development of our immunization product candidate to combat the novel coronavirus pandemic and focused on the development of our Neurology Assets. Our compensation program continues to reflect the challenges associated with designing a compensation program at the beginning of the year that addresses our pre-clinical work and our strategy of acquiring additional product-development assets. Despite such challenges, the Compensation Committee remains committed to a philosophy which strongly aligns pay with demonstrated performance and is confident that the decisions made are reflective of this overarching philosophy.

Compensation Objective

Our named executive officer compensation programs are designed to achieve the following objectives:

- Attract, motivate and reward named executive officers whose knowledge, skills, performance and business relationships are critical to our success;
- Align the interests of our named executive officers and stockholders by motivating named executive officers to ultimately increase stockholder value as well as facilitate retention;
- Motivate our named executive officers to manage our business to meet our short term and long-range goals and reward accomplishment of these goals; and
- Provide a competitive compensation package which includes some pay for performance factors.

Compensation Determination Process

We conduct an annual review of named executive officer compensation, generally in December or January. At the Compensation Committee's direction, our Chief Executive Officer prepares an executive compensation review for each named executive officer, other than their self, which may include recommendations for:

- a proposed year-end bonus, if any, based on the achievement of individual and/or corporate objectives;
- a proposed increase, if any, in base salary and target annual incentive opportunity for the upcoming year; and
- an award, if any, of stock options or stock awards for the year under review.

As part of the compensation review, our Compensation Committee also considers changes to a named executive officer's employment agreement, compensation arrangements and benefits, responsibilities, or severance arrangements.

In accordance with NYSE American requirements, the Compensation Committee also meets in an executive session without the Chief Executive Officer to consider and make recommendations to our Board of Directors regarding the Chief Executive Officer's compensation, including base salary, cash bonus and year-end annual stock options. The Compensation Committee also grants year-end stock options to other named executive officers based on, among other factors, recommendations by our Chief Executive Officer.

In conjunction with the year-end annual compensation review, or as soon as practicable after the fiscal year-end, our Chief Executive Officer recommends to the Compensation Committee the corporate objectives and other criteria to be utilized for purposes of determining cash bonuses (i) for each named executive officer for the upcoming year (in accordance with that named executive officer's employment agreement), and (ii) for all other employees as a group. The Compensation Committee in its discretion may revise our Chief Executive Officer's recommendations or make its own recommendations to our Board of Directors, which may in turn suggest further revisions. At the end of the year, the Compensation Committee, in consultation with our Chief Executive Officer, reviews performance and determines the extent to which any established goals were achieved.

Setting Compensation for Named Executive Officers - Compensation Committee, Board of Directors and Chief Executive Officer or Principal Executive Officer

The Compensation Committee of our Board of Directors has the primary responsibility for determining the compensation of our named executive officers. Our Compensation Committee recommends the compensation of our Chief Executive Officer or Principal Executive Officer and determines all compensation matters for our named executive officers, including base salary, bonuses, and equity compensation. Our Board of Directors, after considering the recommendations of the Compensation Committee, makes the final determination with respect to the compensation of our Chief Executive Officer or Principal Executive Officer. Utilizing input from our Chief Executive Officer or Principal Executive Officer, the Compensation Committee makes an independent decision on compensation for each other named executive officers, although our Compensation Committee has, on occasion, submitted its compensation determinations for named executive officers to our full Board of Directors for its approval.

Role of Compensation Consultant

Our Compensation Committee is authorized to engage a compensation consultants or other advisors to review our executive officers' compensation, including a benchmarking analysis against the compensation of executive officers at comparable companies, to ensure that our compensation is market competitive, with the goal of retaining and adequately motivating our senior management. In March 2019 and January of 2020, our Compensation Committee retained Korn Ferry as a compensation consultant ("Korn Ferry") to assess our current compensation programs and provide recommendations for continued improved alignment of the programs with our compensation philosophy and goals and to review and make recommendations regarding our executive and Director compensation for 2019 and 2020.

Our Compensation Committee evaluates the performance of its compensation consultant, considers alternative compensation consultants, and has the final authority to engage and terminate such services. The Compensation Committee assessed the independence of Korn Ferry pursuant to SEC rules and the applicable listing standards of the NYSE American and concluded that no conflict of interest exists that would prevent Korn Ferry from serving as an independent consultant to our Compensation Committee. This Korn Ferry assessment has not been formally updated, nor has the engagement continued as the Compensation Committee believes, based on a variety of factors, including the small number of employees, that an updated assessment was not warranted

Benchmarking in the Context of Our Other Executive Compensation Principles

From time to time our Compensation Committee reviews the compensation of similarly situated executive officers at companies that we consider to be our peers, taking into consideration the experience, position and functional role, level of responsibility and uniqueness of applicable skills of both our executive officers and those of our peers, and the demand and competitiveness for attracting and retaining an individual with each executive officer's specific expertise and experience. While this analysis is helpful in determining market-competitive compensation for senior management, it is only one factor in determining our executive officers' compensation, and our Compensation Committee exercises its judgment in determining the nature and extent of its use.

For purposes of comparing our executive compensation against the competitive market, our Compensation Committee reviews and considers the compensation levels and practices of a group of comparable biotechnology companies known to the members of the Compensation Committee. This information was then used as a reference point for our Compensation Committee to assess our current compensation levels in the course of its deliberations on forms and amounts of compensation. Given our objective of attracting, retaining, motivating, and rewarding a highly-skilled team of executive officers and other employees, we aim to deliver a total compensation package that is within a competitive range around the median as compared to peers, with an emphasis on equity incentive compensation so as to more effectively tie our named executive officers and employees' interests to those of our shareholders. In light of this, when undertaking such analysis, our Compensation Committee has reviewed data pertaining to the 25th, 50th and 75th percentiles for base salary, total cash compensation (base salary plus annual bonus) and equity compensation. This competitive analysis is one factor, among others, taken into account by our Compensation Committee in assessing current compensation levels and recommending changes to compensation or additional awards of equity. Our Compensation Committee expects to review such compensation data as it believes necessary to make adjustments to its composition, taking into account changes in both our business and the businesses of the companies in the peer group. Due to the small number of employees and executive officers we have, among other factors, our Compensation Committee did not undertake an update to the peer group in 2024.

Our Compensation Committee believes that, given the competitiveness of our industry and our culture, our base compensation, annual cash bonuses and equity programs are flexible enough to reward the achievement of clearly defined corporate goals and are sufficient to retain our existing executive officers and to hire new executive officers with the appropriate qualifications and experience.

Elements of Named Executive Officer Compensation

For 2024, the principal components of compensation for our named executive officers consisted of:

- Annual base salary;
- Annual bonus incentives; and
- Equity Incentive Awards / Option Awards.

Annual Base Salary

We provide our named executive officers with a base salary to compensate them for services rendered during the year. Generally, the base salaries reflect the experience, skills, knowledge, and responsibilities required of each executive officer, and reflect our executive officers' overall performance and contributions to our business.

During its review of base salaries for executives, the Compensation Committee primarily considers:

- the negotiated terms of each named executive officer's employment agreement, if any;
- an internal review of the named executive officer's compensation, both individually and relative to other named executive officers; and
- base salaries paid by comparable companies in the biopharmaceutical industry that have a similar business and financial profile.

Salary levels are considered annually as part of our performance review process. Merit-based increases to salaries are based on management's assessment of the individual's performance, the recommendations made by the Chief Executive Officer to the Compensation Committee, and the comparative compensation at peer companies. The factors used in determining increases in base salary include individual performance, changes in role and/or responsibility and changes in the competitive market environment. The Compensation Committee periodically reviews the base salary for each executive officer.

Annual Incentive Bonuses

We provide an opportunity for each of our named executive officers to receive an annual incentive bonus based on the satisfaction of individual and company objectives established by the Compensation Committee and/or our Board of Directors, or if no objectives are established at the discretion of the Committee. These incentives are paid in cash. For any given year, these objectives may include individualized goals or company-wide goals that relate to operational, strategic or financial factors such as progress in developing our product candidates, achieving certain manufacturing, intellectual property, clinical and regulatory objectives, and managing our capital requirements.

2024 Bonus Plan

The Company established performance-based bonus targets for its named executive officers in 2024 (the "2024 Bonus Plan"). The percentages were weighted for purposes of determining bonuses, if any, for the Company's executive officers with respect to 2024 performance. Under such a cash bonus program, Ms. Huffman, and Mr. Redmond were eligible for cash bonuses of up to 35% and 50%% of their respective base salaries, or $87,500 and $198,000 respectively, (each a "Bonus Target").

The bonuses payable to Mr. Redmond were to be based upon the achievement of the following objectives:

(i) Up to 30% of the Bonus Target for Phase 2 clinical trial patient milestones;

(ii) Up to 40% of the Bonus Target for overseeing the Company's capital raising efforts;

(iii) Up to 30% of the Bonus Target for the Company's strategic planning initiatives.

The bonuses payable to Ms. Huffman were to be based upon the achievement of the following objectives:

(i) Up to 10% of the Bonus Target for the Company's annual meeting planning initiatives;

(ii) Up to 5% of the Bonus Target for strategic talent acquisition in the Company's finance department;

(iii) Up to 40% of the Bonus Target for overseeing the Company's capital raising efforts;

(iv) Up to 15% of the Bonus Target for the Company's strategic planning initiatives; and

(v) Up to 30% of the Bonus Target for the Company's strategy and initiatives related to risk management and internal controls.

The executive officers' actual bonuses for fiscal year 2024 were eligible to exceed 100% of their 2024 Bonus Target percentage in the event performance exceeds the predetermined goals and/or upon the achievement of other specified goals, including stretch goals. Payment of bonuses to the Company's executive officers under the 2024 Bonus Program and the actual amount of such bonus, if any, are at the discretion of the Compensation Committee.

Equity Incentive Compensation

We believe that successful long-term corporate performance is more likely to be achieved with a corporate culture that encourages a long-term focus by our named executive officers and other employees through the use of equity awards, the value of which depends on our stock performance. We established our 2021 Equity Incentive Plan to provide all of our employees, including our named executive officers, with incentives to help align our employees' interests with the interests of our stockholders and to enable them to participate in the long-term appreciation of our stockholder value. Additionally, equity awards provide an important retention tool for all employees, as the awards generally are subject to vesting over an extended period of time based on continued service with us.

We typically grant equity awards in connection with hiring a new employee. In addition, equity awards may also be granted for performance annually at, or soon after, the end of each year, depending on position, performance and tenure at the Company.

The determination of whether to grant stock options, as well as the size of such grants, to our named executive officers involves assessments by the Compensation Committee and our Board of Directors and, with respect to named executive officers other than herself, our Chief Executive Officer. Generally, annual equity awards are driven by our desire to retain and motivate our named executive officers, and we consider individual performance and contributions during the preceding year to the extent the Compensation Committee and our Board of Directors believe such factors are relevant. As with base salary and cash bonuses, in evaluating and determining stock option grants to our named executive officers, the Compensation Committee and our Board of Directors also considers publicly available data from other similar clinical stage companies identified by the Compensation Committee.

We currently grant stock options or stock awards to new employees when they join our Company based upon their position with us and their relevant prior experience. The awards granted by the Compensation Committee generally vest over time during the ten-year option term (although some previously granted awards vest immediately), or upon the achievement of certain milestones. Unless otherwise agreed to by us with respect to a termination without "cause" or for "good reason," vesting and exercise rights generally cease upon termination of employment, except in the case of death (subject to a one-year limitation), disability or retirement. Prior to the exercise of an option, the holder has no rights as a stockholder with respect to the shares subject to such option, including voting rights or the right to receive dividends or dividend equivalents. In addition to the initial option grants, our Compensation Committee may grant additional options to retain our employees and reward, or provide incentive for, the achievement of corporate goals and strong individual performance. Our Board of Directors has not granted our Chief Executive Officer the discretion to grant options to non-executive employees upon joining our Company, or to make grants during each annual non-executive employee review cycle.

It is our policy to award stock options at an exercise price equal to the closing price on the NYSE American Market of our common stock on the date of the grant. For purposes of determining the exercise price of stock options, the grant date generally based upon the later of the first day of employment for newly hired employees, or the date and time on which the Compensation Committee or Board approves the stock option grant.

We have no program, practice, or plan to grant stock options, in coordination with the release of material nonpublic information. We also have not timed the release of material nonpublic information for the purpose of affecting the value of stock options or other compensation, and we have no plan to do so. We do, however, have a policy regarding the adjustment or recovery of stock option awards in connection with the restatement of our financial statements, as our stock option awards have not been tied to the achievement of specific financial statement goals.

Other Compensation

Other aspects of compensation applicable to our named executive officers consist of the following:

Retirement Benefits. We maintain a Simple Individual Retirement Arrangement plan in which all full-time employees, including our named executive officers, are eligible to participate. We provide this plan to help its employees save some amount of their cash compensation for retirement in a tax efficient manner. We do not provide an option for its employees to invest in our stock under the 401k plan. We match 100% of the employee's contribution up to a maximum of 3% of the employee's compensation.

Health and Welfare Benefits. All full-time employees, including our named executive officers, may participate in our health and welfare benefit programs, including medical, dental and vision care coverage as may be provided and applicable to all employees.

Perquisites. We do not provide perquisites or other personal benefits to our named executive officers other than those that we provide to our employees.

Employment Agreements. During 2024, we had employment agreements in effect with Ms. Kimberly Murphy, Ms. Huffman and Mr. Redmond. We entered into employment agreements with these officers and key employees to ensure that they would perform their respective roles with us for an extended period of time. In addition, we also considered the critical nature of each of their positions and our need to retain them when we committed to these agreements.

2024 Named Executive Officer Compensation Decisions

We believe that the total compensation paid to our named executive officers for the fiscal year ended December 31, 2024, achieved the overall objectives of our executive compensation program. In accordance with our overall objectives, we believe executive compensation for 2024 was competitive with other similarly sized companies. The Compensation Committee took the following key compensation actions in 2024:

Base Salaries

During 2024, we made the following changes in annual base salary for named Executive Officers and key employees.

Name	Annual Salary For 2023	Increase	Annual Salary For 2024
Kimberly Murphy	$ 430,000	$ -	$ 430,000(1)
Janet Huffman	$ 250,000	$ -	$ 250,000
Joseph Michael Redmond	$ 396,000	$ -	$ 396,000(2)

(1) Ms. Murphy resigned from her role as President and Chief Executive Officer in February of 2024 and, as a result, effective February 2024, Mr. Redmond, the Company's President, began also serving as the Company's Interim Principal Executive Officer and Mr. Pope began serving, on an interim basis, as Executive Chairman.

(2) The Company elected not to renew Mr. Redmond's Employment Agreement dated December 28, 2023 and on December 16, 2024, the we terminated the employment of Mr. Redmond and appointed the Company's Chief Financial Officer, Janet Huffman, to serve as the new Interim Principal Executive Officer and President until such time as the Company retains a new Chief Executive Officer and President.

Determination of Cash Bonus-2024

Our Board of Directors determined that Ms. Huffman's 2024 performance-based cash bonus award earned to be $75,000, which was paid in February 2025.

Determination of Equity Awards

On September 19, 2024, Ms. Huffman received a stock option grant pursuant to our 2021 Equity Incentive Plan (the "2021 Plan") to purchase 80,000 shares of our common stock at an exercise price of $0.48 per share, the closing price of our common stock on the grant date. This award vested immediately.

On September 19, 2024,Mr. Redmond received a stock option grant pursuant to the 2021 Plan to purchase 100,000 shares of our common stock at an exercise price of $0.48 per share, the closing price of our common stock on the grant date. This award vested immediately.

Other Policies and Considerations - Employment Contracts and Change in Control Arrangements

We entered into employment agreements with our former Chief Executive Officer, Ms. Murphy, our Chief Financial Officer, Ms. Huffman, and our former President, Mr. Redmond (the "Employment Agreements").

Employment Agreements—Ms. Murphy, our former Chief Executive Officer

On June 23, 2022, Ms. Murphy entered into an Executive Employment Agreement with us under terms substantially similar to the employment agreements of existing executives. Under the terms of her Executive Employment Agreement, Ms. Murphy's employment with us became effective June 23, 2022, On February 12, 2024, we entered into a mutually agreeable Separation Agreement (the "Separation Agreement"), with Ms. Murphy pursuant to which her employment with the Company terminated effective February 12, 2024. The Separation Agreement provided Ms. Murphy with the benefits under her employment agreement with the Company for a separation without cause. Ms. Murphy's resignation was not due to any disagreement with the Company on any matter related to its operations, policies, or practices.

In the Executive Employment Agreement Ms. Murphy agreed to duties of non-disclosure of Confidential Information, non-competition and non-solicitation and our ownership of development provisions. Ms. Murphy continued to serve as a member of the Company's board of directors (the "Board") until her term ended on December 11, 2024.

Employment Agreements—Mr. Michael Redmond, our former President

In connection with the purchase of the Neurology Assets we entered into an Executive Employment Agreement with Mr. Redmond with terms substantially similar to existing employment agreements with executives.

Under the terms of the Executive Employment Agreement, Mr. Redmond's employment with the Company became effective December 28, 2023. The Executive Employment Agreement provided that he would receive an annual base salary of $396,000, Mr. Redmond was also eligible for a Performance Bonus with a target of 50% of his annual salary based on appropriate Company based and individual based targets in the discretion of the Compensation Committee as approved by the full Board of Directors. Mr. Redmond was also eligible to participate in the medical insurance and other benefits available to all employees except his annual vacation which was set at four (4) weeks.

In connection with Mr. Redmond's employment, he was awarded stock options to acquire 75,000 shares of common stock under the 2021 Plan at an exercise price of $5.40 per share, which was the Company's closing price on the date of his employment agreement. 37,500 of the options vested immediately, 18,750 options vest on June 24, 2024, and 18,750 options vest on the first anniversary of the effective date, in each case provided Mr. Redmond had remained in continuous employment with the Company through such dates.

The Executive Employment Agreement was terminable at any time by the Company and upon 30 days' notice by Mr. Redmond. Upon separation for any reason Mr. Redmond shall receive his base salary accrued through the date of termination, and any vested rights and benefits provided under employee benefit plans and programs of the Company. In addition, if Mr. Redmond's separation from employment is terminated by the Company without cause, for good reason by Mr. Redmond or for non-renewal by the Company after the end of the initial term and Mr. Redmond signs

On November 26, 2024, we notified Mr. Redmond that we were not renewing his Employment Agreement. The initial term of the Agreement was one year. However, pursuant to the Agreement, the initial term automatically renews for one additional year unless either party provides the other party with a notice of non-renewal at least 30 days prior to the expiration of the initial term. Subsequently, effective December 16, 2024, we terminated Mr. Redmond's employment without cause and appointed the Company's Chief Financial Officer, Janet Huffman, to serve as the new Interim Principal Executive Officer and President until such time as the Company retains a new Chief Executive Officer and President.

In the Executive Employment Agreement Mr. Redmond has agreed to duties of non-disclosure of Confidential Information, non-competition and non-solicitation and Company ownership of development provisions.

Employment Agreements—Ms. Huffman, Chief Financial Officer and Interim Chief Executive Officer

On March 6, 2023, Ms. Huffman entered into an Executive Employment Agreement with us under terms substantially similar to the employment agreements of existing executives. Under the terms of her Executive Employment Agreement, Ms. Huffman's employment with us became effective March 6, 2023, and she receives an annual base salary of $250,000 and will be eligible for a Performance Bonus with a target of 35% of her annual salary based on appropriate Company based and individual based targets in the discretion of the Compensation Committee as approved by the full Board of Directors. Ms. Huffman will be eligible to participate in the medical insurance and other benefits available to all employees except her annual vacation will be set at four (4) weeks.

On January 16, 2025, the Board appointed Ms. Huffman to also serve as the Company's Interim Chief Executive Officer effective as of January 16, 2025, and in connection therewith, the Board determined that, effective January 16, 2025, Ms. Huffman's employment agreement would be modified to (i) include her new title of Interim Chief Executive Officer; (ii) require that as she report directly to the Company's Board of Directors and its Executive Chairman; (iii) increase her base salary by 10% to $275,000; and (iv) change her location to Sarasota (given the Company relocation from Tampa to Sarasota). All other terms of Ms. Huffman's Employment Agreement remain in full force and effect.

In connection with Ms. Huffman's employment, she was awarded stock options to acquire 7,000 shares of our common stock under our 2021 Plan, at an exercise price of $4.00 per share, which was our closing price on the grant date. The options shall vest as follows: 1,400 options shall vest on the grant date, 1,400 options shall vest on September 6, 2023, 1,400 options shall vest on March 6, 2024, 1,400 options shall vest on September 6, 2024, and 1,400 options shall vest on March 6, 2025, in each case provided Ms. Huffman has remained in continuous employment with us through such dates.

The Executive Employment Agreement is terminable at any time by us and upon 60 days' notice by Ms. Huffman. Upon separation for any reason Ms. Huffman shall receive her base salary accrued through the date of termination, and any vested rights and benefits provided under our employee benefit plans and programs. In addition, if Ms. Huffman's separation from employment is terminated by us without Cause or for non-renewal by us after the end of the Initial Term and Ms. Huffman signs a full general release then we would be obligated to pay Ms. Huffman six months of her annual base salary as severance plus any earned but unpaid Performance Bonus.

If Ms. Huffman's employment is terminated by us without Cause during the period of 30 days following a Change in Control and Ms. Huffman signs a full general release then we would be obligated to pay Ms. Huffman six months of her annual base salary as severance, any earned, accrued but unpaid bonus Performance Bonus and Ms. Huffman's Performance Bonus for the year of the Change in Control at target level of performance. Additionally, with any such termination Ms. Huffman's stock options or other stock awards under our 2021 Equity Incentive Plan which are not vested shall vest as of her termination date. Under the Executive Employment Agreement, "Change in Control" is defined as a transaction or series of transactions which constitutes a sale of control of the Company, a change in effective control of the Company, or a sale of all or substantially all of our assets, or a transaction which qualifies as a "change in ownership" or "change in effective control" of the Company or a "change in ownership of substantially all of the assets" of the Company under the standards set forth in Treasury Regulation section 1.409A-3(i)(5).

In the Executive Employment Agreement Ms. Huffman has agreed to duties of non-disclosure of Confidential Information, non-competition and non-solicitation and Company ownership of developments provisions.

Tax and Accounting Implications

Deductibility of Executive Compensation

The Compensation Committee takes into consideration the tax consequences of compensation to the named executive officers, but tax considerations are not a significant part of our Company's compensation policy.

Accounting for Stock-Based Compensation

We account for stock-based compensation in accordance with the requirements of FASB ASC Topic 718. This accounting treatment has not significantly affected our executive compensation decisions.

Clawbacks

In order to further align management's interests with those of shareholders and to support the Company's governance practices, the Board of Directors adopted a recoupment policy applicable to annual bonuses and other short-term and long-term incentive compensation based on financial targets ("Incentive Compensation") received by current and former executive officers of the Company and such other senior executives/employees of the Company who may from time to time be deemed subject to the policy by the Board of Directors ("Covered Executive"). The policy provides that if, as a result of a restatement of the Company's financial statements due to the Company's material noncompliance with any financial reporting requirement under the securities laws, a Covered Executive received more Incentive Compensation than the Covered Executive would have received absent the incorrect financial statements, the Company shall recover said excess Incentive Compensation (defined as the excess of (i) the actual amount of Incentive Compensation paid to the Covered Executive over (ii) the Incentive Compensation that would have been paid based on the restated financial results during the three-year period preceding the date on which the Company is required to prepare such restatement). The policy also provides that if the Board of Directors makes a determination in its sole discretion that a Covered Executive engaged in Misconduct (as defined below), the Board of Directors may require reimbursement or forfeiture of all or part of the Incentive Compensation received by the Covered Executive. The Board of Directors may use its judgment in determining the amount to be recovered. Misconduct is defined as (i) conviction of a felony, (ii) material breach of any agreement with the Company, (iii) material breach of any Company policy or code, (iv) act of theft, embezzlement or fraud, (v) misrepresentation or misstatement of financial or performance results, and (vi) any other act or event that the Board of Directors has determined that recoupment is appropriate.

Consideration of Stockholder Advisory Vote on Executive Compensation

The Compensation Committee also expects to consider the results of our stockholder advisory vote on executive compensation. Our shareholders have historically voted in favor of the compensation of our named executive officers and, at our 2024 Annual Shareholder Meeting, 81.1% of the shares represented in person or by proxy voted in favor of the program. In light of these results, the Compensation Committee has determined to substantially continue the executive compensation program. The Board of Directors determined that shareholder advisory votes on executive compensation will be submitted to our shareholders annually until the next required advisory vote on the frequency of conducting advisory votes on executive compensation.

Summary Compensation Table

The following table sets forth the aggregate compensation in 2024 and 2023 for services in all capacities paid or accrued by the Company to our most highly compensated officer who earned more than $100,000 in total salary and bonus during the fiscal year ended December 31, 2024, as well as two former executive officers (the "Named Executive Officers").

Name and principal position	Year	Salary	Bonus(1)	Stock Awards (2)	Option Awards (2)	All Other Compensation (3)	Total
Kimberly Murphy	2024	$ 53,750	$ -	$ -	$ 10,562	$ 216,612	$ 280,924
Former Chief Executive Officer and President	2023	$ 430,000	$ 65,000	$ 84,250	$ -	$ 12,900	$ 592,150
Janet Huffman	2024	$ 250,000	$ 75,000	$ -	$ 31,200	$ 7,500	$ 363,700
Chief Financial Officer, Interim Chief Executive Officer	2023	$ 208,333	$ 130,000	$ 50,550	$ 27,400	$ 4,063	$ 420,346
Joseph Redmond	2024	$ 397,126	$ -	$ -	$ 39,000	$ 28,015	$ 464,141
Former President and Interim Principal Executive Officer	2023	$ -	$ -	$ -	$ 343,800	$ -	$ 343,800

1) The amounts in this column represent amounts earned pursuant to our Performance-Based Bonus plans. Amounts earned in 2023 were paid in January 2024 and the amount earned in 2024 was paid in February 2025.

(2) The amounts in this column represent the aggregate grant date fair value computed in accordance with Financial Accounting Standards Board Accounting Standards Codification, Topic 718, Compensation—Stock Compensation (ASC 718). See Notes 2 and 8 of Notes to Consolidated Financial Statements for additional information. On August 8, 2023, Ms. Murphy and Ms. Huffman received restricted stock awards, under the Company's 2021 Equity Incentive Plan, of 25,000 and 15,000 shares, respectively, with a grant price of $3.37. The restricted stock awards vested at 20,000 shares immediately for Ms. Murphy with the remaining 5,000 shares to vest over six months. The restricted stock awards vested at 10,000 shares immediately for Ms. Huffman with the remaining 5,000 shares to vest over six months.

(3) Amounts in this column for Ms. Murphy, Ms. Huffman and Mr. Redmond represent our matching contributions to our Simple IRA retirement plan of $1,612, $7,500 and $11,515, respectively. In addition, the amounts in this column reflect severance payments. In 2024, Ms. Murphy and Mr. Redmond received severance of $215,000 and $16,500 respectively.

The Compensation Committee believes that our future success depends, in large part, upon our ability to maintain a competitive position in attracting, retaining and motivating key personnel. The Compensation Committee utilizes the 2021 Equity Incentive Plan to provide incentives to employees. We do not have any separate long-term incentive plans that provide compensation intended to serve as incentives for performance other than awards contemplated under, or pursuant to, our 2021 Equity Incentive Plan.

Outstanding Equity Awards

The following table provides information concerning outstanding equity awards as of December 31, 2024:

	Number of securities underlying unexercised options (#) exercisable	Number of securities underlying unexercised options (#) unexercisable	Option exercise price (s)	Option expiration date
Kim Murphy Former President and Chief Executive Officer	27,083		$ 0.48(3)	3/11/2025
Janet Huffman Chief	80,500		$ 0.48	9/19/2034
Financial Officer	5,600	1,400(2)	$ 4.00	3/7/2033
Joseph Redmond Former President and	100,000		$ 0.48(3)	3/16/2025
Interim Principal Executive Officer	56,250		$ 5.37(3)	3/16/2025

1) Represents awards that are time vested with each award vesting evenly on an annual basis over three years, subject to earlier vesting upon a change in control as defined in the award agreements.
2) Represents awards that are time vested with each award vesting evenly on a semi-annual basis over two years, subject to earlier vesting upon a change in control as defined in the award agreements.
3) Ms. Murphy and Mr. Redmond's vested options will expire 90 days from their employment termination dates – 3/11/25 and 3/16/25 respectively

Director Compensation

The Director Compensation program for 2024 consisted of the following:

Cash Compensation. The Director compensation program for 2024 provided that all non-employee Directors would receive an annual base fee for service on the Board of $45,000. In addition, the Chairperson of the Board and of our Audit Committee, Compensation Committee and Nominating Committee would also receive annual fees of $40,000, $20,000, $15,000, and $10,000 respectively. All non-employee Directors serving on our Audit Committee, Compensation Committee and Nominating Committee (other than as the Chairperson) would receive an annual fee of $10,000, $7,500, and $5,000, respectively, in connection with such committee service. In addition, from time to time, the Board may establish special committees and in connection therewith determine the cash compensation that would be paid to the Directors serving on a special committee at the time of the establishment of such committee. All fees for Board service are generally paid on or before the last business day of each quarter.

The Board expects to meet in-person for a minimum of four meetings each year. To the extent the Board meets in excess of six in-person meetings an additional per meeting fee would also be considered to be paid to each Director by the Board for such additional in-person meeting. To the extent the Board determines to establish a special committee, or a special committee was previously established and continues to function, the Board would determine the cash compensation payable to each Director serving on any such special committee.

Our Compensation Committee and our Board of Directors use market data as one means of evaluating and establishing Board remuneration. From time to time the Compensation Committee seeks the advice for compensation consultants on matters related to executive compensation, board remuneration and related governance matters.

Equity Compensation-New Director. Equity compensation is issued to Directors upon joining our Board. Non-employee Directors receive a stock option for the purchase of shares of Company's Common Stock equating to $60,000 with an exercise price set as the Closing price of the Company's Common Stock on the day immediately prior to the appointment to the Board, which will immediately vest and be exercisable for ten years, subject to early termination under the terms of the 2021 Equity Incentive Plan. If new Directors join the Board before July 1 of the calendar year, they would receive 100% of the value; 50% of such total value if they join between July 1 and October 1; 25% of such total value if they join after October in a calendar year.

Annual Equity Compensation Awards. As part of the Director Compensation Program each non-employee director receives equity awards under the 2021 Equity Incentive Plan. In September 2024, the Board considered and granted stock options to non-employee Directors. Mr. Pope received 100,000 options at a grant price of $0.48 per share. Messrs. Koski, Telling and Dunton received 65,000 options at a grant price of $0.48 per share. Messrs. Gandolfo and Cassidy received 45,000 options at a grant price of $0.48. Ms. Murphy received 27,083 options at a grant price of $0.48 per share. According to the terms of the grants, the options vested immediately.

The stock options are subject to the standard terms and conditions of the Company's form of stock option agreement which includes earlier vesting upon a change in control of the Company.

Discretionary Awards. As part of the Director Compensation Program, the Board may also make discretionary equity-based awards from time to time under our 2021 Equity Incentive Plan.

Minimum dollar value stock ownership requirements. Each non-employee Director receiving the above equity-based awards will be subject to a minimum dollar value stock ownership holding requirement with respect to the awards received as well as all prior equity awards under the 2021 Equity Incentive Plan which requirement is intended to align the ability to sell shares with the performance of the Company's stock price. The non-employee Directors will each be subject to a minimum dollar value stock ownership requirement equal to six times the annual Board retainer ($270,000) which dollar threshold they would be precluded from selling shares of Company stock acquired from the Company under its 2021 Equity Incentive Plan.

Reimbursement of Expenses. Non-employee Directors are also reimbursed for expenses incurred in connection with their attendance at Board or committee meetings and reasonable out-of-pocket business expenses associated with their Board service.

Long-term Incentive Compensation. The Company did not have a Long-Term Incentive Compensation plan in place performance in 2024 for its Non-Employee Directors.

The following table sets forth the compensation of our non-employee Directors in 2024.

Non-Employee Director Compensation Table

Name	Fees earned or paid in cash (1)	Option awards (2)	Total
Dr. Frederick W. Telling	$ 72,500	$ 39,000	$ 111,500
Robert C. Koski	$ 50,000	$ 25,350	$ 75,350
Charles L. Pope	$ 112,500	$ 25,350	$ 137,850
Dr. Alan W. Dunton	$ 75,000	$ 25,350	$ 100,350
Bruce Cassidy	$ 56,250	$ 17,550	$ 73,800
John Gandolfo	$ 45,000	$ 17,550	$ 62,550
Kimberly Murphy	$ 14,456	$ 10,562	$ 25,018

(1) Amounts represent cash compensation earned by our Non-employee Directors during 2024 in connection with their Board service including any service on committees or service in connection with special committees established by the Board.

(2) The amounts in this column represent the aggregate grant date fair value computed in accordance with Financial Accounting Standards Board Accounting Standards Codification, Topic 718, Compensation—Stock Compensation (ASC 718). See Notes 2 and 8 of Notes to Consolidated Financial Statements. On September 19, 2024, Mr. Pope received 100,000 options at a grant price of $0.48 per share. Mssrs. Koski, Telling and Dunton received 65,000 options at a grant price of $0.48 per share. Mssrs. Gandolfo and Cassidy received 45,000 options at a grant price of $0.48. Ms. Murphy received 27,083 options at a grant price of $0.48 per share. According to the terms of the grants, the options vested immediately.

(3) Mr. Cassidy resigned from the Board in January 2025.

(4) Ms. Murphy is a former Director who resigned from the Board in December 2024.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.

The following table sets forth information about beneficial ownership of our Common Stock as of March 10, 2025 (unless otherwise noted) by (i) each shareholder that has indicated in public filings that the shareholder beneficially owns more than five percent of the Common Stock, (ii) each of the Company's directors and named officers and (iii) all directors and officers as a group. Except as otherwise noted, each person listed below, either alone or together with members of the person's family sharing the same household, had, to our knowledge, sole voting and investment power with respect to the shares listed next to the person's name.

Name and address (1)	Number of shares beneficially owned	Percentage of ownership (2)
Directors and officers		
Robert C. Koski (3)	134,401	*
Charles L. Pope (4)	143,565	*
Dr. Alan Dunton (5)	109,054	*
Dr. Frederick W. Telling (6)	121,067	*
Bruce Cassidy (7)	404,830	1.8%
Janet Huffman (8)	102,000	*
Kimberly Murphy (9)	25,000	*
John Gandolfo (10)	50,102	*
(All Directors and officers as a group 6 persons)	1,090,019	4.9%

* Beneficial ownership percentage is less than 1%.

(1) Except as indicated, the address of the person named in the table is c/o Oragenics, Inc., 1990 Main Street Suite 750, Sarasota, Florida 34236.

(2) In computing the number of shares beneficially owned by a person and the percentage ownership of that person, shares of common stock subject to options or warrants held by that person that are currently exercisable or will become exercisable within 60 days after March 14, 2025, are deemed outstanding, while the shares are not deemed outstanding for purposes of computing percentage ownership of any other person. Except as otherwise indicated, and subject to applicable community property laws, the persons named in the table have sole voting and investment power with respect to all shares of common stock held by them. Applicable percentage ownership is based on 21,475,289 shares of common stock outstanding as of March 10, 2025, an admission of beneficial ownership of those shares.
(3) The share amounts include: (i) 14,334 shares held by the Koski Family Limited Partnership ("KFLP") of which Mr. Koski is a general partner; (ii) 5,000 shares acquired by the KFLP upon conversion of Series B Convertible Preferred Stock; (iii) 4,033 shares able to be acquired by the KFLP upon exercise of warrants; (iv) 27,940 shares owned directly by Mr. Koski; and (v) 83,094 shares able to be acquired pursuant to stock options.
(4) Includes: 118,094 shares able to be acquired pursuant to stock options.
(5) Includes: (i) 83,094 shares able to be acquired pursuant to stock options, and (ii) 337 shares able to be acquired upon the exercise of warrants.
(6) Includes: (i) 84,652 shares able to be acquired pursuant to stock options, and (ii) 1,667 shares able to be acquired upon the exercise of warrants.
(7) Includes 50,102 shares able to be acquired upon the exercise of stock options. Excel Family Partners, LLLP ("Excel") acquired 354,728 shares in a private placement on August 4, 2023. Fortress Holdings, LLC ("Fortress") serves as manager for Excel and Mr. Cassidy serves as a manager for Fortress.
(8) Includes: 15,000 shares owned directly by Ms. Huffman; and 87,000 shares able to be acquired upon the exercise of stock options.
(9) Includes: 25,000 shares owned directly by Ms. Murphy.
(10) Represents shares able to be acquired upon the exercise of stock options.

Securities Authorized for Issuance under Equity Compensation Plans

The following table sets forth certain information as of December 31, 2024 with respect to the 2021 Equity Incentive Plan as amended (the "2021 Plan"):

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options (A)	Weighted- Average Exercise Price of Outstanding Options (B)	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (A)) (C)
Equity compensation plans approved by stockholders:			
2021 Equity Incentive Plan (1)	993,753	$ 4.65	2,032,914
Equity compensation plans not approved by stockholders	-	-	-
Total:	993,753	$ 4.65	2,032,914

(1) Our shareholders approved an amendment to our 2021 Equity Incentive Plan (the "2021 Plan") at our 2024 Annual Meeting in December 2024 which provided for an additional two million shares of our common stock to be added to the available shares, increasing the total number of common shares available for issuance under the 2021 Plan from 1,166,667 shares to 3,166,667 shares.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE.

SEC rules require us to disclose any transaction or currently proposed transaction in which we are a participant and in which any related person has or will have a direct or indirect material interest involving an amount that exceeds the lesser of $120,000 or one percent (1%) of the average of the Company's total assets as of the end of last two completed fiscal years. A related person is any executive officer, Director, nominee for Director, or holder of 5% or more of the Company's common stock, or an immediate family member of any of those persons.

The Audit Committee of the Board of Directors (or, to the extent applicable, our disinterested Directors) is responsible for reviewing all transactions between the Company and any officer or Director of the Company or any entity in which an officer of Director has a material interest. Any such transactions must be on terms no less favorable than those that could be obtained on an arms-length basis from independent third parties.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES.

The following table provides the aggregate fees billed for professional services rendered by the Company's prior accountants, Mayer Hoffman McCann P.C. ("MHM"), and Cherry Bekaert, the Company's current principal accountants, in the categories indicated during each of the past two fiscal years ended December 31:

MHM Fees

Services Rendered	2024	2023
Audit Fees (1)	$ 176,956	$ 275,255
Audit-Related Fees (2)	—	—
Tax Fees (3)	—	8,750
All Other Fees (4)	—	—
	$ 176,956	$ 284,005

Cherry Bekaert Fees

Services Rendered	2024	2023
Audit Fees (1)	$ 231,513	$ 125,725
Audit-Related Fees (2)	—	—
Tax Fees (3)	11,223	—
All Other Fees (4)	—	—
	$ 242,736	$ 125,725

(1) *Audit Fees*. This category includes fees for professional services provided in conjunction with the audit of the Company's financial statements and with the audit of management's assessment of internal control over financial reporting and the effectiveness of internal control over financial reporting, review of the Company's quarterly financial statements, assistance and review of documents filed with the Securities and Exchange Commission, consents, and comfort letters and attestation services provided in connection with statutory and other regulatory filings and engagements.

(2) *Audit-Related Fees*. This category includes fees for assurance and related professional services associated with due diligence related to mergers and acquisitions, consultation on accounting standards or transactions, internal control reviews and assistance with internal control reporting requirements, services related to the audit of employee benefit plans, and other attestation services not required by statute or regulation.

(3) *Tax Fees*. This category includes fees for professional services provided related to tax compliance, tax planning and tax advice.

(4) *All Other Fees*. There were no other fees paid to Mayer Hoffman McCann P.C. or Cherry Bekaert.

Substantially all MHM's personnel, who work under the control of MHM shareholders, are employees of wholly owned subsidiaries of CBIZ, Inc., which provides personnel and various services to MHM in an alternative practice structure. Substantially all of Cherry Bekaert LLP's personnel, who work under the control of Cherry Bekaert LLP partners, are employees of Cherry Bekaert Advisory, LLC, which provides personnel and other services to Cherry Bekaert LLP in an alternative practice structure.

Pre-Approval Policy

The Audit Committee approves in advance all audit and non-audit services to be performed by the Company's independent registered public accounting firm. The Audit Committee considers whether the provision of any proposed non-audit services is consistent with the Securities and Exchange Commission rules on auditor independence and has pre-approved certain specified audit and non-audit services to be provided by Cherry Bekaert, LLP for up to twelve (12) months from the date of the pre-approval. If there are any additional services to be provided, a request for pre-approval must be submitted by management to the Audit Committee for its consideration.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES.

(a) The documents filed as part of this report are as follows:

1. The financial statements and accompanying report of independent registered public accounting firm are set forth immediately following the signature page of this report on pages F-1 through F-18.

2. All financial statement schedules are omitted because they are inapplicable, not required or the information is included elsewhere in the financial statements or the notes thereto.

3. The exhibits required to be filed by this report or able to be incorporated by reference are listed in the "Exhibit Index" following the financial statements.

(b) Other Exhibits

Exhibits required by Item 601 of Regulation S-K are submitted (or incorporated by reference) and listed in a separate section herein immediately following the F pages under the heading "Exhibit Index" and are incorporated herein by reference. No exhibits in addition to those previously filed or listed in item 15(a) (3) and filed herein.

(c) Not Applicable.

ITEM 16. FORM 10-K SUMMARY

None.

SIGNATURES

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

Dated: March 14, 2025

ORAGENICS, INC.

By: */s/ Janet Huffman*
Janet Huffman
Chief Financial Officer, Secretary, Treasurer,
President, Interim Chief Executive Officer

POWER OF ATTORNEY

Each of the undersigned officers and directors of Oragenics, Inc., hereby constitutes and appoints Janet Huffman, their true and lawful attorney-in-fact and agent, for them and in their name, place and stead, in any and all capacities, to sign their name to any and all amendments to this Report on Form 10-K, and other related documents, and to cause the same to be filed with the Securities and Exchange Commission, granting unto said attorneys, full power and authority to do and perform any act and thing necessary and proper to be done in the premises, as fully to all intents and purposes as the undersigned could do if personally present, and the undersigned for herself hereby ratifies and confirms all that said attorney shall lawfully do or cause to be done by virtue hereof.

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.

/s/ Janet Huffman Janet Huffman	Chief Financial Officer, Secretary, Treasurer, President, Interim Chief Executive Officer (Principal Accounting and Financial Officer)	March 14, 2025
/s/ Robert. C. Koski Robert C. Koski	Director	March 14, 2025
/s/ Charles L. Pope Charles L. Pope	Chairman and Director	March 14, 2025
/s/ Frederick W. Telling Frederick W. Telling	Director	March 14, 2025
/s/ Alan W. Dunton Alan W. Dunton	Director	March 14, 2025
/s/ John Gandolfo *John Gandolfo*	Director	March 14, 2025

Oragenics, Inc.

Consolidated Financial Statements

Years Ended December 31, 2024 and 2023

Index

Report of Cherry Bekaert LLP, Independent Registered Public Accounting Firm

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Oragenics, Inc.

Opinion on the Financial Statements

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

Substantial Doubt about the Company's Ability to Continue as a Going Concern

The accompanying financial statements have been prepared assuming the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has recurring losses and negative cash flows from operations that raise substantial doubt about its ability to continue as a going concern. Management's evaluations of the events and conditions and management's plans regarding those matters are described in Note 1. 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 audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB. We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit, we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. Our audit included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe our audit provides a reasonable basis for our opinion.

/s/ Cherry Bekaert LLP

We have served as the Company's auditor since 2023.

Tampa, Florida March 14, 2025

Oragenics, Inc.
Consolidated Balance Sheets

	December 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 864,840	$ 3,483,501
Prepaid expenses and other current assets	607,670	382,273
Total current assets	1,472,510	3,865,774
Prepaid research and development expense	-	1,090,750
Operating lease right-of-use assets	-	9,811
Total assets	$ 1,472,510	$ 4,966,335
Liabilities and Shareholders' (Deficit) Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 1,355,867	$ 1,475,667
Short-term notes payable	328,528	312,703
Operating lease liabilities	-	9,811
Total current liabilities	1,684,395	1,798,181
Shareholders' (deficit) equity:		
Preferred stock, no par value; 50,000,000 shares authorized; -0- and 5,417,000 Series A shares, -0- and 4,050,000 Series B shares, -0- and -0- Series C shares, 7,488,692 and 7,488,692 Series F shares outstanding at December 31, 2024 and December 31, 2023, respectively	-	1,592,723
Common stock, $0.001 par value; 350,000,000 shares authorized; 12,570,100 and 3,080,693 shares issued and outstanding at December 31, 2024 and December 31, 2023, respectively	12,570	3,081
Additional paid-in capital	216,561,717	207,790,604
Accumulated Deficit	(216,786,172)	(206,218,254)
Total shareholders' (deficit) equity	(211,885)	3,168,154
Total liabilities and shareholders' (deficit) equity	$ 1,472,510	$ 4,966,335

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

Oragenics, Inc.
Consolidated Statements of Operations

	For the Year Ended December 31,	
	2024	**2023**
Grant revenue	$ -	$ 37,653
Operating expenses:		
Research and development	4,114,434	15,490,604
General and administrative	6,444,381	5,451,952
Total operating expenses	10,558,815	20,942,556
Loss from operations	(10,558,815)	(20,904,903)
Other income (expense):		
Interest income	45,897	210,394
Interest expense	(29,828)	(30,591)
Miscellaneous income	-	69,363
Foreign currency exchange, net	(25,172)	-
Total other income (expense), net	(9,103)	249,166
Loss before income taxes	(10,567,918)	(20,655,737)
Income tax benefit	-	-
Net loss	$ (10,567,918)	$ (20,655,737)
Basic and diluted net loss per share	$ (1.60)	$ (9.18)
Shares used to compute basic and diluted net loss per share	6,621,934	2,249,694

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

Oragenics, Inc.
Consolidated Statements of Changes in Shareholders' (Deficit) Equity

	Common Stock		Preferred Stock		Additional Paid In	Accumulated	Total Shareholders' (Deficit)
	Shares	Amount	Shares	Amount	Capital	Deficit	Equity
Balances at December 31, 2022	2,024,657	$ 2,025	9,467,000	$ 1,592,723	$ 196,977,071	$ (185,562,517)	$ 13,009,302
Compensation expense relating to option issuances	—	—	—	—	550,083	—	550,083
Compensation expense relating to restricted stock issuances	140,000	140	—	—	466,605	—	466,745
Issuance of Series F preferred stock	—	—	8,000,000	—	8,947,834	—	8,947,834
Conversion of Series F preferred stock to common stock	511,308	511	(511,803)	—	(511)	—	—
Common stock issued in private placement	404,728	405	—	—	849,522	—	849,927
Net loss	—	—	—	—	—	(20,655,737)	(20,655,737)
Balances at December 31, 2023	3,080,693	$ 3,081	16,955,197	$ 1,592,723	$ 207,790,604	$ (206,218,254)	$ 3,168,154
Compensation expense relating to option issuances	—	—	—	—	516,049	—	516,049
Sale of common stock	5,548,378	5,578	—	—	6,663,553	—	6,669,860
Conversion of Series A and B preferred Stock to common stock	22,528	22	(9,467,000)	(1,592,723)	1,592,701	—	—
Conversion of prefunded warrants to common stock	3,888,501	3,889	—	—	(1,190)	—	1,970
Net loss	—	—	—	—	—	(10,567,918)	(10,567,918)
Balances at December 31, 2024	12,570,100	$ 12,570	7,488,197	$ —	$ 216,561,717	$ (216,786,172)	$ (211,885)

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

Oragenics, Inc.
Consolidated Statements of Cash Flows

	Year Ended December 31,	
	2024	**2023**
Cash flows from operating activities:		
Net loss	$ (10,567,918)	$ (20,655,737)
Adjustments to reconcile net loss to net cash used in operating activities:		
Write off of in process research and development (IPR&D)	-	10,273,506
Depreciation and amortization	-	27,391
Loss on sale of fixed assets, net	-	29,956
Stock-based compensation expense	516,049	1,016,828
Changes in operating assets and liabilities:		
Operating lease right-of-use assets	9,811	337,629
Prepaid expenses and other current assets	483,537	2,000,824
Prepaid research and development expense	1,090,750	-
Operating lease liabilities	(9,811)	(347,075)
Accounts payable and accrued expenses	(119,800)	25,798
Net cash used in operating activities	(8,597,382)	(7,290,880)
Cash flows from investing activities:		
Proceeds from sale of property and equipment	-	63,716
Cash paid for IPR&D	-	(1,000,000)
Net cash used in investing activities	-	(936,284)
Cash flows from financing activities:		
Payments on short-term notes payable	(693,109)	(566,046)
Proceeds from issuance of common stock for private placement	6,671,830	849,926
Net cash provided by financing activities	5,978,721	283,880
Net decrease in cash and cash equivalents	(2,618,661)	(7,943,284)
Cash and cash equivalents at beginning of year	3,483,501	11,426,785
Cash and cash equivalents at end of year	$ 864,840	$ 3,483,501
Supplemental disclosure of cash flow information:		
Interest paid	$ 29,828	$ 30,591
Non-cash investing and financing activities:		
Borrowings under short term notes payable for prepaid insurance	$ 708,934	$ 611,109
Issuance of Series F Preferred stock for IPR&D	$	$ 8,947,834
Value of Series A preferred stock converted into common stock	$ 562,243	$ —
Value of Series B preferred stock converted into common stock	$ 1,030,480	$ —
Par Value of common stock issued in connection with Series A Preferred Stock Conversion	$ 9	$ —
Par Value of common stock issued in connection with Series B Preferred Stock Conversion	$ 13	$ —

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

Oragenics, Inc.
Notes to Consolidated Financial Statements

1. Basis of Presentation

The Company

Oragenics, Inc. (formerly known as Oragen, Inc.) (the "Company" or "we") was incorporated in November 1996. Commencing in December 2023, we are focused on the development of medical products that treat brain related illnesses and diseases and our lead product candidate and focus is on the development and commercialization of ONP-002 for the treatment of mild traumatic brain injury ("mTBI" or "Concussion").

Basis of Presentation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("US GAAP") including the assumption of a going concern basis which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business.

Going Concern Consideration

In light of our recurring losses, accumulated deficit and negative cash flow, the report of our independent registered public accounting firm on our consolidated financial statements for the year ended December 31, 2024 contained an explanatory paragraph raising substantial doubt about our ability to continue as a going concern.

We have incurred losses and negative cash flows from operations since inception. To date, we have not generated significant revenues from operations. We incurred a net loss of $10.6 million and used cash of $8.6 million in our operating activities during the year ended December 31, 2024. As of December 31, 2024, we had an accumulated deficit of $216.8 million.

Historically, our major sources of cash have been comprised of proceeds from various public and private offerings of our common stock and preferred stock, warrant exercises, income earned on grants and interest income. For the fiscal year ended December 2024, we raised $7.65 million in gross proceeds from private placements and sales of our common stock. We expect to incur substantial expenditures to further develop our concussion drug. We believe the working capital at December 31, 2024 will be sufficient to meet our business objectives through the first quarter of 2025. In February 2025, we raised $2.75 million through the sale of common stock through our At-the-Market Sales Agreement ("ATM") (see Note 7). In March 2025 we entered into a Purchase Agreement with a single investor pursuant to which raised approximately $2.5 million (see Note 7). As a result of this financing, we believe our working capital at the time of this filing to be sufficient to meet our business objectives through the third quarter of 2025.

These matters, when considered in the aggregate, raise substantial doubt about our ability to continue as a going concern for a reasonable period of time, which is defined as within one year after the date that our consolidated financial statements are issued.

Our ability to continue operations after our current cash resources are exhausted depends on our ability to obtain additional financing or achieve profitable operations, as to which no assurances can be given. Cash requirements may vary materially from those now planned because of changes in our focus and direction of our research and development programs, competitive and technical advances, or other developments.

Additional financing will be required to continue operations after we exhaust our current cash resources and to continue our long-term plans for clinical trials and new product development. There can be no assurance that any such financing can be realized or, if realized, what the terms thereof may be, or that any amount that we are able to raise will be adequate to support our working capital requirements until we achieve profitable operations.

We intend to seek additional funding through sublicensing arrangements, joint ventures or partnerships, sales of rights to technology, government grants and public or private financings and may receive funding through the exercise of outstanding warrants. Our future success depends on our ability to raise capital and ultimately generate revenue and attain profitability. We cannot be certain that additional capital, whether through selling additional debt or equity securities or obtaining a line of credit or other loan, will be available or, if available, will be on terms acceptable to us. If we issue additional securities to raise funds, these securities may have rights, preferences, or privileges senior to those of our common stock, and our current shareholders may experience dilution. If we are unable to obtain funds when needed or on acceptable terms, we may be required to curtail our current development programs, cut operating costs and forego future development and other opportunities.

2. Significant Accounting Policies

Basis of Consolidation

The consolidated financial statements include the accounts of Oragenics, Inc. and our wholly-owned subsidiaries Noachis Terra, Inc and Oragenics Australia Pty Ltd. All intercompany balances and transactions have been eliminated.

New Accounting Standards

ASU 2022-03

In June 2022, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2022-03, which states that a contractual restriction on the sale of an equity security is not considered in measuring fair value. Furthermore, it requires an entity to disclose the fair value of equity securities subject to contractual sale restrictions, the nature and remaining duration of the restrictions and the circumstances that could cause a lapse in the restrictions. ASU 2022-03 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2023. The adoption of ASU 2022-03 effective January 1, 2024 did not have any effect on our financial statements.

ASU 2023-07

In November 2023, the FASB issued ASU No. 2023-07, which provides amendments to reportable segment disclosure requirements requiring disclosure of significant segment expenses that are regularly provided to the chief operating decision maker and included within each reported measure of segment profit or loss, an amount and description of its composition for other segment items, and interim disclosures of a reportable segment's profit or loss and assets. All disclosure requirements of ASU 2023-07 are required for entities with a single reportable segment. The new segment disclosures are effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024.

ASU 2023-09

In December 2023, the FASB issued ASU 2023-09 related to improvements to income tax disclosures. The amendments in this update require enhanced jurisdictional and other disaggregated disclosures for the effective tax rate reconciliation and income taxes paid. The amendments in this update are effective for fiscal years beginning after December 15, 2024. We plan to adopt this pronouncement and make the necessary updates to our disclosures for the year ending December 31, 2025, and, aside from these disclosure changes, we do not expect the amendments to have a material effect on our financial statements.

ASU 2024-03

In November 2024, the FASB issued ASU 2024-03 related to the disaggregation of certain income statement expenses. The amendments in this update require public entities to disclose incremental information related to purchases of inventory, team member compensation and depreciation, which will provide investors the ability to better understand entity expenses and make their own judgements about entity performance. The amendments in this update are effective for fiscal years beginning after December 15, 2026. We plan to adopt this pronouncement and make the necessary updates to our disclosures for the year ending December 31, 2027, and, aside from these disclosure changes, we do not expect the amendments to have a material effect on our financial statements.

Use of Estimates

The preparation of financial statements in accordance with U.S. GAAP requires us to make estimates and assumptions that affect reported amounts and related disclosures. There are certain critical estimates that we believe require significant judgment in the preparation of our financial statements. We consider an accounting estimate to be critical if:

- It requires us to make assumptions because information was not available at the time, or it included matters that were highly uncertain at the time, we were making the estimate; and

- Changes in the estimate or different estimates that we could have selected may have had a material impact on our financial condition or results of operations.

Our critical accounting policies and estimates include accounting for stock-based awards and accounting for business combinations or asset purchases as described below.

Cash and Cash Equivalents

Cash and cash equivalents consist of all cash balances and highly liquid investments with an original maturity of three months or less. Our cash and cash equivalents are deposited in a financial institution and consist of demand deposits and overnight repurchase agreements and at times deposits are in excess of federally insured limits.

Business Segments

The Company operates in one reportable segment, which includes all activities related to advancing the development of our concussion drug, ONP-002. The determination of a single reportable segment is consistent with the consolidated financial information regularly provided to our chief operating decision maker (CODM). In 2024, our CODM was our President, Mr. Micheal Redmond. On December 16, 2024 our CODM became, and is presently, our Chief Financial Officer and Interim Chief Executive Officer, who reviews and evaluates consolidated net loss for purposes of assessing performance, making operating decisions, allocating resources and planning and forecasting for future periods. The measure of segment assets is reported on the balance sheet as total assets. During the twelve-month periods ended December 31, 2024, and 2023 there was no segment revenue. The accounting policies for the development of our concussion drug are the same as those described in the summary of significant accounting policies.

Stock-Based Awards

Generally, all forms of stock-based awards, including stock option grants and warrants, are measured at fair value on the grant date typically using a Black-Scholes Option Pricing Model, which requires us to make certain assumptions and estimates related to the risk-free interest rate, expected stock price volatility, expected life of the award and expected dividends.

The expense resulting from stock-based awards is recognized in Research and development or General and administrative in our Consolidated Statements of Operations, depending on the nature of the services provided, on a straight-line basis over the requisite service period. To the extent the stock-based awards do not vest at the grant date they are subject to forfeiture.

For performance-based awards, we record share-based compensation expense only when the performance-based milestone is deemed probable of achievement. We utilize both quantitative and qualitative criteria to judge whether milestones are probable of achievement.

For awards with market-based performance conditions, we recognize the grant-date fair value of the award over the derived service period regardless of whether the underlying performance condition is met.

We account for forfeitures of stock-based awards as a component of stock-based compensation expense as the forfeitures occur.

Impairment of Long-Lived Assets

We periodically review our long-lived assets for impairment and reduce the carrying value to fair value whenever events or changes in circumstances indicate that the carrying value may not be recoverable. There were no impairment losses recorded during the years ended December 31, 2024 and 2023.

Research and Development Expenses

Research and development consist of expenses incurred in connection with the discovery and development of our product candidates and are expensed as incurred on our Consolidated Statements of Operations. Prepayments and upfront payments to third-party vendors for work to be completed in the future are recorded as a prepaid expense on our Consolidated Balance Sheet.

Income Tax

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards.

Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rate is recognized in operations in the period that includes the enactment date. Deferred tax assets are reduced to estimated amounts expected to be realized by the use of a valuation allowance. Based on our historical operating losses, a valuation allowance has been recognized for all deferred tax assets.

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

Concentrations

Financial instruments which potentially subject us to concentrations of credit risk consist principally of cash and cash equivalents. We maintain cash accounts in commercial banks, which may, at times, exceed federally insured limits. We have not experienced any losses in such accounts. We believe we are not exposed to any significant credit risk on cash and cash equivalents. As of December 31, 2024 and 2023, the uninsured portion of this balance was $0.6 million and $3.1 million, respectively.

Grant Revenue

Grant revenue in 2023 was derived from a small business innovation research grant in the amount of $250,000 (“Computer-aided Design for Improved Lantibiotics”) that was completed in September 2023. We recognized grant revenue as reimbursable grant costs were incurred up to the pre-approved award limits within the budget period. The costs associated with these reimbursements were reflected as a component of Research and development in the accompanying Consolidated Statements of Operations.

3. Property and Equipment, net

In September 2023, we terminated our lease for the building where some of our research and development activities for our lantibiotic program were undertaken. As a result, all our property and equipment assets were disposed of as of December 31, 2023. Depreciation and amortization expense was $27,391 in 2023 and we had no depreciation and amortization expense in 2024.

4. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consist of the following as of December 31, 2024 and 2023:

	December 31, 2024	December 31, 2023
Accounts payable trade	$ 1,144,634	$ 1,244,947
Accrued expenses	202,834	222,739
Accrued vacation	8,399	7,981
Total accounts payable and accrued expenses	$ 1,355,867	$ 1,475,667

5. Short-Term Notes Payable

We had the following short-term notes payable as of December 31, 2024 and 2023:

	2024	**2023**
Insurance premium financing of $636,972 and $611,109 due in monthly installments of $67,277 and $54,366 including principal and interest at 9.55% through May 24, 2025 and 2024 respectively.	$ 328,528	$ 312,703

6. Prepaid Expenses - Current and Long-Term

	December 31, 2024	**December 31, 2023**
Prepaid research and expense, current	$ 177,437	$ —
Prepaid insurance	354,467	334,940
Other prepaid expense, current	75,768	47,333
Prepaid research and development expense, long-term	—	1,090,750
Total prepaid expenses – current and long-term	$ 607,672	$ 1,473,023

7. Shareholders' Equity

Common Stock

We currently have 350,000,000 authorized shares of common stock and 50,000,000 shares of authorized preferred stock. On December 31, 2024 and 2023 respectively we had 12,570,100 and 3,080,693 shares of common shares issued and 7,488,692 and 16,966,692 preferred shares issued and outstanding.

At-The-Market Sales Agreement with Dawson James

On October 11, 2024, we entered into an At-the-Market Sales Agreement (the "ATM Agreement") with Dawson James Securities Inc. ("Dawson James") pursuant to which are allowed to issue and sell, from time to time, shares of our common stock (the "Shares") by any method permitted by law as an "at the market offering" as defined in Rule 415(a)(4) of the Securities Act of 1933, including, without limitation, sales made directly on or through the NYSE American (the "Offering"). Dawson James will use its commercially reasonable efforts to sell the Shares requested by us to be sold, consistent with their normal trading and sales practices. We have no obligation to sell any of the Shares. We may instruct Dawson James not to sell the Shares if the sales cannot be effected at or above the price designated by us and we may suspend sales pursuant to the ATM Agreement at any time.

We will pay Dawson James a commission of up to 3.0% of the gross proceeds from the sale of Shares under the ATM Agreement. We will also reimburse Dawson James for the fees and disbursements of its counsel in an amount not to exceed $30,000 in addition to certain ongoing disbursements of its legal counsel up to $2,500 per calendar quarter.

Any sales of Shares under the ATM Agreement will be made pursuant to our Registration Statement on Form S-3 (File No. 333-269225), which allows the sale of up to $10,000,000 of Shares. We will be required to file a prospectus supplement in the event we determine to offer more than $10,000,000 of Shares.

As of December 31, 2024 there have been no shares sold under the ATM Agreement.

Subsequent to December 31, 2024, on February 5, 2025, we sold 7.8 million shares of our common stock pursuant to the ATM for gross proceeds of $2.75 million before subtracting commission and legal expenses.

At-The-Market Sales Agreement with Ascendiant Capital Markets, LLC

On August 8, 2024, we entered into an At-The-Market Issuance Sales Agreement (the "Sales Agreement") with Ascendiant Capital Markets, LLC, as sales agent ("Ascendiant Capital"), pursuant to which we could offer and sell up to $10.0 million in shares of our common stock at-the-market. On October 9, 2024, we terminated the Sales Agreement with Ascendiant Capital. There were no shares sold under the Sales Agreement with Ascendiant Capital.

Public Offering of Common Stock

On March 1, 2024, we sold 1,400,000 shares of our common stock at a price of $1.50 per share to the public. According to the terms of the underwriting agreement, we granted the underwriters an option exercisable for 45 days for the purchase of up to an additional 210,000 shares of our common stock solely for the purpose of covering over-allotments, none of which were not exercised. We also issued warrants to the underwriters exercisable August 25, 2024, and expiring on February 27, 2029, to purchase up to 5% of the shares sold at an exercise price of $1.875 per share. The gross proceeds of this offering were $2.1 million before underwriting discounts and commissions and other expenses paid by us were deducted.

Placement Agency Agreement with Dawson James Securities Inc.

On June 25, 2024, we entered into a placement agency agreement (the "Placement Agency Agreement") with Dawson James Securities Inc. ("Dawson James") pursuant to which we engaged Dawson James as the placement agent for a registered public offering of 1,100,000 shares of our common stock for $1.00 per share. We paid Dawson James a placement agent fee of 7.00% of the gross proceeds from this offering and reimbursed them for certain out of pocket expenses not to exceed $75,000, including legal fees. In addition, we issued Dawson James warrants to purchase 55,000 shares of our common stock, which represented 5% of the aggregate number of securities sold in this offering, with an exercise price of $1.25 per share and exercisable for five years from the date of the closing of this offering. The warrants became initially exercisable six months from the closing of this offering.

This offering resulted in gross proceeds of $1.1 million before subtracting placement agent fees and legal expense.

Second Placement Agency Agreement with Dawson James Securities Inc.

On September 4, 2024, we entered into a second placement agency agreement (the "Second Placement Agency Agreement") with Dawson James pursuant to which we engaged Dawson James as the placement agent for a registered public offering of 8,106,584 shares of our common stock at $0.55 per share or pre-funded warrants to purchase shares of our common stock ("Pre-Funded Warrants") in lieu thereof at $0.549 per Pre-Funded Warrant, which is equal to the offering price per share of the common stock less the $0.001 per share exercise price of each Pre-Funded Warrant. In connection with this offering, we entered into a securities purchase agreement (the "Purchase Agreement") with an institutional investor to purchase the common stock and Pre-Funded Warrants.

The Pre-Funded Warrants are immediately exercisable and terminate when exercised in full.

We sold 3,078,378 shares of our common stock and Pre-Funded Warrants to purchase 5,028,206 shares of our common stock pursuant to this offering. This offering resulted in gross proceeds to the Company of approximately $4.45 million before deducting placement agent fees and other estimated offering expenses payable by the Company.

As of the date of this filing all of the Pre-Funded Warrants have been exercised.

We paid a placement agent fee equal to 7.00% of the gross proceeds from the sale of the common stock and Pre-Funded Warrants in this Offering and reimburse the Placement Agent for certain out-of-pocket expenses not to exceed $125,000, including legal fees. In addition, we issued the Placement Agent warrants to purchase up to 405,329 shares of our common stock, which represented 5% of the aggregate number of securities sold in the Offering, with an exercise price of $0.6875 per share and exercisable commencing 6 months from the closing of the offering and for five years thereafter.

Debt Raise

On March 13, 2025, the Company entered into and consummated a note securities purchase agreement (the "**Purchase Agreement**") with a single investor (the "**Purchaser**") pursuant to which the Company sold, in a private placement (the "**Offering**"), to the Purchaser a promissory note with an aggregate principal amount of $3,000,000 (the "**Note**") and 1,000,000 shares of Series G Mirroring Preferred Stock of the Company (the "**Series G Preferred Stock**"). The aggregate net proceeds to the Company are expected to be approximately $2,250,000 million, after deducting placement agent fees of $175,000 and legal expenses of $75,000.

The Note was issued with an original issue discount of 20%. No interest accrues on the Note unless and until an Event of Default (as defined in the Note) has occurred, upon which interest shall accrue at a rate of twenty percent (20.0%) per annum and shall be computed on the basis of a three hundred sixty (360)-day year and twelve (12) thirty (30)-day months and shall be payable on the maturity date. The Note matures upon the earlier of 120 days from the issuance date or the closing of any subsequent offering by the Company with net proceeds equal to or in excess of all amounts due under the Note. The Note contain certain Events of Default, including (i) the Company's failure to pay any amount of principal, interest, redemption price or other amounts due under the Notes or any other transaction document, (ii) any default under, redemption of, or acceleration prior to maturity of any indebtedness of the Company, as such term is defined in the transaction documents, (iii) bankruptcy of the Company or its subsidiaries, (iv) a final judgement or judgements for the payment of money in excess of $250,000, which is not discharged or stayed pending appeal within 60 days, and (v) any breach or failure to comply with any provision of the Note or any other transaction document. Upon the occurrence of any Event of Default and at any time thereafter, the Purchaser shall have the right to exercise all of the remedies under the Note. The Note also provide for redemption upon a change of control, as such term is defined under the Notes and mandatory redemption upon the receipt of net proceeds from any offering of equity or debt by the Company.

In connection with the Offering, the Company filed a Certificate of Designation with the Secretary of State for the State of Florida (the "**Certificate of Designation**") designating 1,000,000 shares out of the authorized but unissued shares of its preferred stock as Series G Preferred Stock. The following is a summary of the principal terms of the Series G Preferred Stock.

Dividends

No dividends shall be paid on shares of the Series G Preferred Stock.

Voting Rights

The rights and preferences of the Series G Preferred Stock are set forth in the Certificate of Designation filed with Secretary of State for the State of Florida, a copy of which is attached hereto as Exhibit 3.9. The Series G Preferred Stock has no voting rights, except as required by applicable law and except that each share of Series G Preferred Stock shall entitle the holder thereof to 1,000 votes per each share of Series G Preferred Stock solely and exclusively with respect to the Reverse Split Proposal, the Amendment Proposal and any Adjournment Proposal (as defined below), voting together with the Common Stock as a single class. The Purchaser has agreed to vote all of Purchaser's shares of Series G Mirroring Preferred Stock on any proposal presented to the shareholders of the Corporation for purposes of approving the Reverse Split Proposal, the Amendment Proposal and the Adjournment Proposal and has agreed that such shares of Series G Mirroring Preferred Stock, shall, to the extent voted in favor of such proposals, be automatically and without further action of the Purchaser voted in the same proportions as shares of Common Stock (excluding any shares of Common Stock that are not voted) are voted on the Reverse Split Proposal, the Amendment Proposal and the Adjournment Proposal, as applicable. For the avoidance of doubt, and for illustrative purposes only, if 30% of the aggregate votes cast by Common Stock in connection with the Reverse Split Proposal are voted against such proposal and 70% of the aggregate votes cast by Common Stock are voted in favor thereof, then 30% of the votes cast by the shares of Series G Mirroring Preferred Stock voting in connection with the Reverse Split Proposal shall vote against the approval of the Reverse Split Proposal and 70% of such votes shall be cast in favor.

Liquidation

The Series G Preferred Stock shall rank junior to the Series F Preferred Stock. Upon any liquidation, dissolution or winding-up of the Corporation, whether voluntary or involuntary (a "**Liquidation**"), the Holders shall be entitled to receive out of the assets, whether capital or surplus, of the Corporation an amount equal to the Stated Value for each share of Series G Mirroring Preferred Stock before any distribution or payment shall be made to the holders of Common Stock but after any other class of stock than ranks senior to the Series G Mirroring Preferred Stock, including the Series F Preferred Stock, and if the assets of the Corporation shall be insufficient to pay in full such amounts, then the entire assets to be distributed to the Holders shall be ratably distributed among the Holders in accordance with the respective amounts that would be payable on such shares if all amounts payable thereon were paid in full. Each share of Series G Mirroring Preferred Stock shall have no par value and a stated value equal to $0.10.

Cancellation

Upon effectiveness of either the Reverse Split Proposal or the Proposal to Increase Authorized Shares, each share of Series G Preferred Stock shall be automatically transferred to the Company and cancelled for no consideration with no action on behalf of the holders of Series G Preferred Stock. Such shares shall resume the status of authorized but unissued preferred stock and will no longer be designated as Series G Mirroring Preferred Stock.

Preemptive Rights

No holders of Series G Preferred Stock will, as holders of Series G Preferred Stock, have any preemptive rights to purchase or subscribe for our Common Stock or any of our other securities.

Redemption

The Series G Preferred Stock are not redeemable by the Company.

Trading Market

There is no established trading market for any of the Series G Preferred Stock, and we do not expect a market to develop. We do not intend to apply for a listing for any of the Series G Preferred Stock on any securities exchange or other nationally recognized trading system. Without an active trading market, the liquidity of the Series G Preferred Stock will be limited.

The foregoing descriptions of the Certificate of Designation, the Purchase Agreement, the Note, the Lock-Up Agreements and the Placement Agency Agreement do not purport to be complete and are qualified in their entirety by reference to the full text of the Purchase Agreement, Notes, the Lock-Up Agreement and the Placement Agency Agreement, forms of which are attached hereto as Exhibits 3.9, 10.25, 10.26, 10.27 and 10.29, respectively and are each incorporated by reference herein.

The Company intends to use the net proceeds from the Offering for working capital and other general corporate purposes. Dawson James Securities, Inc. served as the placement agent in the Offering, pursuant to the terms of a placement agent agreement dated February 26, 2024. The Note and Series G Preferred Stock sold in the Offering were issued in a private placement under Section 4(a)(2) of the Securities Act of 1933, as amended (the "**Act**"), and Regulation D promulgated thereunder and, have not been registered under the Act, or applicable state securities laws. Accordingly, the Note and Series G Preferred Stock may not be offered or sold in the United States except pursuant to an effective registration statement or an applicable exemption from the registration requirements of the Act and such applicable state securities laws.

Warrants

Outstanding and exercisable warrants as of December 31, 2024 are presented below:

Warrants Outstanding		Exercise Price	Expiration Date
153,334	$	75.00	5/1/2025
52,911	$	60.00	7/17/2025
70,000	$	1.88	2/27/2029
55,000[1]	$	1.25	6/29/2029
405,329[2]	$	0.69	9/4/2029
736,574			

1) Dawson James Placement Agent warrants that became exercisable December 23, 2024.

2) Dawson James Placement Agent warrants that become exercisable March 4, 2025.

We also had 1,139,705 pre-funded warrants outstanding at December 31, 2024 that were exercised in January of 2025.

All outstanding warrants are classified as equity on our Consolidated Balance Sheets.

8. Stock-Based Compensation

2021 Incentive Plan

The 2021 Incentive Plan authorizes the grant of stock options (incentive and non-statutory), stock appreciation rights and restricted stock covering a total of 3,166,167 shares of our common stock. Options are granted at the fair value of our common stock on the date of grant and generally vest either immediately or over a period of up to three years from the date of grant and expire 10 years from the date of grant. As of December 31, 2024, 993,753 shares of our common stock were reserved for issuance related to the 2021 Incentive Plan, and 2,032,914 shares remained available for awards.

Recipients of stock awards under our 2021 Incentive Plan become the owner of record of the stock immediately upon grant, which may be subject to certain restrictions. The balance of unvested restricted stock will be forfeited and automatically transferred back to us at no cost upon the termination of the recipient's employment. Upon vesting of restricted stock that is made to recipients who are employees, the recipient has the option to settle minimum withholding taxes by electing to have us withhold otherwise deliverable shares having a fair value equal to the required tax obligations ("net-settlement"). The net-settlement shares are then immediately cancelled and retired and reduce the shares available for issuance under the 2021 Incentive Plan.

We use the Black-Scholes Pricing Option Pricing Model to estimate the fair value of stock-based awards on the date of grant. The assumptions employed in the calculation of the fair value of share-based compensation expense were calculated as follows for all years presented:

- Expected dividend yield – zero based on the fact that we do not plan to issue dividends.
- Expected volatility – based on our historical market price at consistent points in a period equal to the expected life of the options.
- Risk-free interest rate – based on the U.S. Treasury yield curve in effect at the time of grant.
- Expected life of options – based on the simplified method of estimating the expected life. Forfeitures are accounted for as they occur.

Assumptions used to estimate the fair value of stock options granted were as follows:

Granted in Period	High	Low	Weighted Average
Award/Strike Price	0.48	0.48	0.48
Market Price	0.48	0.48	0.48
Volatility	120.76%	110.12%	114.00%
Dividend Yield	0.00%	0.00%	0.00%
Expected Life	5.50 yrs	2.50 yrs	4.74 yrs
Risk Free Rate	3.53%	3.49%	3.50%

Total stock-based compensation related to stock options was $516,049 and $550,083 for the years ended December 31, 2024 and 2023, respectively. As of December 31, 2024, there was $21,154 of unrecognized stock-based compensation related to stock options, which is expected to be recognized over a weighted average period of less than one year.

Stock option activity for the year ended December 31, 2024 was as follows:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (In Years)	Aggregate Intrinsic Value[(1)]
Outstanding at December 31, 2023	244,733	$ 20.17	8.73	$ 74,559
Granted	799,583	0.48	—	—
Forfeited	(50,563)	13.76	—	—
Outstanding at December 31, 2024	993,753	4.65	6.72	—
Exercisable at December 31, 2024	922,353	4.97	6.49	—

(1) The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying stock option awards and the closing market price of our common stock as of December 31, 2024 and 2023, respectively

Certain other information regarding our stock-based awards was as follows:

	2024	2023
Weighted average grant date fair value of stock options granted per share	$ 0.38	$ 4.59
Grant date fair value of stock options that vested	$ 305,632	$ 291,401

Restricted stock activity was as follows for the year ended December 31, 2024:

	Number of Shares	Weighted Average Grant-Date Fair Value
Non-vested restricted stock at beginning of year	6,000	$ 3.34
Vested	(6,000)	3.34
Non-vested restricted stock at end of year	—	-

The fair value of restricted stock vested in 2024 was $20,220, and stock-based compensation expense related to restricted stock was $5,055. As of December 31, 2024, there was no unrecognized stock-based compensation related to non-vested restricted stock.

9. Retirement Plan

We have a defined contribution Simple Individual Retirement Arrangement plan which covers all employees and provides for a Company match of up to 3% of all employee compensation contributions to the plan. Total matching contributions for the years ended December 31, 2024 and 2023 were $27,325 and $20,045 respectively.

10. Income Taxes

The components of the provision for income taxes for the years ended December 31, 2024 and 2023 are as follows:

	2024	2023
Current	$ —	$ —
Deferred	(1,408,287)	(5,791,558)
Valuation Allowance	1,408,287	5,791,558
Total provision (Deferred benefit) for income taxes	$ —	$ —

At December 31, 2024 and 2023, the Company had temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and their respective income tax bases, as measured by enacted state and federal tax rates, as follows:

	2024	2023
Deferred tax assets (liabilities):		
Net operating loss carryforward	$ 41,070,043	$ 39,810,409
Accrued vacation	13,421	-
Non-qualified stock compensation	1,228,004	1,160,775
Capitalized Research & Development costs	3,694,354	3,417,706
Intangibles	2,360,913	2,569,559
Total deferred tax assets	48,366,736	46,958,449
Less valuation allowance	(48,366,736)	(46,958,449)
Total net deferred tax asset, net of valuation allowance	$ —	$ —

The following is a reconciliation of tax computed at the statutory federal rate to the income tax expense (benefit) in the statements of operations for the years ended December 31, 2024 and 2023:

	2024	2023
Income tax benefit computed at statutory federal rate of 21% and 21%, respectively	$ (2,207,843)	$ (4,337,705)
State income tax benefits, net of federal expense/benefit	(400,411)	(1,204,720)
Australia Tax	(60,962)	—
Prior year adjustment	—	150,533
Change in valuation allowance	2,027,835	5,342,529
Non-deductible expenses	1,100	272
Change in tax rates	590,690	—
Other	49,590	49,091
Total provision (benefit) for income taxes	$ —	$ —

In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, projected future taxable income, and tax planning strategies in making this assessment. Based upon the levels of historical taxable income and projections of future taxable income over which the deferred tax assets are deductible, the Company believes that it is more likely than not that it will not be able to realize the benefits of these deductible differences.

Accordingly, a valuation allowance of $48,366,736 and $46,958,449 has been provided in the accompanying consolidated financial statements as of December 31, 2024 and 2023, respectively. The December 31, 2024 and December 31, 2023 net change in valuation allowance related to deferred tax assets was an increase of $1,408,287 and $5,791,558, respectively, primarily relating to the capitalization of research and development costs and net operating loss carryforwards.

At December 31, 2024, the Company has federal and state tax net operating loss carryforwards of $159,358,389 and $142,594,207, respectively. The State of Pennsylvania tax net operating loss carryforwards will expire through 2036. Federal and Florida tax net operating loss carryforwards generated prior to December 31, 2017 will expire through 2037 and are not subject to taxable income limitations. Federal and Florida tax net operating loss carryforwards generated subsequent to December 31, 2017, do not expire but may be subject to taxable income limitation pursuant to the Tax Cuts and Jobs Act that was enacted on December 22, 2017. The Company also has federal research and development tax credit carryforwards of $4,041,694 of which are included as an uncertain tax position. The federal tax credit carryforward will expire beginning in 2021 and continuing through 2043 unless utilized.

Utilization of net operating loss carryforwards and research and development credit carryforwards may be subject to a substantial annual limitation due to ownership change limitations that may have occurred or, could occur in the future in accordance with Section 382 of the Internal Revenue Code of 1986 (“IRC Section 382”) and with Section 383 of the Internal Revenue Code of 1986, as well as similar state provisions. These ownership changes may limit the amount of net operating loss carryforwards and research and development credit carryforwards that can be utilized annually to offset future taxable income and taxes, respectively. In general, an ownership change, as defined by IRC Section 382, results from transactions increasing the ownership of certain stockholders or public groups in the stock of a corporation by more than 50 percentage points over a three-year period. The Company has completed several financings since its inception which may result in a change in ownership as defined by IRC Section 382, or could result in a change in control in the future.

For the years ended December 31, 2024 and 2023, the Company incurred $0 and $0, respectively, of additional unrecognized tax benefits that related to research and development credits. The entire amount of this unrecognized tax benefit, if recognized, would result in an increase to the deferred tax asset valuation allowance, and would not have an impact on the effective tax rate.

The Company files its income tax returns in the U.S. federal jurisdiction and in Florida and Pennsylvania. With few exceptions, the Company is no longer subject to federal or state income tax examinations by tax authorities for years before 2016.

A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows:

Balance as of December 31, 2021	$	4,027,180
Additions based on tax positions related to the current year		940,106
Reductions for the tax positions of prior years		(115,396)
Expired Tax Credits due to 20-year life		(17,043)
Balance as of December 31, 2022	$	4,834,847
Additions based on tax positions related to the current year		46,229
Reductions for the tax positions of prior years		(680,042)
Expired Tax Credits due to 20-year life		(31,680)
Balance as of December 31, 2023	$	4,169,354
Additions based on tax positions related to the current year		—
Reductions for the tax positions of prior years		(46,229)
Expired Tax Credits due to 20-year life		(81,431)
Balance as of December 31, 2024	$	4,041,694

Included in the balance at December 31, 2024 and 2023, are $4,041,694 and $4,169,354, respectively, of tax positions for which there is uncertainty about the validity of certain credits. The disallowance of the credits would impact the amount of gross deferred tax assets reflected in the accompanying footnotes.

During the years 2024 and 2023 the Company did not recognize any interest and penalties. Due to the potential offset of the Company's operating loss carryforward for any future activity, the amount attributed to interest and penalties would be immaterial.

11. Commitments and Contingencies

Ladenburg Thalmann Litigation

On December 7, 2022, we entered into an investment banking engagement letter with Ladenburg Thalmann, ("Ladenburg"). The engagement letter was subsequently amended at various times (together with amendments to the "Engagement Letter"). We terminated the Engagement Letter as of August 15, 2023. Ladenburg sent us an invoice in the amount of $2,500,000, and a demand letter from Ladenburg's general counsel demanding payment thereof followed shortly thereafter. Ladenburg is of the view that a fee is owed based on tur purchase of assets from Odyssey Health, Inc. We strongly disagree that any such fee is due to Ladenburg and initiated a confidential action for arbitration against Ladenburg with the Financial Industry Regulatory Authority ("FINRA") on March 12, 2024 seeking, among other things, a declaratory judgment that no such fee is owed. On April 17, 2024 Ladenburg filed a Complaint in federal court in the Southern District of Florida, and also filed motion for a temporary restraining order ("TRO") and preliminary injunction seeking to move the venue from FINRA to the federal court in Miami-Dade County. On May 3, 2024 the Magistrate Judge assigned to the case issued a Report and Recommendation denying the motion; although Ladenburg objected to the Report and Recommendation, Magistrate Judge's Report and Recommendation, the District Court Judge adopted the Report and Recommendation, finalizing the Court's denial of the requested injunctive relief. On May 9, 2024, we filed a motion to dismiss in the federal court action, which is still currently pending. Meanwhile, the FINRA action continues and is set to be heard in August of 2025. We believe Ladenburg's claims are unlikely to prevail and we intend to defend the claims vigorously. It is possible, however, that there could be an unfavorable outcome or resolution of the claims asserted, which could negatively and materially impact our business, consolidated financial position and results of operations. Litigation is inherently uncertain and there can be no assurance that we will prevail. We do not include an estimate of legal fees and other related defense costs in its estimate of loss contingencies.

12. Subsequent Events

ATM Financing

In February 2025, we raised $2.75 million through the sale of common stock through our ATM with Dawson James. See Note 7 for additional information.

Debt Raise

On March 13, 2025, the Company entered into and consummated a note securities purchase agreement (the "**Purchase Agreement**") with a single investor (the "**Purchaser**") pursuant to which the Company sold, in a private placement (the "**Offering**"), to the Purchaser a promissory note with an aggregate principal amount of $3,000,000 (the "**Note**") and1,000,000 shares of Series G Mirroring Preferred Stock of the Company (the "**Series G Preferred Stock**"). The aggregate net proceeds to the Company are expected to be approximately $2,250,000 million, after deducting placement agent fees of $175,000 and legal expenses of $75,000.

The Note was issued with an original issue discount of 20%. No interest accrues on the Note unless and until an Event of Default (as defined in the Note) has occurred, upon which interest shall accrue at a rate of twenty percent (20.0%) per annum and shall be computed on the basis of a three hundred sixty (360)-day year and twelve (12) thirty (30)-day months and shall be payable on the maturity date. The Note matures upon the earlier of 120 days from the issuance date or the closing of any subsequent offering by the Company with net proceeds equal to or in excess of all amounts due under the Note. The Note contain certain Events of Default, including (i) the Company's failure to pay any amount of principal, interest, redemption price or other amounts due under the Notes or any other transaction document, (ii) any default under, redemption of, or acceleration prior to maturity of any indebtedness of the Company, as such term is defined in the transaction documents, (iii) bankruptcy of the Company or its subsidiaries, (iv) a final judgement or judgements for the payment of money in excess of $250,000, which is not discharged or stayed pending appeal within 60 days, and (v) any breach or failure to comply with any provision of the Note or any other transaction document. Upon the occurrence of any Event of Default and at any time thereafter, the Purchaser shall have the right to exercise all of the remedies under the Note. The Note also provide for redemption upon a change of control, as such term is defined under the Notes and mandatory redemption upon the receipt of net proceeds from any offering of equity or debt by the Company.

In connection with the Offering, the Company filed a Certificate of Designation with the Secretary of State for the State of Florida (the "**Certificate of Designation**") designating 1,000,000 shares out of the authorized but unissued shares of its preferred stock as Series G Preferred Stock. The following is a summary of the principal terms of the Series G Preferred Stock.

Dividends

No dividends shall be paid on shares of the Series G Preferred Stock.

Voting Rights

The rights and preferences of the Series G Preferred Stock are set forth in the Certificate of Designation filed with Secretary of State for the State of Florida, a copy of which is attached hereto as Exhibit 3.9. The Series G Preferred Stock has no voting rights, except as required by applicable law and except that each share of Series G Preferred Stock shall entitle the holder thereof to 1,000 votes per each share of Series G Preferred Stock solely and exclusively with respect to the Reverse Split Proposal, the Amendment Proposal and any Adjournment Proposal (as defined below), voting together with the Common Stock as a single class. The Purchaser has agreed to vote all of Purchaser's shares of Series G Mirroring Preferred Stock on any proposal presented to the shareholders of the Corporation for purposes of approving the Reverse Split Proposal, the Amendment Proposal and the Adjournment Proposal and has agreed that such shares of Series G Mirroring Preferred Stock, shall, to the extent voted in favor of such proposals, be automatically and without further action of the Purchaser voted in the same proportions as shares of Common Stock (excluding any shares of Common Stock that are not voted) are voted on the Reverse Split Proposal, the Amendment Proposal and the Adjournment Proposal, as applicable. For the avoidance of doubt, and for illustrative purposes only, if 30% of the aggregate votes cast by Common Stock in connection with the Reverse Split Proposal are voted against such proposal and 70% of the aggregate votes cast by Common Stock are voted in favor thereof, then 30% of the votes cast by the shares of Series G Mirroring Preferred Stock voting in connection with the Reverse Split Proposal shall vote against the approval of the Reverse Split Proposal and 70% of such votes shall be cast in favor.

Liquidation

The Series G Preferred Stock shall rank junior to the Series F Preferred Stock. Upon any liquidation, dissolution or winding-up of the Corporation, whether voluntary or involuntary (a "**Liquidation**"), the Holders shall be entitled to receive out of the assets, whether capital or surplus, of the Corporation an amount equal to the Stated Value for each share of Series G Mirroring Preferred Stock before any distribution or payment shall be made to the holders of Common Stock but after any other class of stock than ranks senior to the Series G Mirroring Preferred Stock, including the Series F Preferred Stock, and if the assets of the Corporation shall be insufficient to pay in full such amounts, then the entire assets to be distributed to the Holders shall be ratably distributed among the Holders in accordance with the respective amounts that would be payable on such shares if all amounts payable thereon were paid in full. Each share of Series G Mirroring Preferred Stock shall have no par value and a stated value equal to $0.10.

Cancellation

Upon effectiveness of either the Reverse Split Proposal or the Proposal to Increase Authorized Shares, each share of Series G Preferred Stock shall be automatically transferred to the Company and cancelled for no consideration with no action on behalf of the holders of Series G Preferred Stock. Such shares shall resume the status of authorized but unissued preferred stock and will no longer be designated as Series G Mirroring Preferred Stock.

Preemptive Rights

No holders of Series G Preferred Stock will, as holders of Series G Preferred Stock, have any preemptive rights to purchase or subscribe for our Common Stock or any of our other securities.

Redemption

The Series G Preferred Stock are not redeemable by the Company.

Trading Market

There is no established trading market for any of the Series G Preferred Stock, and we do not expect a market to develop. We do not intend to apply for a listing for any of the Series G Preferred Stock on any securities exchange or other nationally recognized trading system. Without an active trading market, the liquidity of the Series G Preferred Stock will be limited.

The foregoing descriptions of the Certificate of Designation, the Purchase Agreement, the Note, the Lock-Up Agreements and the Placement Agency Agreement do not purport to be complete and are qualified in their entirety by reference to the full text of the Purchase Agreement, Notes, the Lock-Up Agreement and the Placement Agency Agreement, forms of which are attached hereto as Exhibits 3.9, 10.25, 10.26, 10.27 and 10.29, respectively and are each incorporated by reference herein.

The Company intends to use the net proceeds from the Offering for working capital and other general corporate purposes. Dawson James Securities, Inc. served as the placement agent in the Offering, pursuant to the terms of a placement agent agreement dated February 26, 2024. The Note and Series G Preferred Stock sold in the Offering were issued in a private placement under Section 4(a)(2) of the Securities Act of 1933, as amended (the "**Act**"), and Regulation D promulgated thereunder and, have not been registered under the Act, or applicable state securities laws. Accordingly, the Note and Series G Preferred Stock may not be offered or sold in the United States except pursuant to an effective registration statement or an applicable exemption from the registration requirements of the Act and such applicable state securities laws.

EXHIBIT INDEX

Exhibit number	Exhibit description	Incorporated by Reference				Filed herewith
		Form	File no.	Exhibit	Filing date	
3.1	Amended and Restated Articles of Incorporation as amended prior to December 29, 2017 (including certificates of designation of Series A, B and C Preferred Stock).	8-K	001-32188	3.1	12/29/17	
3.2	Articles of Amendment to Amended and Restated Articles of Incorporation dated effective December 29, 2017.	8-K	001-32188	3.2	12/29/17	
3.3	Articles of Amendment to Amended and Restated Articles of Incorporation effective January 19, 2018.	8-K	001-32188	3.1	1/19/18	
3.4	Articles of Amendment to Amended and Restated Articles of Incorporation.	8-K	001-32188	3.4	6/26/18	
3.5	Articles of Amendment to Amended and Restated Articles of Incorporation	8-K	001-32188	3.5	2/28/22	
3.6	Articles of Amendment to Amended and Restated Articles of Incorporation	8-K	001-32188	3.1	1/23/23	
3.7	Amendment to Articles of Incorporation for Certificate of Designation of Series F Convertible Preferred Stock	8-K	001-32188	3.1	12/8/23	
3.8	Amendment to Articles of Incorporation to Increase Common Stock	8-K	001-32188	3.1	12/15/23	
3.9	Certificate of Designation for Series G Preferred Stock					X
3.10	Bylaws	SB-2	333-100568	3.2	10/16/02	
3.11	First Amendment to Bylaws	8-K	001-32188	3.1	6/9/10	
3.12	Second Amendment to Bylaws	8-K	001-32188	3.1	8/24/10	
3.13	Third Amendment to Bylaws	8-K	001-32188	3.9	2/28/22	
4.1	Specimen Stock Certificate	8-K	001-32188	4.1	1/23/23	

4.2	Amended and Restated Warrant Form	8-K	001-32188	4.1	8/1/17
4.3	Form of Common Stock Warrant	8-K	001-32118	4.1	11/9/17
4.4	Form of Investor Warrant.	8-K	001-32188	4.1	4/10/18
4.5	Form of Warrant to purchase shares of Common Stock.	S-1/A	333-224950	4.2	7/9/18
4.6	Warrant Agency Agreement	8-K	001-32188	4.2	7/17/18
4.7	Warrant dated May 1, 2020	8-K	001-32188	4.1	5/4/20
4.8	Form of Representative's Warrants.	8-K	001-32188	4.1	3/1/24
4.9	Form of Placement Agent Warrant.	8-K	001-32188	4.1	6/26/24
4.10	Form of Placement Agent Warrant.	8-K	001-32188	4.2	9/5/24
4.11	Description of the Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934	10-K	001-32188	4.8	3/29/24
10.1	2012 Equity Incentive Plan. +	8-K	001-32188	4.1	10/25/12
10.2	First Amendment to 2012 Equity Incentive Plan. +	8-K	001-32188	4.2	5/5/17
10.3	First Amendment to 2012 Equity Incentive Plan. +	8-K	001-32188	4.2	5/5/17
10.4	Second Amendment to 2012 Equity Incentive Plan. +	8-K	001-32188	4.3	12/29/17
10.5	Third Amendment to 2012 Equity Incentive Plan. +	8-K	001-32188	4.4	6/26/18
10.6	Fourth Amendment to 2012 Equity Incentive Plan. +	8-K	001-32188	4.5	6/21/19
10.7	Form of Employee Stock Option Agreement. +	10-K	001-32188	10.26	3/26/13
10.8	Form of Consultant Stock Option Agreement. +	10-K	001-32188	10.27	3/26/13
10.9	Form of Notice of Grant of Stock Options and Stock Option Award Agreement (Employee). +	8-K	001-32188	10.1	3/18/15
10.10	Form of Notice of Grant of Stock Options and Stock Option Award Agreement (Directors). +	10-K	001-32188	10.23	3/4/20
10.11	Form of Director Restricted Stock Award Agreement. +	8-K	001-32188	10.3	3/18/15
10.12	Executive Employment Agreement between the Company and Kimberly Murphy dated effective June 23, 2022. +	8-K	001-32188	10.1	6/23/22
10.13	Executive Employment Agreement between the Company and Janet Huffman dated effective March 8, 2023. +	8-K			3/8/23

10.14	Amendment to Executive Employment Agreement between the Company and Janet Huffmann dated effective January 16, 2025+	8-K	001-32188	10.2	1/17/25	
10.15	Executive Employment Agreement for Mr. Redmond dated December 28, 2023+	8-K	001-32188	10.1	12/29/23	
10.16	2021 Equity Incentive Plan+	8-K	001-3288	10.1	2/28/22	
10.17	First Amendment to 2021 Equity Incentive Plan. +	8-K	001-32188	4.2	12/15/23	
10.18	Second Amendment to 2021 Equity Incentive Plan+	8-K	001-32188	4.3	12/16/24	
10.19	Form Stock Option Award Agreement (Directors)+	8-K	001-3288	10.2	2/28/22	
10.20	Form Stock Option Award Agreement (Employees)+	8-K	001-3288	10.3	2/28/22	
10.21	Form Stock Option Award Agreement (Consultants)+	8-K	001-3288	10.4	2/28/22	
10.22	At-the-Market Sales Agreement between the Company and Dawson James Securities Inc. Dated October 11, 2024	8-K	001-32188	1.1	10/15/24	
10.23	Placement Agency Agreement dated, September 4, 2024, between Oragenics, Inc. and Dawson James Securities, Inc.	8-K	001-32188	1.1	9/5/24	
10.24	Placement Agency Agreement dated June 25, 2024 between Oragenics, Inc. and Dawson James Securities, Inc.	8-K	001-32188	1.1	6/26/24	
10.25	Form of Securities Purchase Agreement					X
10.26	Form of Note dated March 13, 2025 to Purchasers					X
10.27	Form of Lock-Up Agreement					X
10.28	Placement Agency Agreement dated, March 13, 2025, between Oragenics, Inc. and Dawson James Securities, Inc.					X
21.1	Subsidiaries of Registrant	10-K	001-3288	21.1	3/24/22	
23.1	Consent of Cherry Bekaert LLP, an Independent Public Accounting Firm					X
24.1	Powers of Attorney (included on signature page).					X
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14 and Rule 15d-14(a), promulgated under the Securities and Exchange Act of 1934, as amended.					X
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14 and Rule 15d-14(a), promulgated under the Securities and Exchange Act of 1934, as amended.					X
32.1	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Chief Executive Officer). **					X
32.2	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Chief Financial Officer). **					X
97.1	Clawback Policy	10-K	001-3288	97.1	3/29/24	
101.INS	Inline XBRL Instance Document					X
101.SCH	Inline XBRL Taxonomy Extension Schema					X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase					X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase					X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase					X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase					X
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)					X

* Confidential treatment has been granted as to certain portions of this exhibit pursuant to Rule 406 of the Securities Act of 1933, as amended, or Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

\+ Executive management contract or compensatory plan or arrangement.

** Furnished herewith and not deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.

Exhibit 3.9

ARTICLES OF AMENDMENT

TO

ARTICLES OF INCORPORATION

OF

ORAGENICS, INC.

CERTIFICATE OF DESIGNATION AND RIGHTS OF SERIES G MIRRORING PREFERRED STOCK

Pursuant to Section 607.0602 of the Florida Business Corporation Act

Oragenics, Inc., a corporation organized and existing under the laws of the State of Florida (the "Corporation"), does hereby certify:

FIRST: That pursuant to authority conferred upon the Board of Directors of the Corporation (the "Board of Directors") by the Articles of Incorporation of the Corporation, as amended, the Board adopted the following resolutions on March 13, 2025 pursuant to the Corporation's Articles of Incorporation, as amended, and Sections 607.0602, 607.1002 and 607.1006 of the Florida Business Corporation Act, authorizing a new series of the Corporation's previously authorized Preferred Stock, no par value, designated as Series G Mirroring Preferred Stock. Shareholder action was not required.

SECOND: The Series G Mirroring Preferred Stock shall have the designation, number of shares, rights, qualifications, limitations and other terms and conditions as described herein.

THIRD: The Corporation is authorized to issue 50,000,000 shares of preferred stock, of which 7,488,692 shares of Series F Preferred have been designated, issued and outstanding.

FOURTH: The following resolutions were duly adopted by the Board of Directors of the Corporation:

WHEREAS, the Amended and Restated Articles of Incorporation of the Corporation as amended provide for a class of its authorized stock known as preferred stock, consisting of 50,000,000 shares, no par value, issuable from time to time in one or more series;

WHEREAS, the Board of Directors is authorized to fix the dividend rights, dividend rate, voting rights, conversion rights, rights and terms of redemption and liquidation preferences of any wholly unissued series of preferred stock and the number of shares constituting any series and the designation thereof, of any of them; and

WHEREAS, it is the desire of the Board of Directors, pursuant to its authority as aforesaid, to fix the rights, preferences, restrictions and other matters relating to a series of the preferred stock, which shall consist of, except as otherwise set forth in the Purchase Agreement (as defined below), 1,000,000 shares of the preferred stock which the Corporation has the authority to issue, as follows:

NOW, THEREFORE, BE IT RESOLVED, that the Board of Directors does hereby provide for the issuance of a series of preferred stock for cash or exchange of other securities, rights or property and does hereby fix and determine the rights, preferences, restrictions and other matters relating to such series of preferred stock as follows:

TERMS OF SERIES G PREFERRED STOCK

Section 1. Definitions. For the purposes hereof, the following terms shall have the following meanings:

"Adjournment Proposal" means any resolution presented to the shareholders of the Corporation for the purpose of approving an adjournment of any meeting of the Corporation's shareholders called to vote on either the Amendment Proposal or the Reverse Split Proposal.

"Affiliate" means any Person that, directly or indirectly through one or more intermediaries, controls or is controlled by or is under common control with a Person, as such terms are used in and construed under Rule 405 of the Securities Act.

"Amendment Proposal" means any proposal presented to the shareholders of the Corporation for the purpose of approving an amendment to the Corporation's Amended and Restated Articles of Incorporation to increase the number of authorized shares of Common Stock to 350,000,000 in the event a reverse stock split of the Company's Common Stock is effectuated prior to approval of the Reverse Split Proposal.

"Business Day" means any day except any Saturday, any Sunday, any day which is a federal legal holiday in the United States or any day on which banking institutions in the State of Florida are authorized or required by law or other governmental action to close.

"Certificate of Designation" means these Articles of Amendment.

"Closing" means the closing of the purchase and sale of the Securities pursuant to Section 2.1 of the Purchase Agreement.

"Common Stock" means the Corporation's common stock, par value $0.001 per share, and stock of any other class of securities into which such securities may hereafter be reclassified or changed.

"Holder" shall have the meaning given such term in Section 2.

"Liquidation" shall have the meaning set forth in Section 5.

"Florida Courts" shall have the meaning set forth in Section 7(d).

"Person" means an individual or corporation, partnership, trust, incorporated or unincorporated association, joint venture, limited liability company, joint stock company, government (or an agency or subdivision thereof) or other entity of any kind.

"Series G Mirroring Preferred Stock" shall have the meaning set forth in Section 2.

"Purchase Agreement" means the Securities Purchase Agreement, dated as of March 13, 2025, among the Corporation and the original Holders, as amended, modified or supplemented from time to time in accordance with its terms.

"Reverse Split Proposal" means any proposal presented to the shareholders of the Corporation for the purpose of authorizing the Company's Board of Directors, in its discretion at any time within one year after shareholder approval is obtained, to effect a reverse stock split of then-outstanding shares of the Company's common stock, at a ratio of not less than one-for-five (1:5) and not greater than one-for-sixty (1:60), with the exact ratio to be determined by the Company's Board and included in a public announcement;

"Securities" means the Series G Mirroring Preferred Stock.

"Securities Act" means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

"Stated Value" shall have the meaning set forth in Section 2.

"Trading Day" means a day on which the principal Trading Market is open for business.

"Trading Market" means any of the following markets or exchanges on which the Common Stock is listed or quoted for trading on the date in question: the NYSE American, the Nasdaq Capital Market, the Nasdaq Global Market, the Nasdaq Global Select Market, or the New York Stock Exchange (or any successors to any of the foregoing).

"Transaction Documents" means this Certificate of Designation, the Purchase Agreement, all exhibits and schedules thereto and hereto and any other documents or agreements executed in connection with the transactions contemplated pursuant to the Purchase Agreement.

Section 2. Designation, Amount and Par Value. The series of preferred stock shall be designated as Series G Mirroring Preferred Stock (the "Series G Mirroring PreferredStock") and the number of shares so designated shall be 1,000,000 (which shall not be subject to increase without the written consent of all of the holders of a majority of the then outstanding shares of the Series G Mirroring Preferred Stock (each, a "Holder" and collectively, the "Holders")). Each share of Series G Mirroring Preferred Stock shall have no par value and a stated value equal to $0.10 (the "Stated Value").

Section 3. Dividends. No dividends shall be paid on shares of Series G Mirroring Preferred Stock.

Section 4. Voting Rights.

a) Holders shall have no voting rights whatsoever pursuant to this Certificate of Designation and shall not vote separately or together with holders of shares of Common Stock or any other class or series of capital stock of the Corporation on any matters submitted to a vote of the shareholders of the Corporation, except as expressly specified herein or as required by applicable law. Notwithstanding the foregoing, each share of Series G Mirroring Preferred Stock shall entitle the holder thereof to 1,000 votes per each share of Series G Mirroring Preferred Stock solely and exclusively with respect to the Reverse Split Proposal, the Amendment Proposal and any Adjournment Proposal, voting together with the Common Stock and any other issued and outstanding shares of preferred stock of the Corporation as a single class.

b) Each Holder covenants to vote, and shall cause its Affiliates to vote, the shares of Series G Mirroring Preferred Stock on any proposal presented to the shareholders of the Corporation for purposes of approving the Reverse Split Proposal, the Amendment Proposal and the Adjournment Proposal and agrees that such shares of Series G Mirroring Preferred Stock, shall, to the extent voted in favor of the proposals, be automatically and without further action of the Holders voted in the same proportions as shares of Common Stock (excluding any shares of Common Stock that are not voted) and any other issued and outstanding shares of preferred stock of the Corporation (other than the Series G Mirroring Preferred Stock or shares of such preferred stock not voted) are voted on the Reverse Split Proposal, the Amendment Proposal and the Adjournment Proposal, as applicable. For the avoidance of doubt, and for illustrative purposes only, if 30% of the aggregate votes cast by Common Stock and other preferred stock, if any, in connection with the Amendment Proposal are voted against such proposal and 70% of the aggregate votes cast by Common Stock and other preferred stock, if any, voting in connection with the Amendment Proposal are voted in favor thereof, then 30% of the votes cast by the shares of Series G Mirroring Preferred Stock (assuming all votes made in favor of the proposal) voting in connection with the Amendment Proposal shall vote against the approval of the Amendment and 70% of such votes shall be cast in favor of the Amendment Proposal. Similarly, for the avoidance of doubt, and for illustrative purposes only, if 40% of the aggregate votes cast by Common Stock and other preferred stock, if any, in connection with the Reverse Split Proposal are voted against such proposal and 60% of the aggregate votes cast by Common Stock and other preferred stock, if any, voting in connection with the Reverse Split Proposal are voted in favor thereof, then 40% of the votes cast by the shares of Series G Mirroring Preferred Stock (assuming all votes made in favor of the proposal) voting in connection with the Reverse Split Proposal shall vote against the approval of the Amendment and 60% of such votes shall be cast in favor of the Amendment Proposal.

c) Notwithstanding the provisions set forth in this Section 4, as long as any shares of Series G Mirroring Preferred Stock are outstanding, the Corporation shall not, without the affirmative vote or consent of the Holders of at least a majority of the then outstanding shares of the Series G Mirroring Preferred Stock, voting or consenting (as the case may be) separately as a series, whether by merger, share exchange, consolidation or otherwise, (a) amend, alter or repeal the powers, preferences or rights of the Series G Mirroring Preferred Stock or alter or amend this Certificate of Designation in a manner adverse to the Holders of the Series G Mirroring Preferred Stock, (b) amend the Amended and Restated Articles of Incorporation as amended or other charter documents in a manner adverse to the rights, preferences are powers of the Series G Mirroring Preferred Stock, (c) increase the number of authorized shares of Series G Mirroring Preferred Stock, or (d) enter into any agreement with respect to any of the foregoing.

Section 5. Liquidation. The Series G Mirroring Preferred Stock shall rank junior to the Series F Preferred Stock. Upon any liquidation, dissolution or winding-up of the Corporation, whether voluntary or involuntary (a "Liquidation"), the Holders shall be entitled to receive out of the assets, whether capital or surplus, of the Corporation an amount equal to the Stated Value for each share of Series G Mirroring Preferred Stock before any distribution or payment shall be made to the holders of Common Stock but after any other class of stock than ranks senior to the Series G Mirroring Preferred Stock, including the Series F Preferred Stock, and if the assets of the Corporation shall be insufficient to pay in full such amounts, then the entire assets to be distributed to the Holders shall be ratably distributed among the Holders in accordance with the respective amounts that would be payable on such shares if all amounts payable thereon were paid in full.

Section 6. Cancellation. In the event that either the Reverse Split Proposal or the Amendment Proposal is approved by the shareholders of the Corporation, each share of Series G Mirroring Preferred Stock shall automatically be transferred to the Corporation and cancelled for no consideration on the effective date of the reverse split contemplated by the Reverse Split Proposal or the amendment to the Company's Amended and Restated Articles of Incorporation contemplated by the Amendment Proposal, as applicable, with no action on behalf of the Holder and such shares shall resume the status of authorized but unissued shares of preferred stock and shall no longer be designated as Series G Mirroring Preferred Stock.

Section 7. Miscellaneous.

a) Notices. Any and all notices or other communications or deliveries to be provided by the Holders hereunder shall be in writing and delivered personally, by facsimile or e-mail attachment, or sent by a nationally recognized overnight courier service, addressed to the Corporation, at 1990 Main Street Suite 750, Sarasota, Florida 34236, Attention: Chief Executive Officer, or to any other e-mail address or address as the Corporation may specify for such purposes by notice to the Holders delivered in accordance with this Section 7. Any and all notices or other communications or deliveries to be provided by the Corporation hereunder shall be in writing and delivered personally, by e-mail attachment, or sent by a nationally recognized overnight courier service addressed to each Holder at the e-mail address or address of such Holder appearing on the books of the Corporation, or if no such e-mail address or address appears on the books of the Corporation, at the principal place of business of such Holder, as set forth in the Purchase Agreement. Any notice or other communication or deliveries hereunder shall be deemed given and effective on the earliest of (i) the time of transmission, if such notice or communication is delivered via e-mail attachment at the e-mail address set forth in this Section prior to 5:30 p.m. (New York City time) on any date, (ii) the next Trading Day after the time of transmission, if such notice or communication is delivered via e-mail attachment at the e-mail address set forth in this Section on a day that is not a Trading Day or later than 5:30 p.m. (New York City time) on any Trading Day, (iii) the second Trading Day following the date of mailing, if sent by U.S. nationally recognized overnight courier service, or (iv) upon actual receipt by the party to whom such notice is required to be given.

c) Lost or Mutilated Preferred Stock Certificate. If a Holder's Series G Mirroring Preferred Stock certificate shall be mutilated, lost, stolen or destroyed, the Corporation shall execute and deliver, in exchange and substitution for and upon cancellation of a mutilated certificate, or in lieu of or in substitution for a lost, stolen or destroyed certificate, a new certificate for the shares of Series G Mirroring Preferred Stock so mutilated, lost, stolen or destroyed, but only upon receipt of evidence of such loss, theft or destruction of such certificate, and of the ownership hereof reasonably satisfactory to the Corporation (which shall not include the posting of any bond).

d) Governing Law. All questions concerning the construction, validity, enforcement and interpretation of this Certificate of Designation shall be governed by and construed and enforced in accordance with the internal laws of the State of Florida, without regard to the principles of conflict of laws thereof. All legal proceedings concerning the interpretation, enforcement and defense of the transactions contemplated by any of the Transaction Documents (whether brought against a party hereto or its respective Affiliates, directors, officers, shareholders, employees or agents) shall be commenced in the state and federal courts sitting in Hillsborough County, Florida (the "Florida Courts"). The Corporation and each Holder hereby irrevocably submits to the exclusive jurisdiction of the Florida Courts for the adjudication of any dispute hereunder or in connection herewith or with any transaction contemplated hereby or discussed herein (including with respect to the enforcement of any of the Transaction Documents), and hereby irrevocably waives, and agrees not to assert in any suit, action or proceeding, any claim that it is not personally subject to the jurisdiction of such Florida Courts, or such Florida Courts are improper or inconvenient venue for such proceeding. The Corporation and each Holder hereby irrevocably waives personal service of process and consents to process being served in any such suit, action or proceeding by mailing a copy thereof via registered or certified mail or overnight delivery (with evidence of delivery) to such party at the address in effect for notices to it under this Certificate of Designation and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any other manner permitted by applicable law. The Corporation and each Holder hereby irrevocably waives, to the fullest extent permitted by applicable law, any and all right to trial by jury in any legal proceeding arising out of or relating to this Certificate of Designation or the transactions contemplated hereby. If the Corporation or any Holder shall commence an action or proceeding to enforce any provisions of this Certificate of Designation, then the prevailing party in such action or proceeding shall be reimbursed by the other party for its attorneys' fees and other costs and expenses incurred in the investigation, preparation and prosecution of such action or proceeding.

e) Waiver. Any waiver by the Corporation or a Holder of a breach of any provision of this Certificate of Designation shall not operate as or be construed to be a waiver of any other breach of such provision or of any breach of any other provision of this Certificate of Designation or a waiver by any other Holders. The failure of the Corporation or a Holder to insist upon strict adherence to any term of this Certificate of Designation on one or more occasions shall not be considered a waiver or deprive that party (or any other Holder) of the right thereafter to insist upon strict adherence to that term or any other term of this Certificate of Designation on any other occasion. Any waiver by the Corporation or a Holder must be in writing.

f) Severability. If any provision of this Certificate of Designation is invalid, illegal or unenforceable, the balance of this Certificate of Designation shall remain in effect, and if any provision is inapplicable to any Person or circumstance, it shall nevertheless remain applicable to all other Persons and circumstances. If it shall be found that any interest or other amount deemed interest due hereunder violates the applicable law governing usury, the applicable rate of interest due hereunder shall automatically be lowered to equal the maximum rate of interest permitted under applicable law.

g) Next Business Day. Whenever any payment or other obligation hereunder shall be due on a day other than a Business Day, such payment shall be made on the next succeeding Business Day.

h) Headings. The headings contained herein are for convenience only, do not constitute a part of this Certificate of Designation and shall not be deemed to limit or affect any of the provisions hereof.

RESOLVED, FURTHER, that the Chief Financial Officer of the Corporation be and they hereby are authorized and directed to prepare and file this Certificate of Designation and Rights in accordance with the foregoing resolution and the provisions of Florida law.

****

IN WITNESS WHEREOF, the undersigned has executed and subscribed these Articles of Amendment on this 13th day of March, 2025.

ORAGENICS, INC.

By: */s/ Janet Huffman*
Name: Janet Huffman
Title: Chief Financial Officer

Exhibit 10.25

SECURITIES PURCHASE AGREEMENT

This Securities Purchase Agreement (this "**Agreement**") is dated as of March 13, 2025, between Oragenics, Inc., a Florida corporation (the "**Company**"), and each purchaser identified on the signature pages hereto (including their respective successors and assigns, each a "**Purchaser**" and collectively, the "**Purchasers**").

WHEREAS, subject to the terms and conditions set forth in this Agreement and pursuant to Section 4(a)(2) of the Securities Act of 1933, as amended (the "**Securities Act**"), and Rule 506 promulgated thereunder, the Company desires to issue and sell to each Purchaser, and each Purchaser, severally and not jointly, desires to purchase from the Company, securities of the Company as more fully described in this Agreement.

NOW, THEREFORE, IN CONSIDERATION of the mutual covenants contained in this Agreement, and for other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, the Company and each Purchaser agree as follows:

1. **Definitions**. In addition to the terms defined elsewhere in this Agreement, for all purposes of this Agreement, the following terms have the meanings set forth in this Section 1:

   1.1. "**Acquiring Person**" shall have the meaning ascribed to such term in Section 4.5.

   1.2. "**Action**" shall have the meaning ascribed to such term in Section 3.1.10.

   1.3. "**Adjournment Proposal**" means any resolution presented to the shareholders of the Corporation for the purpose of approving an adjournment of any meeting of the Corporation's shareholders called to vote on either the Amendment Proposal or the Reverse Split Proposal.

   1.4. "**Affiliate**" means any Person that, directly or indirectly through one or more intermediaries, controls or is controlled by or is under common control with a Person, as such terms are used in and construed under Rule 405 under the Securities Act.

   1.5. "**Agreement**" shall have the meaning ascribed to such term in the preamble.

   1.6. "**Amendment Proposal**" means any proposal presented to the shareholders of the Company for the purpose of approving an amendment to the Company's Amended and Restated Articles of Incorporation to increase the number of authorized shares of Common Stock to 350,000,000 in the event a reverse stock split of the Company's Common Stock is effectuated prior to shareholders' approval of the Reverse Split Proposal.

   1.7. "**BHCA**" shall have the meaning ascribed to such term in Section 3.1.42.

   1.8. "**Board of Directors**" means the board of directors of the Company.

   1.9. "**Business Day**" means any day other than Saturday, Sunday or other day on which commercial banks in The City of New York are authorized or required by law to remain closed; provided, however, for clarification, commercial banks shall not be deemed to be authorized or required by law to remain closed due to "stay at home", "shelter-in-place", "non-essential employee" or any other similar orders or restrictions or the closure of any physical branch locations at the direction of any governmental authority so long as the electronic funds transfer systems (including for wire transfers) of commercial banks in The City of New York are generally open for use by customers on such day.

1.10. "**Buy-In Price**" shall have the meaning ascribed to such term in Section 4.1.4.

1.11. "**Closing**" means the closing of the purchase and sale of the Securities pursuant to Section 2.1.

1.12. "**Closing Date**" means the Trading Day on which all of the Transaction Documents have been executed and delivered by the applicable parties thereto, and all conditions precedent to (i) the Purchasers' obligations to pay the Subscription Amount and (ii) the Company's obligations to deliver the Securities, in each case, have been satisfied or waived.

1.13. "**Code**" means the Internal Revenue Code of 1986, as amended.

1.14. "**Commission**" means the United States Securities and Exchange Commission.

1.15. "**Common Stock Equivalents**" means any securities of the Company or the Subsidiaries which would entitle the holder thereof to acquire at any time Common Stock, including, without limitation, any debt, preferred stock, right, option, warrant or other instrument that is at any time convertible into or exercisable or exchangeable for, or otherwise entitles the holder thereof to receive, Common Stock.

1.16. "**Common Stock**" means the common stock of the Company, $0.001 par value per share, and any other class of securities into which such securities may hereafter be reclassified or changed.

1.17. "**Company**" shall have the meaning ascribed to such term in the preamble.

1.18. "**Company Counsel**" means with respect to U.S. federal securities law and Florida law, Shumaker, Loop & Kendrick LLP, 101 East Kennedy Boulevard, Suite 2800, Tampa FL 33602.

1.19. "**Disclosure Schedules**" means the Disclosure Schedules of the Company delivered concurrently herewith.

1.20. "**Disclosure Time**" means, (i) if this Agreement is signed on a day that is not a Trading Day or after 9:00 a.m. (New York City time) and before midnight (New York City time) on any Trading Day, 9:01 a.m. (New York City time) on the Trading Day immediately following the date hereof, unless otherwise instructed as to an earlier time by the Placement Agent, and (ii) if this Agreement is signed between midnight (New York City time) and 9:00 a.m. (New York City time) on any Trading Day, no later than 9:01 a.m. (New York City time) on the date hereof, unless otherwise instructed as to an earlier time by the Placement Agent.

1.21. "**Disqualification Event**" shall have the meaning ascribed to such term in Section 3.1.44.

1.22. "**Escrow Agent**" means Shumaker, Loop & Kendrick, LLLP.

1.23. "**Escrow Agreement**" means the escrow agreement entered into as of the date hereof, by and among the Company, the Escrow Agent and the Placement Agent, pursuant to which the Purchasers shall deposit Subscription Amounts with the Escrow Agent to be applied to the transactions contemplated hereunder.

1.24. "**Evaluation Date**" shall have the meaning ascribed to such term in Section 3.1.19.

1.25. "**Exchange Act**" means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

1.26. "**FCPA**" means the Foreign Corrupt Practices Act of 1977, as amended.

1.27. "**Federal Reserve**" shall have the meaning ascribed to such term in Section 3.1.42.

1.28. "**GAAP**" shall have the meaning ascribed to such term in Section 3.1.8.

1.29. "**Indebtedness**" shall have the meaning ascribed to such term in Section 3.1.28.

1.30. "**Issuer Covered Person**" shall have the meaning ascribed to such term in Section 3.1.44.

1.31. "**IT Systems and Data**" shall have the meaning ascribed to such term in Section 3.1.47.

1.32. "**Legend Removal Date**" shall have the meaning ascribed to such term in Section 4.1.3.

1.33. "**Liens**" means a lien, charge pledge, security interest, encumbrance, right of first refusal, preemptive right or other restriction.

1.34. "**Lock-Up Agreement**" means the Lock-Up Agreement, dated as of the date hereof, by and among the Company and the directors, executive officers, employees and shareholders holding at least ten percent (10%) of the outstanding shares of Common Stock on a fully converted basis, in the form of **Exhibit 1.36** attached hereto.

1.35. "**Material Adverse Effect**" shall have the meaning assigned to such term in Section 3.1.2.

1.36. "**Material Permits**" shall have the meaning ascribed to such term in Section 3.1.14.

1.37. "**Notes**" means the Senior Notes, issued by the Company to the Purchasers hereunder, in the form attached hereto.

1.38. "**Person**" means an individual or corporation, partnership, trust, incorporated or unincorporated association, joint venture, limited liability company, joint stock company, government (or an agency or subdivision thereof) or other entity of any kind.

1.39. "**PFIC**" shall have the meaning ascribed to such term in Section 4.17.

1.40. "**Placement Agent**" means Dawson James Securities, Inc.

1.41. "**Placement Agent Agreement**" means the placement agent agreement, dated on or about the date hereof, between the Company and the Placement Agent.

1.42. "**Proceeding**" means an action, claim, suit, investigation or proceeding (including, without limitation, an informal investigation or partial proceeding, such as a deposition), whether commenced or threatened.

1.43. "**Public Information Failure**" shall have the meaning ascribed to such term in Section 4.2.2.

1.44. "**Purchaser**" shall have the meaning ascribed to such term in the preamble.

1.45. "**Purchaser Party**" shall have the meaning ascribed to such term in Section 4.8.

1.46. "**Qualified Equity Raise**" shall mean the first transaction after the date hereof in which the Company receives at least $5,000,000 in net proceeds from the sale of any of the Company's capital stock or derivative securities that allow the holder thereof to purchase the Company's capital stock.

1.47. "**Required Approvals**" shall have the meaning ascribed to such term in Section 3.1.5.

1.48. "**Reverse Split Proposal**" means any proposal presented to the shareholders of the Company for the purpose of authorizing the Company's Board of Directors, in its discretion at any time within one year after shareholder approval is obtained, to effect a reverse stock split of then-outstanding shares of the Company's common stock, at a ratio of not less than one-for-five (1:5) and not greater than one-for-sixty (1:60), with the exact ratio to be determined by the Company's Board of Directors and included in a public announcement.

1.49. "**Rule 144**" means Rule 144 promulgated by the Commission pursuant to the Securities Act, as such Rule may be amended or interpreted from time to time, or any similar rule or regulation hereafter adopted by the Commission having substantially the same purpose and effect as such Rule.

1.50. "**Rule 424**" means Rule 424 promulgated by the Commission pursuant to the Securities Act, as such Rule may be amended or interpreted from time to time, or any similar rule or regulation hereafter adopted by the Commission having substantially the same purpose and effect as such Rule.

1.51. "**SEC Reports**" shall have the meaning ascribed to such term in Section 3.1.8.

1.52. "**Securities**" means the Shares and the Notes purchased pursuant to this Agreement.

1.53. "**Securities Act**" means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

1.54. "**Series G Stock**" means the Series G Mirroring Preferred Stock of the Company, no par value per share, and any other class of securities into which such securities may hereafter be reclassified or changed, with the rights and preferences set forth in the Certificate of Designation attached hereto as **Exhibit 1.51**.

1.55. "**Shares**" means the shares of Series G Stock issued or issuable to each Purchaser pursuant to this Agreement.

1.56. "**Short Sales**" means all "short sales" as defined in Rule 200 of Regulation SHO under the Exchange Act (but shall not be deemed to include locating and/or borrowing shares of Common Stock).

1.57. "**Subscription Amount**" means, as to each Purchaser, the aggregate amount to be paid for Securities purchased hereunder as specified below such Purchaser's name on the signature page of this Agreement and next to the heading "Subscription Amount," in United States dollars and in immediately available funds.

1.58. "**Subsidiary**" means any subsidiary of the Company as set forth in Schedule 3.1.1 and shall, where applicable, also include any direct or indirect subsidiary of the Company formed or acquired after the date hereof.

1.59. "**Trading Day**" means a day on which the principal Trading Market is open for trading.

1.60. "**Trading Market**" means any of the following markets or exchanges on which the Common Stock is listed or quoted for trading on the date in question: the NYSE American, the Nasdaq Capital Market, the Nasdaq Global Market, the Nasdaq Global Select Market, the New York Stock Exchange, the OTCQB, OTCQX, Pink Open Market (or any successors to any of the foregoing).

1.61. "**Transaction Documents**" means this Agreement, the Securities, the Placement Agent Agreement, the Escrow Agreement, the Lock-Up Agreements, and all exhibits and schedules thereto and hereto and any other documents or agreements executed in connection with the transactions contemplated hereunder.

1.62. "**Transfer Agent**" means Continental Stock Transfer & Trust Company, the current transfer agent of the Company, with a mailing address of 1 State Street, 30th Floor, New York, NY 10004 and an email address of [●]@continentalstock.com, and any successor transfer agent of the Company.

1.63. "**VWAP**" means, for any date, the price determined by the first of the following clauses that applies: (a) if the Common Stock is then listed or quoted on a Trading Market, the daily volume weighted average price of the Common Stock for such date (or the nearest preceding date) on the Trading Market on which the Common Stock is then listed or quoted as reported by Bloomberg L.P. (based on a Trading Day from 9:30 a.m. (New York City time) to 4:02 p.m. (New York City time)), (b) if OTCQB or OTCQX is not a Trading Market, the volume weighted average price of the Common Stock for such date (or the nearest preceding date) on OTCQB or OTCQX as applicable, (c) if the Common Stock is not then listed or quoted for trading on OTCQB or OTCQX and if prices for the Common Stock are then reported on the OTC Pink (or a similar organization or agency succeeding to its functions of reporting prices), the most recent bid price per share of Common Stock so reported, or (d) in all other cases, the fair market value of the Common Stock as determined by an independent appraiser selected in good faith by the Purchasers of a majority in interest of the Securities then outstanding and reasonably acceptable to the Company, the fees and expenses of which shall be paid by the Company.

2. **Purchase and Sale**.

2.1. **Closing**. On the Closing Date, upon the terms and subject to the conditions set forth herein, substantially concurrent with the execution and delivery of this Agreement by the parties hereto, the Company agrees to sell, and the Purchasers, severally and not jointly, agree to purchase, for an aggregate of $2,500,000 in Subscription Amount, the following Securities: for each $$2,500,000 in Subscription Amount, (i) $3,00,000 aggregate principal amount of Notes and (ii) 1,000,000 Shares. Each Purchaser shall deliver to the Company, or cause the Escrow Agent to deliver to the Company, via wire transfer, immediately available funds equal to such Purchaser's Subscription Amount as set forth on the signature page hereto executed by such Purchaser, and the Company shall deliver to each Purchaser its respective Securities, as determined pursuant to Section 2.2.1, and the Company and each Purchaser shall deliver the other items set forth in Section 2.2.2 deliverable at the Closing. Upon satisfaction of the covenants and conditions set forth in Sections 2.3.1 and 2.3.2, the Closing shall occur at the offices of counsel to the Placement Agent or such other location (or remotely by electronic means) as the parties shall mutually agree.

2.2. **Deliveries**.

2.2.1. The Company shall deliver or cause to be delivered to each Purchaser or the Placement Agent, as appropriate, the following at the times stated:

2.2.1.1. on the date hereof:

2.2.1.1.1. this Agreement duly executed by the Company.

2.2.1.1.2. a certificate executed by the Chief Financial Officer of the Company in customary form reasonably satisfactory to the Placement Agent and its counsel.

2.2.1.1.3. the Lock-Up Agreements.

2.2.1.1.4. the Escrow Agreement.

2.2.1.2. on or prior to the Closing Date:

2.2.1.2.1. a copy of the irrevocable instructions to the Transfer Agent instructing the Transfer Agent to deliver, on an expedited basis, a certificate (or at the request of the Purchaser, book entry statement) evidencing a number of Shares equal to (i) 1,000,000 multiplied by (ii) such Purchaser's Subscription Amount divided by (iii) $2,500,000, registered in the name of such Purchaser.

2.2.1.2.2. a Note with a principal amount equal to such Purchaser's Subscription Amount multiplied by 1.20, registered in the name of such Purchaser.

2.2.1.2.3. the Company shall have provided each Purchaser with the Company's wire instructions, on Company letterhead and executed by the Chief Executive Officer or Chief Financial Officer.

2.2.1.2.4. a duly executed and delivered Officers' Certificate, in customary form reasonably satisfactory to the Placement Agent and its counsel.

2.2.2. Each Purchaser, and the Placement Agent, as applicable, shall deliver or cause to be delivered the following at the times stated:

2.2.2.1. on the date hereof, to the Escrow Agent, to the Escrow Agent such Purchaser's Subscription Amount; and

2.2.2.2. on the date hereof, to the Company:

2.2.2.2.1. this Agreement duly executed by such Purchaser.

2.2.2.2.2. the Escrow Agreement duly executed by such Purchaser and the Placement Agent.

2.2.2.2.3. the Placement Agent Agreement, duly executed by the Placement Agent.

2.2.2.3. on or prior to the Closing Date:

2.2.2.3.1. duly executed joint written instructions to the Escrow Agent instructing it to release the aggregate Subscription Amount to the Company via wire transfer to the account specified in writing by the Company.

2.3. **Closing Conditions**.

2.3.1. The obligations of the Company hereunder in connection with the Closing are subject to each of the following conditions being met:

2.3.1.1. the accuracy in all material respects (or, to the extent representations or warranties are qualified by materiality or Material Adverse Effect, in all respects) when made and on the Closing Date of the representations and warranties of the Purchasers contained herein (unless as of a specific date therein in which case they shall be accurate as of such date.

2.3.1.2. all obligations, covenants and agreements of each Purchaser required to be performed at or prior to the Closing Date shall have been performed.

2.3.1.3. the delivery by each Purchaser of the items set forth in Section 2.2.2 of this Agreement.

2.3.2. The respective obligations of the Purchasers hereunder in connection with the Closing are subject to each of the following conditions being met:

2.3.2.1. the accuracy in all material respects (or, to the extent representations or warranties are qualified by materiality or Material Adverse Effect, in all respects) when made and on the Closing Date of the representations and warranties of the Company contained herein (unless as of a specific date therein in which case they shall be accurate as of such date).

2.3.2.2. all obligations, covenants and agreements of the Company required to be performed at or prior to the Closing Date shall have been performed.

2.3.2.3. the delivery by the Company of the items set forth in Section 2.2.1 of this Agreement.

2.3.2.4. there shall have been no Material Adverse Effect with respect to the Company since the date hereof.

2.3.2.5. from the date hereof to the Closing Date, trading in the Common Stock shall not have been suspended by the Commission or the Company's principal Trading Market, and, at any time prior to the Closing Date, trading in securities generally as reported by Bloomberg L.P. shall not have been suspended or limited, or minimum prices shall not have been established on securities whose trades are reported by such service, or on any Trading Market, nor shall a banking moratorium have been declared either by the United States or New York State authorities nor shall there have occurred any material outbreak or escalation of hostilities or other national or international calamity of such magnitude in its effect on, or any material adverse change in, any financial market which, in each case, in the reasonable judgment of such Purchaser, makes it impracticable or inadvisable to purchase the Securities at the Closing.

3. **Representations and Warranties**.

3.1. **Representations and Warranties of the Company**. The Company hereby makes the following representations and warranties to each Purchaser:

3.1.1. **Subsidiaries**. All of the direct and indirect subsidiaries of the Company are set forth on Schedule 3.1.1. The Company owns, directly or indirectly, all of the capital stock or other equity interests of each Subsidiary free and clear of any Liens, and all of the issued and outstanding shares of capital stock of each Subsidiary are validly issued and are fully paid, non-assessable and free of preemptive and similar rights to subscribe for or purchase securities. If the Company has no subsidiaries, all other references to the Subsidiaries or any of them in the Transaction Documents shall be disregarded.

3.1.2. **Organization and Qualification**. The Company and each of the Subsidiaries is an entity duly incorporated or otherwise organized, validly existing and in good standing under the laws of the jurisdiction of its incorporation or organization, with the requisite power and authority to own and use its properties and assets and to carry on its business as currently conducted. Neither the Company nor any Subsidiary is in violation nor default of any of the provisions of its respective certificate or articles of incorporation, bylaws or other organizational or charter documents. Each of the Company and the Subsidiaries is duly qualified to conduct business and is in good standing as a foreign corporation or other entity in each jurisdiction in which the nature of the business conducted or property owned by it makes such qualification necessary, except where the failure to be so qualified or in good standing, as the case may be, could not have or reasonably be expected to result in: (i) a material adverse effect on the legality, validity or enforceability of any Transaction Document, (ii) a material adverse effect on the results of operations, assets, business, prospects or condition (financial or otherwise) of the Company and the Subsidiaries, taken as a whole, or (iii) a material adverse effect on the Company's ability to perform in any material respect on a timely basis its obligations under any Transaction Document (any of (i), (ii) or (iii), a "**Material Adverse Effect**"; provided, however, that "**Material Adverse Effect**" shall not include any event, occurrence, fact, condition or change, directly or indirectly, arising out of or attributable to: (i) the announcement, pendency or completion of the transactions contemplated by the Transaction Documents, or (ii) any action required or permitted by the Transaction Documents or any action taken (or omitted to be taken) with the written consent of or at the written request of Purchaser). As to all Company and Subsidiary power, authority and qualification, no Proceeding has been instituted in any such jurisdiction revoking, limiting or curtailing or seeking to revoke, limit or curtail such power and authority or qualification.

3.1.3. **Authorization; Enforcement**. The Company has the requisite corporate power and authority to enter into and to consummate the transactions contemplated by this Agreement and each of the other Transaction Documents and otherwise to carry out its obligations hereunder and thereunder. The execution and delivery of this Agreement and each of the other Transaction Documents by the Company and the consummation by it of the transactions contemplated hereby and thereby have been duly authorized by all necessary action on the part of the Company and no further action is required by the Company, the Board of Directors or the Company's shareholders in connection herewith or therewith other than in connection with the Required Approvals. This Agreement and each other Transaction Document to which it is a party has been (or upon delivery will have been) duly executed by the Company and, when delivered in accordance with the terms hereof and thereof, will constitute the valid and binding obligation of the Company enforceable against the Company in accordance with its terms, except (i) as limited by applicable bankruptcy, insolvency, reorganization, moratorium and other laws of general application affecting enforcement of creditors' rights generally, (ii) as limited by general equitable principles and laws relating to the availability of specific performance, injunctive relief or other equitable remedies and (iii) insofar as indemnification and contribution provisions may be limited by applicable law.

3.1.4. **No Conflicts**. The execution, delivery and performance by the Company of this Agreement and the other Transaction Documents to which it is a party, the issuance and sale of the Securities and the consummation by it of the transactions contemplated hereby and thereby do not and will not (i) conflict with or violate any provision of the Company's or any Subsidiary's certificate or articles of incorporation, bylaws or other organizational or charter documents, or (ii) conflict with, or constitute a default (or an event that with notice or lapse of time or both would become a default) under, result in the creation of any Lien upon any of the properties or assets of the Company or any Subsidiary, or give to others any rights of termination, amendment, anti-dilution or similar adjustments, acceleration or cancellation (with or without notice, lapse of time or both) of, any agreement, credit facility, debt or other instrument (evidencing a Company or Subsidiary debt or otherwise) or other understanding to which the Company or any Subsidiary is a party or by which any property or asset of the Company or any Subsidiary is bound or affected, or (iii) subject to the Required Approvals, conflict with or result in a violation of any law, rule, regulation, order, judgment, injunction, decree or other restriction of any court or governmental authority to which the Company or a Subsidiary is subject (including federal and state securities laws and regulations), or by which any property or asset of the Company or a Subsidiary is bound or affected; except in the case of each of clauses (ii) and (iii), such as could not have or reasonably be expected to result in a Material Adverse Effect.

3.1.5. **Filings, Consents and Approvals**. The Company is not required to obtain any consent, waiver, authorization or order of, give any notice to, or make any filing or registration with, any court or other federal, state, local or other governmental authority or other Person in connection with the execution, delivery and performance by the Company of the Transaction Documents, other than: (i) the filings required pursuant to Section 4.4 of this Agreement, (ii) the notice and/or application(s) to each applicable Trading Market for the issuance and sale of the Securities and the listing of the Shares for trading thereon in the time and manner required thereby, (iv) the filing of Form D with the Commission and such other filings as are required to be made under applicable state securities laws (the "**Required Approvals**").

3.1.6. **Issuance of the Securities**. The Securities are duly authorized and, when issued and paid for in accordance with the applicable Transaction Documents, will be duly and validly issued, fully paid and nonassessable (which means that no further sums are required to be paid by the holders thereof in connection with the issue thereof), free and clear of all Liens imposed by the Company other than restrictions on transfer provided for in the Transaction Documents and applicable law.

3.1.7. **Capitalization**. The capitalization of the Company is as set forth in the SEC Reports as of the dates indicated therein. Other than as stated in the SEC Reports, the Company has not issued any capital stock since its most recently filed periodic report under the Exchange Act, other than pursuant to the exercise of employee stock options under the Company's stock option plans, the issuance of shares of Common Stock to employees pursuant to the Company's employee stock purchase plans and pursuant to the conversion and/or exercise of Common Stock Equivalents outstanding as of the date of the most recently filed periodic report under the Exchange Act. No Person has any right of first refusal, preemptive right, right of participation, or any similar right to participate in the transactions contemplated by the Transaction Documents. Except as set forth in the SEC Reports, or pursuant to this Agreement, there are no outstanding options, warrants, scrip rights to subscribe to, calls or commitments of any character whatsoever relating to, or securities, rights or obligations convertible into or exercisable or exchangeable for, or giving any Person any right to subscribe for or acquire, any shares of Common Stock or the capital stock of any Subsidiary, or contracts, commitments, understandings or arrangements by which the Company or any Subsidiary is or may become bound to issue additional shares of Common Stock or Common Stock Equivalents or capital stock of any Subsidiary. The issuance and sale of the Securities will not obligate the Company or any Subsidiary to issue shares of Common Stock or other securities to any Person (other than the Purchasers). Except as set forth in the SEC Reports, there are no outstanding securities or instruments of the Company or any Subsidiary with any provision that adjusts the exercise, conversion, exchange or reset price of such security or instrument upon an issuance of securities by the Company or any Subsidiary. Except as set forth in the SEC Reports, there are no outstanding securities or instruments of the Company or any Subsidiary that contain any redemption or similar provisions, and there are no contracts, commitments, understandings or arrangements by which the Company or any Subsidiary is or may become bound to redeem a security of the Company or such Subsidiary. The Company does not have any stock appreciation rights or "phantom stock" plans or agreements or any similar plan or agreement. All of the outstanding shares of capital stock of the Company are duly authorized, validly issued, fully paid and nonassessable, have been issued in compliance with all federal and state securities laws, and none of such outstanding shares was issued in violation of any preemptive rights or similar rights to subscribe for or purchase securities. No further approval or authorization of any shareholder, the Board of Directors or others is required for the issuance and sale of the Securities. Except as set forth in the SEC Reports, there are no shareholders' agreements, voting agreements or other similar agreements with respect to the Company's capital stock to which the Company is a party or, to the knowledge of the Company, between or among any of the Company's shareholders.

3.1.8. **SEC Reports; Financial Statements**. The Company has filed all reports, schedules, forms, statements and other documents required to be filed by the Company under the Securities Act and the Exchange Act, including pursuant to Section 13(a) or 15(d) thereof, for the two years preceding the date hereof (or such shorter period as the Company was required by law or regulation to file such material) (the foregoing materials, including the exhibits thereto and documents incorporated by reference therein, being collectively referred to herein as the "**SEC Reports**") on a timely basis or has received a valid extension of such time of filing and has filed any such SEC Reports prior to the expiration of any such extension. As of their respective dates, the SEC Reports complied in all material respects with the requirements of the Securities Act and the Exchange Act, as applicable, and none of the SEC Reports, when filed, contained any untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading. The Company has never been an issuer subject to Rule 144(i) under the Securities Act. The financial statements of the Company included in the SEC Reports comply in all material respects with applicable accounting requirements and the rules and regulations of the Commission with respect thereto as in effect at the time of filing. Such financial statements have been prepared in accordance with United States generally accepted accounting principles applied on a consistent basis during the periods involved ("**GAAP**"), except as may be otherwise specified in such financial statements or the notes thereto, and fairly present in all material respects the financial position of the Company and its consolidated Subsidiaries as of and for the dates thereof and the results of operations and cash flows for the periods then ended, subject, in the case of unaudited statements, to normal, immaterial, year-end audit adjustments.

3.1.9. **Material Changes; Undisclosed Events, Liabilities or Developments**. Since the date of the latest unaudited financial statements included within the SEC Reports, (i) there has been no event, occurrence or development that has had or that could reasonably be expected to result in a Material Adverse Effect, (ii) the Company has not incurred any liabilities (contingent or otherwise) other than (A) trade payables and accrued expenses incurred in the ordinary course of business consistent with past practice and (B) liabilities not required to be reflected in the Company's financial statements pursuant to GAAP or disclosed in filings made with the Commission, (iii) the Company has not altered its method of accounting, (iv) the Company has not declared or made any dividend or distribution of cash or other property to its shareholders or purchased, redeemed or made any agreements to purchase or redeem any shares of its capital stock and (v) the Company has not issued any equity securities to any officer, director or Affiliate, except pursuant to existing Company stock option plans. The Company does not have pending before the Commission any request for confidential treatment of information. Except for the issuance of the Securities contemplated by this Agreement, no event, liability, fact, circumstance, occurrence or development has occurred or exists or is reasonably expected to occur or exist with respect to the Company or its Subsidiaries or their respective businesses, prospects, properties, operations, assets or financial condition that would be required to be disclosed by the Company under applicable securities laws at the time this representation is made or deemed made that has not been publicly disclosed at least one (1) Trading Day prior to the date that this representation is made.

3.1.10. **Litigation**. Except as set forth in the SEC Reports, there is no action, suit, inquiry, notice of violation, proceeding or investigation pending or, to the knowledge of the Company, threatened against or affecting the Company, any Subsidiary or any of their respective properties before or by any court, arbitrator, governmental or administrative agency or regulatory authority (federal, state, county, local or foreign) (collectively, an "**Action**") that (i) adversely affects or challenges the legality, validity or enforceability of any of the Transaction Documents or (ii) would, if there were an unfavorable decision, have or reasonably be expected to result in a Material Adverse Effect. Neither the Company nor any Subsidiary, nor any director or officer thereof, is or has been the subject of any Action involving a claim of violation of or liability under federal or state securities laws or a claim of breach of fiduciary duty. There has not been, and to the knowledge of the Company, there is not pending or contemplated, any investigation by the Commission involving the Company or any current or former director or officer of the Company, except in the ordinary course of business that would not have a Material Adverse Effect. The Commission has not issued any stop order or other order suspending the effectiveness of any registration statement filed by the Company or any Subsidiary under the Exchange Act or the Securities Act.

3.1.11. **Labor Relations**. No labor dispute exists or, to the knowledge of the Company, is imminent with respect to any of the employees of the Company, which could reasonably be expected to result in a Material Adverse Effect. None of the Company's or its Subsidiaries' employees is a member of a union that relates to such employee's relationship with the Company or such Subsidiary, and neither the Company nor any of its Subsidiaries is a party to a collective bargaining agreement, and the Company and its Subsidiaries believe that their relationships with their employees are good. To the knowledge of the Company, no executive officer of the Company or any Subsidiary is, or is now expected to be, in violation of any material term of any employment contract, confidentiality, disclosure or proprietary information agreement or non-competition agreement, or any other contract or agreement or any restrictive covenant in favor of any third party, and the continued employment of each such executive officer does not subject the Company or any of its Subsidiaries to any liability with respect to any of the foregoing matters. The Company and its Subsidiaries are in compliance with all applicable U.S. federal, state, local and foreign laws and regulations relating to employment and employment practices, terms and conditions of employment and wages and hours, except where the failure to be in compliance could not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

3.1.12. **Compliance**. Neither the Company nor any Subsidiary: (i) is in default under or in violation of (and no event has occurred that has not been waived that, with notice or lapse of time or both, would result in a default by the Company or any Subsidiary under), nor has the Company or any Subsidiary received notice of a claim that it is in default under or that it is in violation of, any indenture, loan or credit agreement or any other agreement or instrument to which it is a party or by which it or any of its properties is bound (whether or not such default or violation has been waived), (ii) is in violation of any judgment, decree, or order of any court, arbitrator or other governmental authority or (iii) is or has been in violation of any statute, rule, ordinance or regulation of any governmental authority, including without limitation all foreign, federal, state and local laws relating to taxes, environmental protection, occupational health and safety, product quality and safety and employment and labor matters, except in each case as could not have or reasonably be expected to result in a Material Adverse Effect.

3.1.13. **Environmental Laws**. The Company and its Subsidiaries (i) are in compliance with all federal, state, local and foreign laws relating to pollution or protection of human health or the environment (including ambient air, surface water, groundwater, land surface or subsurface strata), including laws relating to emissions, discharges, releases or threatened releases of chemicals, pollutants, contaminants, or toxic or hazardous substances or wastes (collectively, "**Hazardous Materials**") into the environment, or otherwise relating to the manufacture, processing, distribution, use, treatment, storage, disposal, transport or handling of Hazardous Materials, as well as all authorizations, codes, decrees, demands, or demand letters, injunctions, judgments, licenses, notices or notice letters, orders, permits, plans or regulations, issued, entered, promulgated or approved thereunder ("**Environmental Laws**"); (ii) have received all permits licenses or other approvals required of them under applicable Environmental Laws to conduct their respective businesses; and (iii) are in compliance with all terms and conditions of any such permit, license or approval where in each clause (i), (ii) and (iii), the failure to so comply could be reasonably expected to have, individually or in the aggregate, a Material Adverse Effect.

3.1.14. **Regulatory Permits**. The Company and the Subsidiaries possess all certificates, authorizations and permits issued by the appropriate federal, state, local or foreign regulatory authorities necessary to conduct their respective businesses as described in the SEC Reports, except where the failure to possess such permits could not reasonably be expected to result in a Material Adverse Effect ("**Material Permits**"), and neither the Company nor any Subsidiary has received any notice of proceedings relating to the revocation or modification of any Material Permit.

3.1.15. **Title to Assets**. The Company and the Subsidiaries have good and marketable title in fee simple to, or have valid and marketable rights to lease or otherwise use, all real property and all personal property that is material to the business of the Company and the Subsidiaries, in each case free and clear of all Liens, except for (i) Liens that do not materially affect the value of such property and do not materially interfere with the use made and proposed to be made of such property by the Company and the Subsidiaries and (ii) Liens for the payment of federal, state or other taxes, for which appropriate reserves have been made in accordance with GAAP, and the payment of which is neither delinquent nor subject to penalties. Neither the Company nor any of its Subsidiaries has received any written notice of any claim of any sort that has been asserted by anyone adverse to the rights of the Company or its Subsidiaries under any of the leases or subleases or licenses or with respect to the properties mentioned above, or affecting or questioning the rights of the Company or any Subsidiary to the continued possession or use of the leased or subleased or licensed premises or the properties mentioned above, other than such claims which would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

3.1.16. **Intellectual Property**. The Company and the Subsidiaries have, or have rights to use, all patents, patent applications, trademarks, trademark applications, service marks, trade names, trade secrets, inventions, copyrights, licenses and other intellectual property rights and similar rights necessary or required for use in connection with their respective businesses as described in the SEC Reports and which the failure to so have could have a Material Adverse Effect (collectively, the "**Intellectual Property Rights**"). None of, and neither the Company nor any Subsidiary has received notice (written or otherwise) that any of, the Intellectual Property Rights has expired, terminated or been abandoned, or is expected to expire or terminate or be abandoned, within two (2) years after the date of this Agreement. Neither the Company nor any Subsidiary has received, since the date of the latest audited financial statements included within the SEC Reports, a written notice of a claim or otherwise has any knowledge that the Intellectual Property Rights violate or infringe upon the rights of any Person, except as could not have or reasonably be expected to not have a Material Adverse Effect. To the knowledge of the Company, all such Intellectual Property Rights are enforceable and there is no existing infringement by another Person of any of the Intellectual Property Rights. The Company and its Subsidiaries have taken reasonable security measures to protect the secrecy, confidentiality and value of all of their intellectual properties, except where failure to do so could not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

3.1.17. **Insurance**. The Company and the Subsidiaries are insured by insurers of recognized financial responsibility against such losses and risks and in such amounts as are prudent and customary in the businesses in which the Company and the Subsidiaries are engaged, including, but not limited to, directors and officers insurance coverage in amount deemed prudent by the Company. Neither the Company nor any Subsidiary has any reason to believe that it will not be able to renew its existing insurance coverage as and when such coverage expires or to obtain similar coverage from similar insurers as may be necessary to continue its business without a significant increase in cost.

3.1.18. **Transactions with Affiliates and Employees**. Except as set forth in the SEC Reports during the past three fiscal years and the subsequent interim period through the date of this Agreement, none of the officers or directors of the Company or any Subsidiary and, to the knowledge of the Company, none of the employees of the Company or any Subsidiary is presently a party to any transaction with the Company or any Subsidiary (other than for services as employees, officers and directors), including any contract, agreement or other arrangement providing for the furnishing of services to or by, providing for rental of real or personal property to or from, providing for the borrowing of money from or lending of money to or otherwise requiring payments to or from any officer, director or such employee or, to the knowledge of the Company, any entity in which any officer, director, or any such employee has a substantial interest or is an officer, director, trustee, shareholder, member or partner, in each case in excess of $120,000 other than for (i) payment of salary or consulting fees for services rendered, (ii) reimbursement for expenses incurred on behalf of the Company and (iii) other employee benefits, including stock option agreements under any stock option plan of the Company.

3.1.19. **Sarbanes-Oxley; Internal Accounting Controls**. Except as set forth in the SEC Reports, the Company and the Subsidiaries are in material compliance with all applicable requirements of the Sarbanes-Oxley Act of 2002, as amended, that are effective as of the date hereof, and any and all applicable rules and regulations promulgated by the Commission thereunder that are effective as of the date hereof and as of the Closing Date. Except as set forth in the SEC Reports, the Company and the Subsidiaries maintain a system of internal accounting controls sufficient to provide reasonable assurance that: (i) transactions are executed in accordance with management's general or specific authorizations, (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with GAAP and to maintain asset accountability, (iii) access to assets is permitted only in accordance with management's general or specific authorization, and (iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences. Except as set forth in the SEC Reports, the Company and the Subsidiaries have established disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the Company and the Subsidiaries and designed such disclosure controls and procedures to ensure that information required to be disclosed by the Company in the reports it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Commission's rules and forms. The Company's certifying officers have evaluated the effectiveness of the disclosure controls and procedures of the Company and the Subsidiaries as of the end of the period covered by the most recently filed periodic report under the Exchange Act (such date, the "**Evaluation Date**"). The Company presented in its most recently filed periodic report under the Exchange Act the conclusions of the certifying officers about the effectiveness of the disclosure controls and procedures based on their evaluations as of the Evaluation Date. Since the Evaluation Date, there have been no changes in the internal control over financial reporting (as such term is defined in the Exchange Act) of the Company and its Subsidiaries that have materially affected, or is reasonably likely to materially affect, the internal control over financial reporting of the Company and its Subsidiaries.

3.1.20. **Certain Fees**. Except for the fees and expenses of the Placement Agent, no brokerage or finder's fees or commissions are or will be payable by the Company or any Subsidiary to any broker, financial advisor or consultant, finder, placement agent, investment banker, bank or other Person with respect to the transactions contemplated by the Transaction Documents. Other to Persons engaged by any Purchaser, the Purchasers shall have no obligation with respect to any fees or with respect to any claims made by or on behalf of other Persons for fees of a type contemplated in this Section 3.1.20 that may be due in connection with the transactions contemplated by the Transaction Documents.

3.1.21. **Private Placement**. Assuming the accuracy of the Purchasers' representations and warranties set forth in Section 3.2, no registration under the Securities Act is required for the offer and sale of the Securities by the Company to the Purchasers as contemplated hereby. To the Company's knowledge, the issuance and sale of the Securities hereunder does not contravene the rules and regulations of the Trading Market.

3.1.22. **Investment Company**. The Company is not, and is not an Affiliate of, and immediately after receipt of payment for the Securities, will not be or be an Affiliate of, an "investment company" within the meaning of the Investment Company Act of 1940, as amended. The Company shall conduct its business in a manner so that it will not become an "investment company" subject to registration under the Investment Company Act of 1940, as amended.

3.1.23. **Registration Rights**. Except as disclosed in the SEC Reports, no Person has any right to cause the Company or any Subsidiary to effect the registration under the Securities Act of any securities of the Company or any Subsidiary.

3.1.24. **Listing and Maintenance Requirements**. Except as disclosed in the SEC Reports, the Common Stock is registered pursuant to Section 12(b) or 12(g) of the Exchange Act, and the Company has taken no action designed to, or which to its knowledge is likely to have the effect of, terminating the registration of the Common Stock under the Exchange Act nor has the Company received any notification that the Commission is contemplating terminating such registration. Except as disclosed in the Company's SEC filings, the Company has not, in the 12 months preceding the date hereof, received notice from any Trading Market on which the Common Stock is or has been listed or quoted to the effect that the Company is not in compliance with the listing or maintenance requirements of such Trading Market. The Common Stock is currently eligible for electronic transfer through the Depository Trust Company or another established clearing corporation and the Company is current in payment of the fees to the Depository Trust Company (or such other established clearing corporation) in connection with such electronic transfer.

3.1.25. **Application of Takeover Protections**. The Company and the Board of Directors have taken all necessary action, if any, in order to render inapplicable any control share acquisition, business combination, poison pill (including any distribution under a rights agreement) or other similar anti-takeover provision under the Company's certificate of incorporation (or similar charter documents) or the laws of its state of incorporation that is or could become applicable to the Purchasers as a result of the Purchasers and the Company fulfilling their obligations or exercising their rights under the Transaction Documents, including without limitation as a result of the Company's issuance of the Securities and the Purchasers' ownership of the Securities.

3.1.26. **Disclosure**. Except with respect to the material terms and conditions of the transactions contemplated by the Transaction Documents, the Company confirms that neither it nor any other Person acting on its behalf has provided any of the Purchasers or their agents or counsel with any information that it believes constitutes or might constitute material, non-public information, other than such information that will be publicly disclosed pursuant to Section 4.4. The Company understands and confirms that the Purchasers will rely on the foregoing representation in effecting transactions in securities of the Company. All of the disclosure furnished by or on behalf of the Company to the Purchasers regarding the Company and its Subsidiaries, their respective businesses and the transactions contemplated hereby, is true and correct and does not contain any untrue statement of a material fact or omit to state any material fact necessary in order to make the statements made therein, in the light of the circumstances under which they were made, not misleading. The press releases disseminated by the Company during the twelve months preceding the date of this Agreement taken as a whole do not contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary in order to make the statements therein, in the light of the circumstances under which they were made and when made, not misleading. The Company acknowledges and agrees that no Purchaser makes or has made any representations or warranties with respect to the transactions contemplated hereby other than those specifically set forth in Section 3.2 hereof.

3.1.27. **No Integrated Offering**. Assuming the accuracy of the Purchasers' representations and warranties set forth in Section 3.2, neither the Company, nor any of its Affiliates, nor any Person acting on its or their behalf has, directly or indirectly, made any offers or sales of any security or solicited any offers to buy any security, under circumstances that would cause this offering of the Securities to be integrated with prior offerings by the Company for purposes of (i) the Securities Act which would require the registration of any such securities under the Securities Act, or (ii) any applicable shareholder approval provisions of any Trading Market on which any of the securities of the Company are listed or designated.

3.1.28. **Indebtedness**. The SEC Reports set forth, as of their respective dates, all outstanding secured and unsecured Indebtedness of the Company or any Subsidiary, or for which the Company or any Subsidiary has commitments. For the purposes of this Agreement, "**Indebtedness**" means (x) any liabilities for borrowed money or amounts owed in excess of $50,000 (other than trade accounts payable incurred in the ordinary course of business), (y) all guaranties, endorsements and other contingent obligations in respect of indebtedness of others, whether or not the same are or should be reflected in the Company's consolidated balance sheet (or the notes thereto), except guaranties by endorsement of negotiable instruments for deposit or collection or similar transactions in the ordinary course of business; and (z) the present value of any lease payments in excess of $50,000 due under leases required to be capitalized in accordance with GAAP. Neither the Company nor any Subsidiary is in default with respect to any Indebtedness.

3.1.29. **Tax Status**. Except as set forth in the SEC Reorts, the Company and its Subsidiaries each (i) has made or filed all material United States federal, state and local income and all foreign income and franchise tax returns, reports and declarations required by any jurisdiction to which it is subject, (ii) has paid all material taxes and other governmental assessments and charges that are material in amount, shown or determined to be due on such returns, reports and declarations and (iii) has set aside on its books provision reasonably adequate for the payment of all material taxes for periods subsequent to the periods to which such returns, reports or declarations apply. There are no unpaid taxes in any material amount claimed to be due by the taxing authority of any jurisdiction, and the officers of the Company or of any Subsidiary know of no basis for any such claim.

3.1.30. **No General Solicitation**. Neither the Company nor any Person acting on behalf of the Company has offered or sold any of the Securities by any form of general solicitation or general advertising. The Company has offered the Securities for sale only to the Purchasers and certain other "accredited investors" within the meaning of Rule 501 under the Securities Act.

3.1.31. **Foreign Corrupt Practices Act**. Neither the Company nor any Subsidiary, nor to the knowledge of the Company or any Subsidiary, any agent or other person acting on behalf of the Company or any Subsidiary, has (i) directly or indirectly, used any funds for unlawful contributions, gifts, entertainment or other unlawful expenses related to foreign or domestic political activity, (ii) made any unlawful payment to foreign or domestic government officials or employees or to any foreign or domestic political parties or campaigns from corporate funds, (iii) failed to disclose fully any contribution made by the Company or any Subsidiary (or made by any person acting on its behalf of which the Company is aware) which is in violation of law or (iv) violated in any material respect any provision of FCPA.

3.1.32. **Accountants**. The Company's accounting firm is Cherry Bekaert LLP, with offices Tampa, Florida. To the knowledge and belief of the Company, such accounting firm (i) is a registered public accounting firm as required by the Exchange Act and (ii) shall express its opinion with respect to the financial statements to be included in the Company's Annual Report for the now current fiscal year.

3.1.33. **No Disagreements with Accountants and Lawyers**. There are no disagreements of any kind presently existing, or reasonably anticipated by the Company to arise, between the Company and the accountants and lawyers formerly or presently employed by the Company and the Company is current with respect to any fees owed to its accountants and lawyers which could affect the Company's ability to perform any of its obligations under any of the Transaction Documents.

3.1.34. **Acknowledgment Regarding Purchasers' Purchase of Securities**. The Company acknowledges and agrees that each of the Purchasers is acting solely in the capacity of an arm's length purchaser with respect to the Transaction Documents and the transactions contemplated thereby. The Company further acknowledges that no Purchaser is acting as a financial advisor or fiduciary of the Company (or in any similar capacity) with respect to the Transaction Documents and the transactions contemplated thereby and any advice given by any Purchaser or any of their respective representatives or agents in connection with the Transaction Documents and the transactions contemplated thereby is merely incidental to the Purchasers' purchase of the Securities. The Company further represents to each Purchaser that the Company's decision to enter into this Agreement and the other Transaction Documents has been based solely on the independent evaluation of the transactions contemplated hereby by the Company and its representatives.

3.1.35. **Regulation M Compliance**. The Company has not, and to its knowledge no one acting on its behalf (other than the Placement Agent, as to which no representation is made) has, (i) taken, directly or indirectly, any action designed to cause or to result in the stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of any of the Securities, (ii) sold, bid for, purchased, or paid any compensation for soliciting purchases of, any of the Securities, or (iii) paid or agreed to pay to any Person any compensation for soliciting another to purchase any other securities of the Company, other than, in the case of clauses (ii) and (iii), compensation paid to the Company's Placement Agent in connection with the placement of the Securities.

3.1.36. **Officers' Certificate**. Any certificate signed by any duly authorized officer of the Company and delivered to the Purchasers shall be deemed a representation and warranty by the Company to the Purchasers as to the matters covered thereby.

3.1.37. **D&O Questionnaires**. To the Company's knowledge, all information contained in the questionnaires most recently completed by each of the Company's directors and officers and beneficial owner of 10% or more of the shares of Common Stock is true and correct in all respects and the Company has not become aware of any information which would cause the information disclosed in such questionnaires become inaccurate and incorrect.

3.1.38. **Stock Option Plans**. Each stock option granted by the Company under the Company's stock option plan, if any, was granted (i) in accordance with the terms of the Company's stock option plan and (ii) with an exercise price at least equal to the fair market value of the Common Stock on the date such stock option would be considered granted under GAAP and applicable law. No stock option granted under the Company's stock option plan has been backdated. The Company has not knowingly granted, and there is no and has been no Company policy or practice to knowingly grant, stock options prior to, or otherwise knowingly coordinate the grant of stock options with, the release or other public announcement of material information regarding the Company or its Subsidiaries or their financial results or prospects.

3.1.39. **Office of Foreign Assets Control**. Neither the Company nor any Subsidiary nor, to the Company's knowledge, any director, officer, agent, employee or affiliate of the Company or any Subsidiary is currently subject to any U.S. sanctions administered by the Office of Foreign Assets Control of the U.S. Treasury Department ("**OFAC**").

3.1.40. **U.S. Real Property Holding Corporation**. The Company is not and has never been a U.S. real property holding corporation within the meaning of Section 897 of the Internal Revenue Code of 1986, as amended, and the Company shall so certify upon Purchaser's request.

3.1.41. **Bank Holding Company Act**. Neither the Company nor any of its Subsidiaries or Affiliates is subject to the Bank Holding Company Act of 1956, as amended (the "**BHCA**") and to regulation by the Board of Governors of the Federal Reserve System (the "**Federal Reserve**"). Neither the Company nor any of its Subsidiaries or Affiliates owns or controls, directly or indirectly, five percent (5%) or more of the outstanding shares of any class of voting securities or twenty-five percent (25%) or more of the total equity of a bank or any entity that is subject to the BHCA and to regulation by the Federal Reserve. Neither the Company nor any of its Subsidiaries or Affiliates exercises a controlling influence over the management or policies of a bank or any entity that is subject to the BHCA and to regulation by the Federal Reserve.

3.1.42. **Money Laundering**. The operations of the Company and its Subsidiaries are and have been conducted at all times in compliance with applicable financial record-keeping and reporting requirements of the Currency and Foreign Transactions Reporting Act of 1970, as amended, applicable money laundering statutes and applicable rules and regulations thereunder (collectively, the "**Money Laundering Laws**"), and no Action or Proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company or any Subsidiary with respect to the Money Laundering Laws is pending or, to the knowledge of the Company or any Subsidiary, threatened.

3.1.43. **No Disqualification Events**. With respect to the Securities to be offered and sold hereunder in reliance on Rule 506 under the Securities Act, none of the Company, any of its predecessors, any affiliated issuer, any director, executive officer, other officer of the Company participating in the offering hereunder, any beneficial owner of 20% or more of the Company's outstanding voting equity securities, calculated on the basis of voting power, nor any promoter (as that term is defined in Rule 405 under the Securities Act) connected with the Company in any capacity at the time of sale (each, an "**Issuer Covered Person**" and, together, "**Issuer Covered Persons**") is subject to any of the "Bad Actor" disqualifications described in Rule 506(d)(1)(i) to (viii) under the Securities Act (a "**Disqualification Event**"), except for a Disqualification Event covered by Rule 506(d)(2) or (d)(3). The Company has exercised reasonable care to determine whether any Issuer Covered Person is subject to a Disqualification Event. The Company has complied, to the extent applicable, with its disclosure obligations under Rule 506(e), and has furnished to the Purchasers a copy of any disclosures provided thereunder.

3.1.44. **Other Covered Persons**. Other than the Placement Agent, the Company is not aware of any person (other than any Issuer Covered Person) that has been or will be paid (directly or indirectly) remuneration for solicitation of purchasers in connection with the sale of any Securities.

3.1.45. **Notice of Disqualification Events**. The Company will notify the Purchasers and the Placement Agent in writing, prior to the Closing Date of (i) any Disqualification Event relating to any Issuer Covered Person and (ii) any event that would, with the passage of time, become a Disqualification Event relating to any Issuer Covered Person.

3.1.46. **Cybersecurity**. (i) (a) There has been no security breach or other compromise of or relating to any of the Company's or any Subsidiary's information technology and computer systems, networks, hardware, software, data (including the data of its respective customers, employees, suppliers, vendors and any third party data maintained by or on behalf of it), equipment or technology (collectively, "**IT Systems and Data**") and (b) the Company and the Subsidiaries have not been notified of, and has no knowledge of any event or condition that would reasonably be expected to result in, any security breach or other compromise to its IT Systems and Data; (ii) the Company and the Subsidiaries are presently in compliance with all applicable laws or statutes and all judgments, orders, rules and regulations of any court or arbitrator or governmental or regulatory authority, internal policies and contractual obligations relating to the privacy and security of IT Systems and Data and to the protection of such IT Systems and Data from unauthorized use, access, misappropriation or modification, except, in the case of clauses (i) and (ii) herein, as would not, individually or in the aggregate, have a Material Adverse Effect; (iii) the Company and the Subsidiaries have implemented and maintained commercially reasonable safeguards to maintain and protect its material confidential information and the integrity, continuous operation, redundancy and security of all IT Systems and Data; and (iv) the Company and the Subsidiaries have implemented backup and disaster recovery technology consistent with industry standards and practices.

3.2. **Representations and Warranties of the Purchasers**. Each Purchaser, for itself and for no other Purchaser, hereby represents and warrants as of the date hereof and as of the Closing Date to the Company as follows (unless as of a specific date therein, in which case they shall be accurate as of such date):

3.2.1. **Organization; Authority**. Such Purchaser is either an individual or an entity duly incorporated or formed, validly existing and in good standing under the law of the jurisdiction of its incorporation or formation with full right, corporate, partnership, limited liability company or similar power and authority to enter into and to consummate the transactions contemplated by the Transaction Documents and otherwise to carry out its obligations hereunder and thereunder. The execution and delivery of the Transaction Documents and performance by such Purchaser of the transactions contemplated by the Transaction Documents have been duly authorized by all necessary corporate, partnership, limited liability company or similar action, as applicable, on the part of such Purchaser. Each Transaction Document to which it is a party has been duly executed by such Purchaser, and when delivered by such Purchaser in accordance with the terms hereof, will constitute the legal, valid and binding obligation of such Purchaser, enforceable against it in accordance with its terms, except (i) as limited by general equitable principles and applicable bankruptcy, insolvency, reorganization, moratorium and other laws of general application affecting enforcement of creditors' rights generally, (ii) as limited by laws relating to the availability of specific performance, injunctive relief or other equitable remedies and (iii) insofar as indemnification and contribution provisions may be limited by applicable law.

3.2.2. **Own Account**. Such Purchaser understands that the Securities are "restricted securities" as defined in Rule 144 and have not been registered under the Securities Act or any applicable state securities law and is acquiring the Securities as principal for its own account and not with a view to or for distributing or reselling such Securities or any part thereof in violation of the Securities Act or any applicable state securities law, has no present intention of distributing any of such Securities in violation of the Securities Act or any applicable state securities law and has no direct or indirect arrangement or understandings with any other persons to distribute or regarding the distribution of such Securities in violation of the Securities Act or any applicable state securities law (this representation and warranty shall not limit such Purchaser's right to sell the Securities pursuant to a registration statement or otherwise in compliance with applicable federal and state securities laws). Such Purchaser is acquiring the Securities hereunder in the ordinary course of its business.

3.2.3. **Purchaser Status**. At the time such Purchaser was offered the Securities, it was, and as of the date hereof it is either: (i) an "accredited investor" as defined in Rule 501(a)(1), (a)(2), (a)(3), (a)(7), (a)(8), (a)(9), (a)(12), or (a)(13) under the Securities Act or (ii) a "qualified institutional buyer" as defined in Rule 144A(a)(1) under the Securities Act. Such Purchaser hereby represents that neither such Purchaser nor any of its Rule 506(d) Related Parties (as defined below) is a "bad actor" within the meaning of Rule 506(d) promulgated under the Securities Act. For purposes of this Agreement, "Rule 506(d) Related Party" shall mean a person or entity covered by the "Bad Actor disqualification" provision of Rule 506(d) of the Securities Act.

3.2.4. **Experience of Such Purchaser**. Such Purchaser, either alone or together with its representatives, has such knowledge, sophistication and experience in business and financial matters so as to be capable of evaluating the merits and risks of the prospective investment in the Securities, and has so evaluated the merits and risks of such investment. Such Purchaser is able to bear the economic risk of an investment in the Securities and, at the present time, is able to afford a complete loss of such investment.

3.2.5. **General Solicitation**. Such Purchaser is not, to such Purchaser's knowledge, purchasing the Securities as a result of any advertisement, article, notice or other communication regarding the Securities published in any newspaper, magazine or similar media or broadcast over television or radio or presented at any seminar or, to the knowledge of such Purchaser, any other general solicitation or general advertisement.

3.2.6. **Access to Information**. Such Purchaser acknowledges that it has had the opportunity to review and has reviewed the Transaction Documents (including all exhibits and schedules thereto) and the SEC Reports and has been afforded (i) the opportunity to ask such questions as it has deemed necessary of, and to receive answers from, representatives of the Company concerning the terms and conditions of the offering of the Securities and the merits and risks of investing in the Securities; (ii) access to information about the Company and its financial condition, results of operations, business, properties, management and prospects sufficient to enable it to evaluate its investment; and (iii) the opportunity to obtain such additional information that the Company possesses or can acquire without unreasonable effort or expense that is necessary to make an informed investment decision with respect to the investment. Without limiting the foregoing, such Purchaser acknowledges that the Company has recurring losses and negative cash flows from operations that raise substantial doubt about its ability to continue as a going concern. Such Purchaser acknowledges and agrees that neither the Placement Agent nor any Affiliate of the Placement Agent has provided such Purchaser with any information or advice with respect to the Securities nor is such information or advice necessary or desired. Neither the Company, the Placement Agent nor any of their respective Affiliates has made or makes any representation as to the Company or the quality of the Securities other than those set forth in this Agreement. Furthermore, the Placement Agent and any Affiliate may have acquired non-public information with respect to the Company which such Purchaser agrees need not be and has not been provided to it (other than with respect to the transactions contemplated by the Transaction Documents). In connection with the issuance of the Securities to such Purchaser, neither the Placement Agent nor any of its Affiliates has acted as a financial advisor or fiduciary to such Purchaser.

3.2.7. **Certain Transactions and Confidentiality**. Other than consummating the transactions contemplated hereunder, such Purchaser has not, nor has any Person acting on behalf of or pursuant to any understanding with such Purchaser, directly or indirectly executed any purchases or sales, including Short Sales, of the securities of the Company during the period commencing as of the time that such Purchaser first received a term sheet (written or oral) from the Company or any other Person representing the Company setting forth the material terms of the transactions contemplated hereunder and ending immediately prior to the execution hereof. Notwithstanding the foregoing, in the case of a Purchaser that is a multi-managed investment vehicle whereby separate portfolio managers manage separate portions of such Purchaser's assets and the portfolio managers have no direct knowledge of the investment decisions made by the portfolio managers managing other portions of such Purchaser's assets, the representation set forth above shall only apply with respect to the portion of assets managed by the portfolio manager that made the investment decision to purchase the Securities covered by this Agreement. Other than to other Persons party to this Agreement or to such Purchaser's representatives, including, without limitation, its officers, directors, partners, legal and other advisors, employees, agents and Affiliates, such Purchaser has maintained the confidentiality of all disclosures made to it in connection with this transaction (including the existence and terms of this transaction). Notwithstanding the foregoing, for the avoidance of doubt, nothing contained herein shall constitute a representation or warranty, or preclude any actions, with respect to locating or borrowing shares in order to effect Short Sales or similar transactions in the future.

3.2.8. No Voting Agreements. The Purchaser is not a party to any agreement or arrangement, whether written or oral, between the Purchaser and any other Purchaser and any of the Company's stockholders as of the date hereof, regulating the management of the Company, the stockholders' rights in the Company, the transfer of shares in the Company, including any voting agreements, stockholder agreements or any other similar agreement, even if its title is different or has any other relations or agreements with any of the Company's stockholders, directors or officers.

3.2.9. Brokers. No agent, broker, investment banker, person or firm acting in a similar capacity on behalf of or under the authority of the Purchaser is or will be entitled to any broker's or finder's fee or any other commission or similar fee, directly or indirectly, for which the Company or any of its Affiliates after the Closing could have any liabilities in connection with this Agreement, any of the transactions contemplated by this Agreement, or on account of any action taken by the Purchaser in connection with the transactions contemplated by this Agreement.

3.2.10. Independent Advice. Each Purchaser understands that nothing in this Agreement or any other materials presented by or on behalf of the Company to the Purchaser in connection with the purchase of the Securities constitutes legal, tax or investment advice.

The Company acknowledges and agrees that the representations contained in this Section 3.2 shall not modify, amend or affect such Purchaser's right to rely on the Company's representations and warranties contained in this Agreement or any representations and warranties contained in any other Transaction Document or any other document or instrument executed and/or delivered in connection with this Agreement or the consummation of the transactions contemplated hereby. Notwithstanding the foregoing, for the avoidance of doubt, nothing contained herein shall constitute a representation or warranty, or preclude any actions, except as set forth in this Agreement, with respect to locating or borrowing shares in order to effect Short Sales or similar transactions in the future.

4. **Other Agreements of the Parties**.

4.1. **Transfer Restrictions**.

4.1.1. The Securities may only be disposed of in compliance with state and federal securities laws. In connection with any transfer of Securities other than pursuant to an effective registration statement or Rule 144, to the Company or to an Affiliate of a Purchaser or in connection with a pledge as contemplated in Section 4.1.2, the Company may require the transferor thereof to provide to the Company an opinion of counsel selected by the transferor and reasonably acceptable to the Company, the form and substance of which opinion shall be reasonably satisfactory to the Company, to the effect that such transfer does not require registration of such transferred Securities under the Securities Act. As a condition of transfer, any such transferee shall agree in writing to be bound by the terms of this Agreement and shall have the rights and obligations of a Purchaser under this Agreement.

4.1.2. The Purchasers agree to the imprinting, so long as is required by this Section 4.1, of a legend on any of the Securities in substantially the following form:

THIS SECURITY HAS NOT BEEN REGISTERED WITH THE SECURITIES AND EXCHANGE COMMISSION OR THE SECURITIES COMMISSION OF ANY STATE IN RELIANCE UPON AN EXEMPTION FROM REGISTRATION UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "SECURITIES ACT"), AND, ACCORDINGLY, MAY NOT BE OFFERED OR SOLD EXCEPT PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT UNDER THE SECURITIES ACT OR PURSUANT TO AN AVAILABLE EXEMPTION FROM, OR IN A TRANSACTION NOT SUBJECT TO, THE REGISTRATION REQUIREMENTS OF THE SECURITIES ACT AND IN ACCORDANCE WITH APPLICABLE STATE SECURITIES LAWS. THIS SECURITY MAY BE PLEDGED IN CONNECTION WITH A BONA FIDE MARGIN ACCOUNT WITH A REGISTERED BROKER-DEALER OR OTHER LOAN WITH A FINANCIAL INSTITUTION THAT IS AN "ACCREDITED INVESTOR" AS DEFINED IN RULE 501(a) UNDER THE SECURITIES ACT OR OTHER LOAN SECURED BY SUCH SECURITIES.

The Company acknowledges and agrees that a Purchaser may from time to time pledge pursuant to a bona fide margin agreement with a registered broker-dealer or grant a security interest in some or all of the Securities to a financial institution that is an "accredited investor" as defined in Rule 501(a) under the Securities Act and, if required under the terms of such arrangement, such Purchaser may transfer pledged or secured Securities to the pledgees or secured parties. Such a pledge or transfer would not be subject to approval of the Company and no legal opinion of legal counsel of the pledgee, secured party or pledgor shall be required in connection therewith. Further, no notice shall be required of such pledge. At the appropriate Purchaser's expense, the Company will execute and deliver such reasonable documentation as a pledgee or secured party of Securities may reasonably request in connection with a pledge or transfer of the Securities.

4.1.3. Each Purchaser, severally and not jointly with the other Purchasers, agrees with the Company that such Purchaser will sell any Securities pursuant to either the registration requirements of the Securities Act, including any applicable prospectus delivery requirements, or an exemption therefrom, and acknowledges that the removal of the restrictive legend from certificates representing Securities is predicated upon the Company's reliance upon this understanding.

4.2. **Furnishing of Information; Public Information**.

4.2.1. Until no Purchaser owns any Securities, the Company covenants to maintain the effectiveness of the registration of the Common Stock under Section 12(b) or 12(g) of the Exchange Act and to use reasonable best efforts to timely file (or obtain extensions in respect thereof and file within the applicable grace period) all reports required to be filed by the Company after the date hereof pursuant to the Exchange Act even if the Company is not then subject to the reporting requirements of the Exchange Act.

4.2.2. If the Notes remain outstanding on the six (6) month anniversary of the date hereof, then, at any time during the period commencing from the six (6) month anniversary of the date hereof and ending on the earlier of (X) such time that all of the Notes may be sold without the requirement for the Company to be in compliance with Rule 144(c)(1) and otherwise without restriction or limitation pursuant to Rule 144 and (Y) such date on which no Purchaser owns any Notes, if the Company (i) shall fail for any reason to satisfy the current public information requirement under Rule 144(c) or (ii) has ever been an issuer described in Rule 144(i)(1)(i) or becomes such an issuer in the future, and the Company shall fail to satisfy any condition set forth in Rule 144(i)(2) (a "**Public Information Failure**") then, in addition to such Purchaser's other available remedies, the Company shall pay to a Purchaser, in cash, as partial liquidated damages and not as a penalty, by reason of any such delay in or reduction of its ability to sell the Securities, an amount in cash equal to two percent (2.0%) of the aggregate Subscription Amount of such Purchaser's Securities on the day of a Public Information Failure and on every thirtieth (30th) day (prorated for periods totaling less than thirty days) thereafter until the earlier of (a) the date such Public Information Failure is cured and (b) such time that such public information is no longer required for the Purchasers to transfer the Shares pursuant to Rule 144. The payments to which a Purchaser shall be entitled pursuant to this Section 4.2.2 are referred to herein as "**Public Information Failure Payments**." Public Information Failure Payments shall be paid on the earlier of (i) the last day of the calendar month during which such Public Information Failure Payments are incurred and (ii) the third (3rd) Business Day after the event or failure giving rise to the Public Information Failure Payments is cured. In the event the Company fails to make Public Information Failure Payments in a timely manner, such Public Information Failure Payments shall bear interest at the rate of 1.5% per month (prorated for partial months) until paid in full. Nothing herein shall limit such Purchaser's right to pursue actual damages for the Public Information Failure, and such Purchaser shall have the right to pursue all remedies available to it at law or in equity including, without limitation, a decree of specific performance and/or injunctive relief.

4.3. **Integration**. The Company shall not sell, offer for sale or solicit offers to buy or otherwise negotiate in respect of any security (as defined in Section 2 of the Securities Act) that would be integrated with the offer or sale of the Securities in a manner that would require the registration under the Securities Act of the sale of the Securities or that would be integrated with the offer or sale of the Securities for purposes of the rules and regulations of any Trading Market such that it would require shareholder approval prior to the closing of such other transaction unless shareholder approval is obtained before the closing of such subsequent transaction.

4.4. **Securities Laws Disclosure; Publicity**. The Company shall by the Disclosure Time, issue a press release disclosing the material terms of the transactions contemplated hereby and file a Current Report on Form 8-K, including the Transaction Documents as exhibits thereto, with the Commission. From and after the filing of such Form 8-K, the Company represents to the Purchasers that it shall have publicly disclosed all material, non-public information delivered to any of the Purchasers by the Company or any of its Subsidiaries, or any of their respective officers, directors, employees or agents (including, without limitation, the Placement Agent) in connection with the transactions contemplated by the Transaction Documents. In addition, effective upon the filing of such Form 8-K, the Company acknowledges and agrees that any and all confidentiality or similar obligations under any agreement, whether written or oral, between the Company, any of its Subsidiaries, or any of their respective officers, directors, agents (including, without limitation, the Placement Agent), employees or Affiliates on the one hand, and any of the Purchasers or any of their Affiliates on the other hand, shall terminate and be of no further force or effect. The Company understands and confirms that each Purchaser shall be relying on the foregoing covenant in effecting transactions in securities of the Company. The Company and each Purchaser shall consult with each other in issuing any other press releases with respect to the transactions contemplated hereby, and neither the Company nor any Purchaser shall issue any such press release nor otherwise make any such public statement without the prior consent of the Company, with respect to any press release of any Purchaser, or without the prior consent of each Purchaser, with respect to any press release of the Company, which consent shall not unreasonably be withheld or delayed, except if such disclosure is required by law, in which case the disclosing party shall promptly provide the other party with prior notice of such public statement or communication. Notwithstanding the foregoing, the Company shall not publicly disclose the name of any Purchaser, or include the name of any Purchaser in any filing with the Commission or any regulatory agency or Trading Market, without the prior written consent of such Purchaser, except (a) to the extent required by federal securities law in connection with the filing of final Transaction Documents with the Commission and (b) to the extent such disclosure is required by law or Trading Market regulations, in which such cases the Company shall (x) obtain prior advice of competent counsel that such disclosure is required, (y) provide the Purchasers with prior notice of such disclosure permitted under this Section 4.4 and (z) reasonably cooperate with such Purchasers regarding such disclosure.

4.5. **Participation Right**. Each Purchaser shall have the right to invest in the Company's next Qualified Equity Raise on the same terms and conditions as that offered to third parties in such Qualified Equity Raise. The total amount that a Purchaser may invest in a Qualified Equity Raist shall not exceed fifty percent (50%) of the total gross proceeds raised by the Company in such Qualified Equity Raise multiplied by a fraction, the numerator of which is the Purchaser's Subscription Amount and the denominator of which is the aggregate amount of all the Purchasers' Subscription Amounts. The Company shall provide to each Purchaser (a) copies of the subscription documents related to the Qualified Equity Raise and (b) notice to each Purchaser of the anticipated closing of a Qualified Equity Raise at least fifteen (15) Business Days before such anticipated closing (the "**Equity Raise Notice**"). To exercise such right to participate, a Purchaser must return to the Company its completed and executed subscription documents related to such Qualified Equity Raise within five (5) Business Days of receipt of the Equity Raise Notice and such subscription documents.

4.6. **Shareholder Rights Plan**. No claim will be made or enforced by the Company or, with the consent of the Company, any other Person, that any Purchaser is an "**Acquiring Person**" under any control share acquisition, business combination, poison pill (including any distribution under a rights agreement) or similar anti-takeover plan or arrangement in effect or hereafter adopted by the Company, or that any Purchaser could be deemed to trigger the provisions of any such plan or arrangement, by virtue of receiving Securities under the Transaction Documents or under any other agreement between the Company and the Purchasers.

4.7. **Non-Public Information**. Except with respect to the material terms and conditions of the transactions contemplated by the Transaction Documents, which shall be disclosed pursuant to Section 4.4, the Company covenants and agrees that neither it, nor any other Person acting on its behalf will provide any Purchaser or its agents or counsel with any information that constitutes, or the Company reasonably believes constitutes, material non-public information, unless prior thereto such Purchaser shall have consented in writing to the receipt of such information and agreed in writing with the Company to keep such information confidential. The Company understands and confirms that each Purchaser shall be relying on the foregoing covenant in effecting transactions in securities of the Company. To the extent that the Company, any of its Subsidiaries, or any of their respective officers, directors, agents, employees or Affiliates delivers any material, non-public information to a Purchaser without such Purchaser's consent, the Company hereby covenants and agrees that such Purchaser shall not have any duty of confidentiality to the Company, any of its Subsidiaries, or any of their respective officers, directors, agents, employees or Affiliates, or a duty to the Company, any of its Subsidiaries or any of their respective officers, directors, agents, employees or Affiliates not to trade on the basis of, such material, non-public information, provided that the Purchaser shall remain subject to applicable law. To the extent that any notice provided pursuant to any Transaction Document constitutes, or contains, material, non-public information regarding the Company or any Subsidiaries, the Company shall simultaneously with the delivery of such notice file such notice with the Commission pursuant to a Current Report on Form 8-K. The Company understands and confirms that each Purchaser shall be relying on the foregoing covenant in effecting transactions in securities of the Company.

4.8. **Use of Proceeds**. The Company shall use the net proceeds from the sale of the Securities hereunder for general corporate purposes (which for the avoidance of doubt may include acquisitions, in the Company's discretion), including working capital. The Company shall not use such proceeds: (a) for the satisfaction of any portion of the Company's commercial debt (other than payment of trade payables in the ordinary course of the Company's business and prior practices), (b) for the redemption of any shares of Common Stock or Common Stock Equivalents, (c) for the settlement of any outstanding litigation or (d) in violation of FCPA or OFAC regulations.

4.9. **Indemnification of Purchasers**. Subject to the provisions of this Section 4.8, the Company will indemnify and hold each Purchaser and its directors, officers, shareholders, members, partners, employees and agents (and any other Persons with a functionally equivalent role of a Person holding such titles notwithstanding a lack of such title or any other title), each Person who controls such Purchaser (within the meaning of Section 15 of the Securities Act and Section 20 of the Exchange Act), and the directors, officers, shareholders, agents, members, partners or employees (and any other Persons with a functionally equivalent role of a Person holding such titles notwithstanding a lack of such title or any other title) of such controlling persons (each, a "**Purchaser Party**") harmless from any and all losses, liabilities, obligations, claims, contingencies, damages, costs and expenses, including all judgments, amounts paid in settlements, court costs and reasonable attorneys' fees and costs of investigation that any such Purchaser Party may suffer or incur as a result of or relating to (a) any breach of any of the representations, warranties, covenants or agreements made by the Company in this Agreement or in the other Transaction Documents, (b) any action instituted against the Purchaser Parties in any capacity (including a Purchaser Party's status as an investor), or any of them or their respective Affiliates, by the Company or any shareholder of the Company who is not an Affiliate of such Purchaser Party, arising out of or relating to any of the transactions contemplated by the Transaction Documents (except to the extent such action is based upon a material breach of the representations, warranties or covenants made by such Purchaser Party in any Transaction Document or any conduct by such Purchaser Party which is finally judicially determined to constitute fraud, gross negligence or willful misconduct). If any action shall be brought against any Purchaser Party in respect of which indemnity may be sought pursuant to this Agreement, such Purchaser Party shall promptly notify the Company in writing, and, except with respect to direct claims brought by the Company, the Company shall have the right to assume the defense thereof with counsel of its own choosing reasonably acceptable to the Purchaser Party. Any Purchaser Party shall have the right to employ separate counsel in any such action and participate in the defense thereof, but the fees and expenses of such counsel shall be at the expense of such Purchaser Party except to the extent that (i) the employment thereof has been specifically authorized by the Company in writing, (ii) the Company has failed after a reasonable period of time to assume such defense and to employ counsel or (iii) in such action there is, in the reasonable opinion of counsel to the applicable Purchaser Party (which may be internal counsel), a material conflict on any material issue between the position of the Company and the position of such Purchaser Party, in which case the Company shall be responsible for the reasonable fees and expenses of no more than one such separate counsel. The Company will not be liable to any Purchaser Party under this Agreement for (1) any settlement by a Purchaser Party effected without the Company's prior written consent, which shall not be unreasonably withheld or delayed or (2) to the extent, but only to the extent that a loss, claim, damage or liability is attributable to any Purchaser Party's breach of any of the representations, warranties, covenants or agreements made by such Purchaser Party in this Agreement or in the other Transaction Documents. In addition, if any Purchaser Party takes actions to collect amounts due under any Transaction Documents or to enforce the provisions of any Transaction Documents, then the Company shall pay the costs incurred by such Purchaser Party for such collection, enforcement or action, including, but not limited to, reasonable attorneys' fees and disbursements. The indemnification and other payment obligations required by this Section 4.8 shall be made by periodic payments of the amount thereof during the course of the investigation, defense, collection, enforcement or action, as and when bills are received or are incurred; provided, however, that if any Purchaser Party is finally judicially determined not to be entitled to indemnification or payment under this Section 4.8, such Purchaser Party shall promptly reimburse the Company for any payments that are advanced under this sentence. The indemnity agreements contained herein shall be in addition to any cause of action or similar right of any Purchaser Party against the Company or others and any liabilities the Company may be subject to pursuant to law.

4.10. **Equal Treatment of Purchasers**. No consideration (including any modification of any Transaction Document) shall be offered or paid to any Person to amend or consent to a waiver or modification of any provision of the Transaction Documents unless the same consideration is also offered to all of the parties to the Transaction Documents. The Company shall not make any payment of principal or interest on the Notes in amounts which are disproportionate to the respective principal amounts outstanding on the Notes at any applicable time. For clarification purposes, this provision constitutes a separate right granted to each Purchaser by the Company and negotiated separately by each Purchaser, and is intended for the Company to treat the Purchasers as a class and shall not in any way be construed as the Purchasers acting in concert or as a group with respect to the purchase, disposition or voting of Securities or otherwise.

4.11. **Certain Transactions and Confidentiality**. Each Purchaser, severally and not jointly with the other Purchasers, covenants that neither it, nor any Affiliate acting on its behalf or pursuant to any understanding with it will execute any purchases or sales, including Short Sales, of any of the Company's securities during the period commencing with the execution of this Agreement and ending at such time that the transactions contemplated by this Agreement are first publicly announced pursuant to the initial Form 8-K as described in Section 4.4. Each Purchaser, severally and not jointly with the other Purchasers, covenants that until such time as the transactions contemplated by this Agreement are publicly disclosed by the Company pursuant to the initial Form 8-K as described in Section 4.4, such Purchaser will maintain the confidentiality of the existence and terms of this transaction. Notwithstanding the foregoing and notwithstanding anything contained in this Agreement to the contrary, the Company expressly acknowledges and agrees that (i) no Purchaser makes any representation, warranty or covenant hereby that it will not engage in effecting transactions in any securities of the Company after the time that the transactions contemplated by this Agreement are first publicly announced pursuant to the initial Form 8-K as described in Section 4.4, (ii) no Purchaser shall be restricted or prohibited from effecting any transactions in any securities of the Company in accordance with applicable securities laws from and after the time that the transactions contemplated by this Agreement are first publicly announced pursuant to the initial Form 8-K as described in Section 4.4 and (iii) no Purchaser shall have any duty of confidentiality or duty not to trade in the securities of the Company to the Company, any of its Subsidiaries, or any of their respective officers, directors, employees, agents or Affiliates after the issuance of the initial Form 8-K as described in Section 4.4. Notwithstanding the foregoing, in the case of a Purchaser that is a multi-managed investment vehicle whereby separate portfolio managers manage separate portions of such Purchaser's assets and the portfolio managers have no direct knowledge of the investment decisions made by the portfolio managers managing other portions of such Purchaser's assets, the covenant set forth above shall only apply with respect to the portion of assets managed by the portfolio manager that made the investment decision to purchase the Securities covered by this Agreement.

4.12. **Form D; Blue Sky Filings**. The Company agrees to timely file a Form D with respect to the Securities as required under Regulation D and to provide a copy thereof, promptly upon request of any Purchaser. The Company shall take such action as the Company shall reasonably determine is necessary in order to obtain an exemption for, or to qualify the Securities for, sale to the Purchasers at the Closing under applicable securities or "Blue Sky" laws of the states of the United States, and shall provide evidence of such actions promptly upon request of any Purchaser.

4.13. **Lock-Up Agreements**. The Company shall not amend, modify, waive or terminate any provision of any of the Lock-Up Agreements (and any lock-up agreements contemplated in the Lock-Up Agreements) except to extend the term of the lock-up period and shall enforce the provisions of each Lock-Up Agreement (and any lock-up agreements contemplated in the Lock-Up Agreements) in accordance with its terms. If any party to a Lock-Up Agreement (and any lock-up agreements contemplated in the Lock-Up Agreements) breaches any provision of a Lock-Up Agreement, the Company shall promptly use its best efforts to seek specific performance of the terms of such Lock-Up Agreement (and any lock-up agreements contemplated in the Lock-Up Agreements).

4.14. **QEF Election**. If a Purchaser so requests in writing for any taxable year of the Company, the Company, after consulting with its outside accounting firm, shall within fifteen (15) Business Days notify such Purchaser in writing that either (A) neither the Company nor any of its Subsidiaries was a "passive foreign investment company" as defined in Section 1297 of the Code ("**PFIC**") for such year, or (B) the Company and/or one or more of its Subsidiaries was a PFIC for such year, in which event the Company shall provide to such Purchaser, upon the reasonable written request of such Purchaser, the information reasonably necessary to allow such Purchaser to elect to treat each of the Company and any applicable Subsidiaries (if any), respectively, as a "qualified electing fund" (within the meaning of Section 1295 of the Code for such year, including a "PFIC Annual Information Statement" as described in Treasury Regulation Section 1.1295-1(g)(1) (or any successor Treasury Regulation).

4.15. **Security**.

4.15.1. **Security**. Effective upon the occurrence of an Event of Default (as defined in the Notes), the Company hereby grants to the holders of the Notes, in order to secure the Company's obligations under the Notes, a first lien and continuing security interest in and to all present and future intellectual property rights owned by the Company, including all patents, copyrights and trademarks and all cash and noncash proceeds thereof, whether now owned or hereafter acquired by the Company, wherever located, and whether now or hereafter existing or arising (collectively, the "**Collateral**") (terms used in this section 4.14 shall have the meaning provided in the Uniform Commercial Code of New York ("UCC"); provided, however, that in the event that, by reason of mandatory provisions of law, any or all of the perfection or priority of, or remedies with respect to, any Collateral is governed by the Uniform Commercial Code as enacted and in effect in a jurisdiction other than the State of New York, the term "UCC" shall mean the Uniform Commercial Code as enacted and in effect in such other jurisdiction solely for purposes of the provisions hereof relating to such perfection, priority or remedies). Upon written notice of an Event of Default, the Company shall file, within five (5) days of the date thereof, a UCC-1 Financing Statement perfecting the Purchasers security interest in the Collateral. The Company shall perform any and all acts reasonably requested by the Purchasers to establish, maintain and continue the security interests on the Collateral. In addition, regardless of whether an Event of Default exists, the Company will not, while the Notes are outstanding, without the prior written consent of the Purchasers, permit or suffer to exist any lien or encumbrance on the Collateral, or any interest therein (legal or equitable), or any part thereof, either inferior or superior in right to the lien contemplated herein.

4.15.2. Cooperation. The Company will, at its own expense, make, execute, endorse, acknowledge, file and/or deliver to the Purchasers from time to time such confirmatory assignments, conveyances, financing statements, powers of attorney, certificates and other assurances or instruments and take such further steps relating to the Collateral and other property or rights covered by the interests hereby granted, which a Purchaser, upon written discretion, deems reasonably appropriate or advisable to perfect, preserve or protect its security interest in the Collateral. Without limiting the foregoing, the Company hereby authorizes the Purchasers to file any such financing statements as the Purchasers shall determine to be necessary or advisable to perfect the security interest contemplated hereunder, without the signature of the Company. Notwithstanding anything to the contrary herein, the Company shall not be required to take any action in any non-U.S. jurisdiction or required by the laws of any non-U.S. jurisdiction to create any security interests in assets located or titled outside of the United States or to perfect or make enforceable any security interests in any such assets (it being understood that there shall be no security agreements, pledge agreements or other collateral documents governed under the laws of any jurisdiction other than the United States, any State thereof or the District of Columbia).

4.15.3. Remedies. In addition to all other rights, options, and remedies granted to the Purchasers, upon the occurrence and during the continuation of an Event of Default, the Purchasers may exercise all other rights granted to it under the Notes and all rights under the UCC in effect in the applicable jurisdiction(s) and under any other applicable law, including the right to take possession of, send notices regarding, and collect directly the Collateral, with or without judicial process, and to exercise all rights and remedies available to the Purchasers with respect to the Collateral under the UCC in effect in the applicable jurisdiction(s).

4.16. **Voting**. Each Purchaser covenants to vote, and shall cause its Affiliates to vote, the Shares of Series G Stock on any proposal presented to the shareholders of the Corporation for purposes of approving the Reverse Split Proposal, the Amendment Proposal and the Adjournment Proposal and agrees that such Shares of Series G Mirroring Preferred Stock, shall, to the extent voted in favor of the proposals, be automatically and without further action of the Purchasers voted in the same proportions as shares of Common Stock (excluding any shares of Common Stock that are not voted) and any other issued and outstanding shares of preferred stock of the Corporation (other than the Series G Mirroring Preferred Stock or shares of such preferred stock not voted) are voted on the Reverse Split Proposal, the Amendment Proposal and the Adjournment Proposal, as applicable. For the avoidance of doubt, and for illustrative purposes only, if 30% of the aggregate votes cast by Common Stock and other preferred stock, if any, in connection with the Amendment Proposal are voted against such proposal and 70% of the aggregate votes cast by Common Stock and other preferred stock, if any, voting in connection with the Amendment Proposal are voted in favor thereof, then 30% of the votes cast by the shares of Series G Mirroring Preferred Stock (assuming all votes made in favor of the proposal) voting in connection with the Amendment Proposal shall vote against the approval of the Amendment and 70% of such votes shall be cast in favor of the Amendment Proposal.

5. **Miscellaneous**.

5.1. **Termination**. This Agreement may be terminated by any Purchaser, as to such Purchaser's obligations hereunder only and without any effect whatsoever on the obligations between the Company and the other Purchasers, by written notice to the other parties, if the Closing has not been consummated on or before the fifth (5^{th}) Trading Day following the date hereof; provided, however, that no such termination will affect the right of any party to sue for any breach by any other party (or parties).

5.2. **Fees and Expenses**. Except as expressly set forth in the Transaction Documents to the contrary, each party shall pay the fees and expenses of its advisers, counsel, accountants and other experts, if any, and all other expenses incurred by such party incident to the negotiation, preparation, execution, delivery and performance of this Agreement. The Company shall pay all Transfer Agent fees (including, without limitation, any fees required for same-day processing of any instruction letter delivered by the Company and any exercise notice delivered by a Purchaser), stamp taxes and other taxes and duties levied in connection with the delivery of any Securities to the Purchasers.

5.3. **Entire Agreement**. The Transaction Documents, together with the exhibits and schedules thereto, contain the entire understanding of the parties with respect to the subject matter hereof and thereof and supersede all prior agreements and understandings, oral or written, with respect to such matters, which the parties acknowledge have been merged into such documents, exhibits and schedules.

5.4. **Notices**. Any and all notices or other communications or deliveries required or permitted to be provided hereunder shall be in writing and shall be deemed given and effective on the earliest of: (a) the time of transmission, if such notice or communication is delivered via email at the email address as set forth on the signature pages attached hereto at or prior to 5:30 p.m. (New York City time) on a Trading Day, (b) the next Trading Day after the time of transmission, if such notice or communication is delivered via email at the email address as set forth on the signature pages attached hereto on a day that is not a Trading Day or later than 5:30 p.m. (New York City time) on any Trading Day, (c) the second (2^{nd}) Trading Day following the date of mailing, if sent by U.S. nationally recognized overnight courier service or (d) upon actual receipt by the party to whom such notice is required to be given. The address for such notices and communications shall be as set forth on the signature pages attached hereto. To the extent that any notice provided pursuant to any Transaction Document constitutes, or contains material, non-public information regarding the Company or any of the Subsidiaries, the Company shall simultaneously file such notice with the Commission pursuant to a Current Report on Form 8-K.

5.5. **Amendments; Waivers**. No provision of this Agreement may be waived, modified, supplemented or amended except in a written instrument signed, in the case of an amendment, by the Company and Purchasers which purchased at least 50.1% in interest of the Securities based on the initial Subscription Amounts hereunder (or, prior to Closing, the Company and each Purchaser) or, in the case of a waiver, by the party against whom enforcement of any such waived provision is sought, provided that if any amendment, modification or waiver disproportionately and adversely impacts a Purchaser (or multiple Purchasers), the consent of such disproportionately impacted Purchaser (or multiple Purchasers) shall also be required. No waiver of any default with respect to any provision, condition or requirement of this Agreement shall be deemed to be a continuing waiver in the future or a waiver of any subsequent default or a waiver of any other provision, condition or requirement hereof, nor shall any delay or omission of any party to exercise any right hereunder in any manner impair the exercise of any such right. Any proposed amendment or waiver that disproportionately, materially and adversely affects the rights and obligations of any Purchaser relative to the comparable rights and obligations of the other Purchasers shall require the prior written consent of such adversely affected Purchaser. Any amendment effected in accordance with this Section 5.5 shall be binding upon each Purchaser and holder of Securities and the Company.

5.6. **Headings**. The headings herein are for convenience only, do not constitute a part of this Agreement and shall not be deemed to limit or affect any of the provisions hereof.

5.7. **Successors and Assigns**. This Agreement shall be binding upon and inure to the benefit of the parties and their successors and permitted assigns. The Company may not assign this Agreement or any rights or obligations hereunder without the prior written consent of each Purchaser (other than by merger). Any Purchaser may assign any or all of its rights under this Agreement to any Person to whom such Purchaser assigns or transfers any Securities, provided that such transferee agrees in writing to be bound, with respect to the transferred Securities, by the provisions of the Transaction Documents that apply to the "Purchasers."

5.8. **No Third-Party Beneficiaries**. The Placement Agent shall be the third party beneficiary of the representations and warranties of the Company in Section 3.1 and the representations and warranties of the Purchasers in Section 3.2. This Agreement is intended for the benefit of the parties hereto and their respective successors and permitted assigns and is not for the benefit of, nor may any provision hereof be enforced by, any other Person, except as otherwise set forth in Section 4.8 and this Section 5.8.

5.9. **Governing Law**. All questions concerning the construction, validity, enforcement and interpretation of the Transaction Documents shall be governed by and construed and enforced in accordance with the law of the State of New York without regard to the principles of conflicts of law thereof. Each party agrees that all legal Proceedings concerning the interpretations, enforcement and defense of the transactions contemplated by this Agreement and any other Transaction Documents (whether brought against a party hereto or its respective affiliates, directors, officers, shareholders, partners, members, employees or agents) shall be commenced exclusively in the state and federal courts sitting in the City of New York. Each party hereby irrevocably submits to the exclusive jurisdiction of the state and federal courts sitting in the City and County of New York for the adjudication of any dispute hereunder or in connection herewith or with any transaction contemplated hereby or discussed herein (including with respect to the enforcement of any of the Transaction Documents), and hereby irrevocably waives, and agrees not to assert in any Action or Proceeding, any claim that it is not personally subject to the jurisdiction of any such court, that such Action or Proceeding is improper or is an inconvenient venue for such Proceeding. Each party hereby irrevocably waives personal service of process and consents to process being served in any such Action or Proceeding by mailing a copy thereof via registered or certified mail or overnight delivery (with evidence of delivery) to such party at the address in effect for notices to it under this Agreement and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any other manner permitted by law. If any party shall commence an Action or Proceeding to enforce any provisions of the Transaction Documents, then, in addition to the obligations of the Company under Section 4.8, the prevailing party in such Action or Proceeding shall be reimbursed by the non-prevailing party for its reasonable attorneys' fees and other costs and expenses incurred with the investigation, preparation and prosecution of such Action or Proceeding.

5.10. **Survival**. The representations and warranties contained herein shall survive the Closing and the delivery of the Securities.

5.11. **Execution**. This Agreement may be executed in two or more counterparts, all of which when taken together shall be considered one and the same agreement and shall become effective when counterparts have been signed by each party and delivered to each other party, it being understood that the parties need not sign the same counterpart. In the event that any signature is delivered by e-mail delivery of a ".pdf" format data file, such signature shall create a valid and binding obligation of the party executing (or on whose behalf such signature is executed) with the same force and effect as if such ".pdf" signature page were an original thereof.

5.12. **Severability**. If any term, provision, covenant or restriction of this Agreement is held by a court of competent jurisdiction to be invalid, illegal, void or unenforceable, the remainder of the terms, provisions, covenants and restrictions set forth herein shall remain in full force and effect and shall in no way be affected, impaired or invalidated, and the parties hereto shall use their commercially reasonable efforts to find and employ an alternative means to achieve the same or substantially the same result as that contemplated by such term, provision, covenant or restriction. It is hereby stipulated and declared to be the intention of the parties that they would have executed the remaining terms, provisions, covenants and restrictions without including any of such that may be hereafter declared invalid, illegal, void or unenforceable.

5.13. **Rescission and Withdrawal Right**. Notwithstanding anything to the contrary contained in (and without limiting any similar provisions of) any of the other Transaction Documents, whenever any Purchaser exercises a right, election, demand or option under a Transaction Document and the Company does not timely perform its related obligations within the periods therein provided, then such Purchaser may rescind or withdraw, in its sole discretion from time to time upon written notice to the Company, any relevant notice, demand or election in whole or in part without prejudice to its future actions and rights .

5.14. **Replacement of Securities**. If any certificate or instrument evidencing any Securities is mutilated, lost, stolen or destroyed, the Company shall issue or cause to be issued in exchange and substitution for and upon cancellation thereof (in the case of mutilation), or in lieu of and substitution therefor, a new certificate or instrument, but only upon receipt of evidence reasonably satisfactory to the Company of such loss, theft or destruction. The applicant for a new certificate or instrument under such circumstances shall also pay any reasonable third-party costs (including customary indemnity) associated with the issuance of such replacement Securities.

5.15. **Remedies**. In addition to being entitled to exercise all rights provided herein or granted by law, including recovery of damages, each of the Purchasers and the Company will be entitled to specific performance under the Transaction Documents. The parties agree that monetary damages may not be adequate compensation for any loss incurred by reason of any breach of obligations contained in the Transaction Documents and hereby agree to waive and not to assert in any Action for specific performance of any such obligation the defense that a remedy at law would be adequate.

5.16. **Payment Set Aside**. To the extent that the Company makes a payment or payments to any Purchaser pursuant to any Transaction Document or a Purchaser enforces or exercises its rights thereunder, and such payment or payments or the proceeds of such enforcement or exercise or any part thereof are subsequently invalidated, declared to be fraudulent or preferential, set aside, recovered from, disgorged by or are required to be refunded, repaid or otherwise restored to the Company, a trustee, receiver or any other Person under any law (including, without limitation, any bankruptcy law, state or federal law, common law or equitable cause of action), then to the extent of any such restoration the obligation or part thereof originally intended to be satisfied shall be revived and continued in full force and effect as if such payment had not been made or such enforcement or setoff had not occurred.

5.17. **Independent Nature of Purchasers' Obligations and Rights**. The obligations of each Purchaser under any Transaction Document are several and not joint with the obligations of any other Purchaser, and no Purchaser shall be responsible in any way for the performance or non-performance of the obligations of any other Purchaser under any Transaction Document. Nothing contained herein or in any other Transaction Document, and no action taken by any Purchaser pursuant hereto or thereto, shall be deemed to constitute the Purchasers as a partnership, an association, a joint venture or any other kind of entity, or create a presumption that the Purchasers are in any way acting in concert or as a group with respect to such obligations or the transactions contemplated by the Transaction Documents. Each Purchaser shall be entitled to independently protect and enforce its rights including, without limitation, the rights arising out of this Agreement or out of the other Transaction Documents, and it shall not be necessary for any other Purchaser to be joined as an additional party in any Proceeding for such purpose. Each Purchaser has been represented by its own separate legal counsel in its review and negotiation of the Transaction Documents. For reasons of administrative convenience only, each Purchaser and its respective counsel have chosen to communicate with the Company through the legal counsel to the Placement Agent. The legal counsel of the Placement Agent does not represent any of the Purchasers and only represents the Placement Agent. The Company has elected to provide all Purchasers with the same terms and Transaction Documents for the convenience of the Company and not because it was required or requested to do so by any of the Purchasers. It is expressly understood and agreed that each provision contained in this Agreement and in each other Transaction Document is between the Company and a Purchaser, solely, and not between the Company and the Purchasers collectively and not between and among the Purchasers.

5.18. **Liquidated Damages**. The Company's obligations to pay any partial liquidated damages or other amounts owing under the Transaction Documents is a continuing obligation of the Company and shall not terminate until all unpaid partial liquidated damages and other amounts have been paid notwithstanding the fact that the instrument or security pursuant to which such partial liquidated damages or other amounts are due and payable shall have been canceled.

5.19. **Saturdays, Sundays, Holidays, etc**. If the last or appointed day for the taking of any action or the expiration of any right required or granted herein shall not be a Business Day, then such action may be taken or such right may be exercised on the next succeeding Business Day.

5.20. **Construction**. The parties agree that each of them and/or their respective counsel have reviewed and had an opportunity to revise the Transaction Documents and, therefore, the normal rule of construction to the effect that any ambiguities are to be resolved against the drafting party shall not be employed in the interpretation of the Transaction Documents or any amendments thereto. In addition, each and every reference to share prices and shares of Common Stock in any Transaction Document shall be subject to adjustment for reverse and forward stock splits, stock dividends, stock combinations and other similar transactions of the Common Stock that occur after the date of this Agreement.

5.21. **WAIVER OF JURY TRIAL. IN ANY ACTION, SUIT, OR PROCEEDING IN ANY JURISDICTION BROUGHT BY ANY PARTY AGAINST ANY OTHER PARTY, THE PARTIES EACH KNOWINGLY AND INTENTIONALLY, TO THE GREATEST EXTENT PERMITTED BY APPLICABLE LAW, HEREBY ABSOLUTELY, UNCONDITIONALLY, IRREVOCABLY AND EXPRESSLY WAIVES FOREVER TRIAL BY JURY.**

[Securities Purchase Agreement Signature Pages Follows]

IN WITNESS WHEREOF, the parties hereto have caused this Securities Purchase Agreement to be duly executed by their respective authorized signatories as of the date first indicated above.

ORAGENICS, INC.

By: _____
Name:
Title:

Address for Notice:
Oragenics, Inc.
1990 Main Street, Suite 750
Sarasota, FL 34236
Attention: Janet Huffman, CFO and Interim CEO
Email: jhuffman@oragenics.com

With a copy to (which shall not constitute notice):

Shumaker, Loop & Kendrick, LLC
Bank of America Plaza, Suite 2800
101 East Kennedy Boulevard
Tampa, FL 33602
Attention: Mark Catchur
Email: mcatchur@shumaker.com

[Securities Purchase Agreement – Investor Signature Page]

IN WITNESS WHEREOF, the undersigned has caused this Securities Purchase Agreement to be duly executed by its authorized signatory as of the date first indicated above.

Name of Purchaser: _____

Signature of Authorized Signatory of Purchaser: _____

Name of Authorized Signatory: _____

Title of Authorized Signatory: _____

Email Address of Authorized Signatory: _____

Address for Notice to Purchaser: _____

Address for Delivery of Securities to Purchaser (if not same as address for notice): _____

Subscription Amount: _____

Shares: _____

Employer Identification Number: _____

Schedule 3.1.1

Subsidiaries

Noachis Terra, Inc. ("NTI") and Oragenics Australia Pty Ltd.

Exhibit 1.36

Form of Lock-Up Agreement

Exhibit 1.51

Form of Certificate of Designation

Exhibit 10.26

[FORM OF SENIOR NOTE]

THIS SECURITY HAS NOT BEEN REGISTERED WITH THE SECURITIES AND EXCHANGE COMMISSION OR THE SECURITIES COMMISSION OF ANY STATE IN RELIANCE UPON AN EXEMPTION FROM REGISTRATION UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "SECURITIES ACT"), AND, ACCORDINGLY, MAY NOT BE OFFERED OR SOLD EXCEPT PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT UNDER THE SECURITIES ACT OR PURSUANT TO AN AVAILABLE EXEMPTION FROM, OR IN A TRANSACTION NOT SUBJECT TO, THE REGISTRATION REQUIREMENTS OF THE SECURITIES ACT AND IN ACCORDANCE WITH APPLICABLE STATE SECURITIES LAWS. THIS SECURITY MAY BE PLEDGED IN CONNECTION WITH A BONA FIDE MARGIN ACCOUNT WITH A REGISTERED BROKER-DEALER OR OTHER LOAN WITH A FINANCIAL INSTITUTION THAT IS AN "ACCREDITED INVESTOR" AS DEFINED IN RULE 501(a) UNDER THE SECURITIES ACT OR OTHER LOAN SECURED BY SUCH SECURITIES. ANY TRANSFEREE OF THIS NOTE SHOULD CAREFULLY REVIEW THE TERMS OF THIS NOTE.

THIS NOTE HAS BEEN ISSUED WITH ORIGINAL ISSUE DISCOUNT ("OID"). PURSUANT TO TREASURY REGULATION §1.1275-3(b)(1), JANET HUFFMAN, A REPRESENTATIVE OF THE COMPANY HEREOF WILL, BEGINNING TEN DAYS AFTER THE ISSUANCE DATE OF THIS NOTE, PROMPTLY MAKE AVAILABLE TO THE HOLDER UPON REQUEST THE INFORMATION DESCRIBED IN TREASURY REGULATION §1.1275-3(b)(1)(i).

Oragenics, INC.

SENIOR NOTE

Issuance Date: March 13, 2025 Original Principal Amount: U.S. $3,000,000

FOR VALUE RECEIVED, Oragenics, Inc., a Delaware corporation (the "**Company**"), hereby promises to pay to [●] or its registered assigns (the "**Holder**") in cash the amount set forth above as the Original Principal Amount (as reduced pursuant to the terms hereof pursuant to redemption or otherwise, the "**Principal**") when due, whether upon the Maturity Date (as defined below), acceleration, redemption or otherwise (in each case in accordance with the terms hereof) and to pay interest ("**Interest**"), if applicable, on any outstanding Principal at the applicable Default Rate at any time during the occurrence and continuance of an Event of Default (as defined in **Section 4(a)**) occurring from the date set out above as the Issuance Date (the "**Issuance Date**") until the same becomes due and payable, whether upon the Maturity Date, acceleration, redemption or otherwise (in each case in accordance with the terms hereof). This Senior Note (including all Notes issued in exchange, transfer or replacement hereof, this "**Note**") is one of an issue of Notes issued pursuant to the Securities Purchase Agreement on the Closing Date (collectively, the "**Notes**" and such other Notes, the "**Other Notes**"). Certain capitalized terms used herein are defined in **Section 29**.

1. ORIGINAL ISSUE DISCOUNT; PAYMENTS OF PRINCIPAL; PREPAYMENT. The Company acknowledges and agrees that this Note was issued at an original issue discount. On the Maturity Date, if any portion of this Note remains outstanding, the Company shall pay to the Holder an amount in cash representing all outstanding Principal and any accrued and unpaid Interest. The "**Maturity Date**" shall be the earlier of (a) July 14, 2025, (b) the closing of one or more subsequent equity, debt or other capital raise(s) in an amount equal to or in excess of all remaining amounts due under all the Notes outstanding, or (c) any sale of tangible or intangible assets with the net proceeds therefrom equal to or in excess of all remaining amounts due under all the Notes outstanding. In the event of a Maturity Date under clause (b) or (c), all amounts due under the Note will be repaid from the closing flow of funds for such subsequent capital raise(s) or asset sale. The Maturity Date may be extended at the option of the Holder (x) in the event that, and for so long as, an Event of Default shall have occurred and be continuing on the Maturity Date (as may be extended pursuant to this **Section 1**) or any event shall have occurred and be continuing on the Maturity Date (as may be extended pursuant to this **Section 1**) that with the passage of time and the failure to cure would result in an Event of Default and/or (y) through the date that is ten (10) Business Days after the consummation of a Change of Control in the event that a Change of Control is publicly announced or a Change of Control Notice (as defined in **Section 5(b)**) is delivered prior to the Maturity Date. Other than as specifically permitted by this Note, the Company may not prepay any portion of the outstanding Principal or accrued and unpaid Interest, if any.

2. INTEREST. No Interest shall accrue hereunder unless and until an Event of Default has occurred. From and after the occurrence and during the continuance of any Event of Default, Interest shall accrue hereunder at twenty percent (20.0%) per annum (the "**Default Rate**"). Accrued and unpaid Interest, if any, may also be payable, at the election of the Holder, by way of inclusion of the Interest in the Note Amount (as defined below) upon any redemption hereunder occurring prior to the Maturity Date, including, without limitation, upon a Bankruptcy Event of Default redemption. In the event that an Event of Default is subsequently cured (and no other Event of Default then exists (including, without limitation, for the Company's failure to pay such Interest at the Default Rate on the Maturity Date)), Interest at the Default Rate shall cease to accrue hereunder as of the calendar day immediately following the date of such cure; provided that the Interest as calculated and unpaid during the continuance of such Event of Default shall continue to apply; provided, further, that for the purpose of this **Section 2**, such Event of Default shall not be deemed cured unless and until any accrued and unpaid Interest shall be paid to the Holder. As used herein, "**Note Amount**" means the sum of (x) the portion of the Principal to be redeemed or otherwise with respect to which this determination is being made, and (y) accrued and unpaid Interest, if any, with respect to such Principal.

3. NOTE REGISTRATION; BOOK ENTRY. The Company shall maintain a register (the "**Register**") for the recordation of the names and addresses of the holders of each Note and the Principal amount of the Notes (and stated interest thereon) held by such holders (the "**Registered Notes**"). The entries in the Register shall be conclusive and binding for all purposes absent manifest error. The Company and the holders of the Notes shall treat each Person whose name is recorded in the Register as the owner of a Note for all purposes, including, without limitation, the right to receive payments of Principal and Interest, if any, hereunder, notwithstanding notice to the contrary. A Registered Note may be assigned or sold in whole or in part only by registration of such assignment or sale on the Register. Upon its receipt of a request to assign or sell all or part of any Registered Note by the Holder, the Company shall record the information contained therein in the Register and issue one or more new Registered Notes in the same aggregate Principal amount as the Principal amount of the surrendered Registered Note to the designated assignee or transferee pursuant to **Section 17**. Notwithstanding anything to the contrary in this **Section 3**, the Holder may assign any Note or any portion thereof to an Affiliate of the Holder or a Related Fund of the Holder without delivering a request to assign or sell the Note to the Company and the recordation of such assignment or sale in the Register (a "**Related Party Assignment**"); provided, that (x) the Company may continue to deal solely with such assigning or selling Holder unless and until the Holder has delivered a request to assign or sell the Note or portion thereof to the Company for recordation in the Register; (y) the failure of such assigning or selling Holder to deliver a request to assign or sell the Note or portion thereof to the Company shall not affect the legality, validity, or binding effect of such assignment or sale and (z) such assigning or selling Holder shall, acting solely for this purpose as a non-fiduciary agent of the Company, maintain a register (the "**Related Party Register**") comparable to the Register on behalf of the Company, and any such assignment or sale shall be effective upon recordation of such assignment or sale in the Related Party Register.

4. RIGHTS UPON EVENT OF DEFAULT.

a. Event of Default. Each of the following events or failure to comply therewith shall constitute an "**Event of Default**" and each of the events described in clauses (iii) and (iv) shall also constitute a "**Bankruptcy Event of Default**":

i. the Company's failure to pay to the Holder any amount of Principal, Interest, Redemption Price or other amounts when and as due under this Note or any other Transaction Document;

ii. any default under, redemption of, or acceleration prior to maturity of any Indebtedness of the Company or any of its Subsidiaries other than with respect to this Note or any Other Notes occurring after this Issuance Date;

iii. the Company or any of its Subsidiaries, pursuant to or within the meaning of Title 11, U.S. Code, or any similar federal, foreign or state law for the relief of debtors (collectively, "**Bankruptcy Law**"), (A) commences a bankruptcy voluntary case, (B) consents to the entry of an order for relief against it in an involuntary bankruptcy case, (C) consents to the appointment of a receiver, trustee, assignee, liquidator or similar official (a "**Custodian**"), (D) makes a general assignment for the benefit of its creditors or (E) admits in writing that it is generally unable to pay its debts as they become due;

iv. a court of competent jurisdiction enters an order or decree under any Bankruptcy Law that (A) is for relief against the Company or any of its Subsidiaries in an involuntary case, (B) appoints a Custodian of the Company or any of its Subsidiaries or (C) orders the liquidation of the Company or any of its Subsidiaries;

v. a final judgment or judgments for the payment of money aggregating in excess of $250,000 are rendered against the Company or any of its Subsidiaries and which judgments are not, within sixty (60) days after the entry thereof, bonded, discharged or stayed pending appeal, or are not discharged within sixty (60) days after the expiration of such stay; provided, however, that any judgment which is covered by insurance or an indemnity from a credit worthy party shall not be included in calculating the $250,000 amount set forth above so long as the Company provides the Holder a written statement from such insurer or indemnity provider (which written statement shall be reasonably satisfactory to the Holder) to the effect that such judgment is covered by insurance or an indemnity and the Company or such Subsidiary (as the case may be) will receive the proceeds of such insurance or indemnity within thirty (30) days of the issuance of such judgment;

vi. other than as specifically set forth in another clause of this **Section 4(a)**, the Company or any of its Subsidiaries materially breaches any representation, warranty, covenant or other term or condition of any Transaction Document, except, in the case of a breach of a covenant or other term or condition of any Transaction Document which is curable, only if such breach continues for a period of at least an aggregate of five (5) Business Days from the date the Purchaser notifies the Company of such breach;

vii. any breach or failure in any material respect to comply with either **Sections 13 or 14** of this Note if such breach or failure continues uncured for more than an aggregate of five (5) Business Days from the date the Purchaser notifies the Company of such breach or failure; or

viii. any Event of Default (as defined in the Other Notes) occurs with respect to any Other Notes.

b. Redemption Right. At any time after the earlier of the Holder's receipt of an Event of Default Notice (as defined in **Section 14(e)**) and the Holder becoming aware of an Event of Default, the Holder may require the Company to redeem (an "**Event of Default Redemption**") all or any portion of this Note by delivering written notice thereof (the "**Event of Default Redemption Notice**") to the Company, which Event of Default Redemption Notice shall indicate the portion of this Note the Holder is electing to require the Company to redeem. Each portion of this Note subject to redemption by the Company pursuant to this **Section 4(b)** shall be redeemed by the Company in cash by wire transfer of immediately available funds at a price equal to the product of (A) the Redemption Premium and (B) the Note Amount being redeemed (the "**Event of Default Redemption Price**"). Redemptions required by this **Section 4(b)** shall be made in accordance with the provisions of **Section 9**. To the extent redemptions required by this **Section 4(b)** are deemed or determined by a court of competent jurisdiction to be prepayments of the Note by the Company, such redemptions shall be deemed to be voluntary prepayments. The parties hereto agree that in the event of the Company's redemption of any portion of the Note under this **Section 4(b)**, the Holder's damages would be uncertain and difficult to estimate because of the parties' inability to predict future interest rates and the uncertainty of the availability of a suitable substitute investment opportunity for the Holder. Accordingly, any Redemption Premium with respect to an Event of Default due under this **Section 4(b)** is intended by the parties to be, and shall be deemed, a reasonable estimate of the Holder's actual loss of its investment opportunity and not as a penalty.

c. Redemption upon Bankruptcy Event of Default. Notwithstanding anything to the contrary herein upon any Bankruptcy Event of Default, whether occurring prior to or following the Maturity Date, the Company shall immediately pay to the Holder an amount in cash representing 100% of all outstanding Principal, accrued and unpaid Interest, if any, in addition to any and all other amounts due hereunder (the "**Bankruptcy Event of Default Redemption Price**"), without the requirement for any notice or demand or other action by the Holder or any other Person; provided that the Holder may, in its sole discretion, waive such right to receive payment upon a Bankruptcy Event of Default, in whole or in part, and any such waiver shall not affect any other rights of the Holder hereunder, including any other rights in respect of such Bankruptcy Event of Default, and any right to payment of the Event of Default Redemption Price or any other Redemption Price, as applicable. Redemptions required by this **Section 4(c)** shall be made in accordance with the provisions of **Section 9**.

5. RIGHTS UPON FUNDAMENTAL TRANSACTION AND CHANGE OF CONTROL.

a. Assumption. The Company shall cause any successor entity in a Fundamental Transaction in which the Company is not the survivor (the "**Successor Entity**") to assume in writing all of the obligations of the Company under this Note and the other Transaction Documents in accordance with the provisions of this **Section 5(a)** pursuant to written agreements in form and substance reasonably satisfactory to the Holder and approved by the Holder (without unreasonable delay) prior to such Fundamental Transaction and shall, at the option of the Holder, deliver to the Holder in exchange for this Note a security of the Successor Entity evidenced by a written instrument substantially similar in form and substance to this Note. Upon the occurrence of any such Fundamental Transaction, the Successor Entity shall be added to the term "Company" under this Note (so that from and after the occurrence or consummation of such Fundamental Transaction, each and every provision of this Note and the other Transaction Documents referring to the "Company" shall refer instead to each of the Company and the Successor Entity or Successor Entities, jointly and severally), and the Successor Entity or Successor Entities, jointly and severally with the Company, may exercise every right and power of the Company prior thereto and the Successor Entity or Successor Entities shall assume all of the obligations of the Company prior thereto under this Note and the other Transaction Documents with the same effect as if the Company and such Successor Entity or Successor Entities, jointly and severally, had been named as the Company in this Note.

b. Redemption Right. No later than ten (10) days prior to the consummation of a Change of Control, the Company shall deliver written notice thereof via electronic mail and overnight courier to the Holder (a "**Change of Control Notice**") setting forth a description of such transaction in reasonable detail and the anticipated Change of Control Redemption Date (as defined in **Section 11(a)**) if then known. At any time during the period beginning on the earlier to occur of (x) any oral or written agreement by the Company or any of its Subsidiaries, upon consummation of which the transaction contemplated thereby would reasonably be expected to result in a Change of Control, (y) the Holder becoming aware of a Change of Control and (z) the Holder's receipt of a Change of Control Notice and ending twenty-five (25) days after the date of the consummation of such Change of Control, the Holder may require the Company to redeem (a "**Change of Control Redemption**") all or any portion of this Note by delivering written notice thereof ("**Change of Control Redemption Notice**") to the Company, which Change of Control Redemption Notice shall indicate the Note Amount the Holder is electing to require the Company to redeem. The portion of this Note subject to redemption pursuant to this **Section 5(b)** shall be redeemed by the Company in cash by wire transfer of immediately available funds at a price equal to the Note Amount being redeemed (the "**Change of Control Redemption Price**"). Redemptions required by this **Section 5** shall be made in accordance with the provisions of **Section 9** and shall have priority to payments to stockholders in connection with a Change of Control. To the extent redemptions required by this **Section 5(b)** are deemed or determined by a court of competent jurisdiction to be prepayments of the Note by the Company, such redemptions shall be deemed to be voluntary prepayments. The parties hereto agree that in the event of the Company's redemption of any portion of the Note under this **Section 5(b)**, the Holder's damages would be uncertain and difficult to estimate because of the parties' inability to predict future interest rates and the uncertainty of the availability of a suitable substitute investment opportunity for the Holder.

6. MANDATORY REDEMPTION.

a. Occurrence of Mandatory Redemption. While this Note is outstanding, the Company shall use at 100% of the net proceeds of any offering of its securities (including any securities of its direct or indirect subsidiaries), including any underwritten or other public offering of securities (any such offering, a "**Subsequent Offering**" and 100% of the net proceeds from such Subsequent Offering, the "**Net Proceeds**") to redeem this Note in full, including the Note Amount and all other amounts due and payable pursuant to this Note, and all other then outstanding Notes (a "**Mandatory Redemption**"); provided, however, that if the Net Proceeds of the Subsequent Offering are less than the amount required to repay all of the Notes in full, (i) the Company's repayment obligation under this **Section 6(a)** shall be limited to the amount of such Net Proceeds, (ii) the Net Proceeds shall be applied to all of the Notes then outstanding pro rata based on the principal amount of such Notes then outstanding and (iii) the Company shall effect successive Mandatory Redemptions upon each Subsequent Offering until the Notes are repaid in full or otherwise no longer outstanding.

b. Mandatory Notices. With respect to each Mandatory Redemption, the Company shall deliver a written notice to all, but not less than all, of the holders of Notes (the "**Mandatory Redemption Notice**" and the date such notice is delivered to all such holders is referred to as a "**Mandatory Redemption Notice Date**") (a) stating the date on which the Mandatory Redemption shall occur (a "**Mandatory Redemption Date**"), which date shall be the date of the consummation of the applicable Subsequent Offering, (b) stating the expected amount of Net Proceeds with respect to the applicable Subsequent Offering and (c) contain a certification from the Chief Executive Officer or Chief Financial Officer of the Company that the Company has simultaneously taken the same action with respect to all of the Notes. Each Mandatory Redemption Notice shall be delivered no later than the first (1st) Business Day following the announcement of the pricing of the applicable Subsequent Offering, and the Company shall make a public announcement containing the information set forth in the applicable Mandatory Redemption Notice on or before the related Mandatory Redemption Notice Date to the extent that the notice contains any, or constitutes, material, non-public information.

c. Mandatory Redemption Procedure. The payment of cash pursuant to the Mandatory Redemption shall be payable in full on the Business Day immediately following the Mandatory Redemption Date by wire transfer of immediately available funds in accordance with the Holder's wire instructions. If any portion of the payment pursuant to a Mandatory Redemption shall not be paid by the Company by the applicable due date, interest shall accrue thereon at an interest rate equal to the lesser of eighteen percent (18%) per annum or the maximum rate permitted by applicable law until such amount is paid in full. Notwithstanding anything to the contrary in this **Section 6(c),** the Net Proceeds shall be applied ratably among the Holders of the Notes.

7. OPTIONAL PREPAYMENT. The Company may prepay (each, an "**Optional Prepayment**") the Note in whole or in part at any time or from time to time by paying the Holder in cash by wire transaction of immediately available funds 100% of the Note Amount being prepaid provided, however, that in the event of any such redemption, the Company shall also pay to the Investors an amount sufficient to ensure that the Investors receive the full amount of Interest, if any, that would have accrued on the Principal amount being prepaid through July 14, 2025. The Company may exercise its right to require Optional Prepayment under this **Section 7** by delivering a written notice thereof by electronic mail and overnight courier to the Holder and all, but not less than all, of the holders of the Other Notes (an "**Optional Prepayment Notice**" and the date all of the holders of the Notes received such notice is referred to as the "**Optional Prepayment Notice Date**"). Each Optional Prepayment Notice shall be irrevocable. Each Optional Prepayment Notice shall (i) state the date on which the Optional Prepayment shall occur (the "**Optional Prepayment Date**"), which date shall not be less than two (2) Business Days following the applicable Optional Prepayment Notice Date, and (ii) state the aggregate Note Amount of the Notes which the Company has elected to be subject to Optional Prepayment from the Holder and all of the other holders of the Other Notes pursuant to this **Section 7** (and analogous provisions under the Other Notes) on the related Optional Prepayment Date. If the Company elects to cause an Optional Prepayment pursuant to this **Section** , then it must simultaneously take the same action in the same proportion with respect to the Other Notes.

8. **NONCIRCUMVENTION**. The Company hereby covenants and agrees that the Company will not, by amendment of its Certificate of Incorporation or Bylaws or through any reorganization, transfer of assets, consolidation, merger, scheme of arrangement, dissolution, issue or sale of securities, or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms of this Note, and will at all times in good faith carry out all of the provisions of this Note and take all action as may be required to protect the rights of the Holder of this Note.

9. **REDEMPTIONS**.

a. Mechanics. The Company shall deliver the applicable Event of Default Redemption Price to the Holder within three (3) Business Days after the Company's receipt of the Holder's Event of Default Redemption Notice; provided that upon a Bankruptcy Event of Default, the Company shall deliver the applicable Bankruptcy Event of Default Redemption Price in accordance with **Section 4(c)** (as applicable, the "**Event of Default Redemption Date**"). If the Holder has submitted a Change of Control Redemption Notice in accordance with **Section 5(b)**, the Company shall deliver the applicable Change of Control Redemption Price to the Holder (i) concurrently with the consummation of such Change of Control if such notice is received prior to the consummation of such Change of Control and (ii) within three (3) Business Days after the Company's receipt of such notice otherwise (such date, the "**Change of Control Redemption Date**"). The Company shall deliver the applicable Note Amount being prepaid to the Holder on the applicable Optional Prepayment Date. The Company shall pay the applicable Redemption Price to the Holder in cash by wire transfer of immediately available funds pursuant to wire instructions provided by the Holder in writing to the Company on the applicable due date. In the event of a redemption of less than all of the Note Amount of this Note, the Company shall promptly cause to be issued and delivered to the Holder a new Note (in accordance with **Section 17(d)**) representing the outstanding Principal which has not been redeemed and any accrued Interest on such Principal which shall be calculated as if no Redemption Notice has been delivered. In the event that the Company does not pay a Redemption Price to the Holder within the time period required, at any time thereafter and until the Company pays such unpaid Redemption Price in full, the Holder shall have the option, in lieu of redemption, to require the Company to promptly return to the Holder all or any portion of this Note representing the Note Amount that was submitted for redemption and for which the applicable Redemption Price has not been paid. Upon the Company's receipt of such notice, (x) the applicable Redemption Notice shall be null and void with respect to such Note Amount, and (y) the Company shall immediately return this Note, or issue a new Note (in accordance with **Section 17(d)**) to the Holder representing such Note Amount to be redeemed.

b. Redemption by Other Holders. Upon the Company's receipt of notice from any of the holders of the Other Notes for redemption or repayment as a result of an event or occurrence substantially similar to the events or occurrences described in **Section 4(b)**, **Section 5(b)** or **Section 6** or pursuant to corresponding provisions set forth in the Other Notes (each, an "**Other Redemption Notice**"), the Company shall immediately, but no later than one (1) Business Day of its receipt thereof, forward to the Holder by electronic mail a copy of such Other Redemption Notice. If the Company receives a Redemption Notice and one or more Other Redemption Notices, during the seven (7) Business Day period beginning on and including the date which is three (3) Business Days prior to the Company's receipt of the Holder's Redemption Notice and ending on and including the date which is three (3) Business Days after the Company's receipt of the Holder's Redemption Notice and the Company is unable to redeem all principal, interest and other amounts designated in such Redemption Notice and such Other Redemption Notices received during such seven (7) Business Day period, then the Company shall redeem, a pro rata amount from the Holder and each holder of the Other Notes based on the Principal amount of this Note and the Other Notes submitted for redemption pursuant to such Redemption Notice and such Other Redemption Notices received by the Company during such seven (7) Business Day period.

c. Insufficient Assets. If upon a Redemption Date, the assets of the Company are insufficient to pay the applicable Redemption Price, the Company shall (i) take all appropriate action reasonably within its means to maximize the assets available for paying the applicable Redemption Price, (ii) redeem out of all such assets available therefor on the applicable Redemption Date the maximum possible portion of the applicable Redemption Price that it can redeem on such date, pro rata among the Holder and the holders of the Other Notes to be redeemed in proportion to the aggregate Principal amount of this Note and the Other Notes outstanding on the applicable Redemption Date and (iii) following the applicable Redemption Date, at any time and from time to time when additional assets of the Company become available to pay the balance of the applicable Redemption Price of this Note and the Other Notes, the Company shall use such assets, at the end of the then current fiscal quarter, to pay the balance of such Redemption Price of this Note and the Other Notes, or such portion thereof for which assets are then available, on the basis set forth above at the applicable Redemption Price, and such assets will not be used prior to the end of such fiscal quarter for any other purpose. Interest on the Principal amount of this Note and the Other Notes that have not been redeemed shall continue to accrue until such time as the Company redeems this Note and the Other Notes. The Company shall pay to the Holder the applicable Redemption Price without regard to the legal availability of funds unless expressly prohibited by applicable law or unless the payment of the applicable Redemption Price could reasonably be expected to result in personal liability to the directors of the Company.

10. **VOTING RIGHTS**. The Holder shall have no voting rights as the holder of this Note, except as required by law and as expressly provided in this Note.

11. **RANK**. All payments due under this Note (a) shall rank *pari passu* with all Other Notes and (b) shall be senior to all other Indebtedness of the Company and its Subsidiaries (other than Permitted Indebtedness secured by Permitted Liens (pursuant to clause (iv) of such definition) that are not subordinate to the Notes).

12. **SECURITY**. This Note and the Other Notes are unsecured.

13. **NEGATIVE COVENANTS**. Except as noted below, until all of the Notes have been redeemed or otherwise satisfied in full in accordance with their terms, the Company shall not, and the Company shall not permit any of its Subsidiaries, without the prior written consent of the Required Holders to, directly or indirectly by merger or otherwise:

a. while any Notes remain outstanding, incur or guarantee, assume or suffer to exist any Indebtedness, other than Permitted Indebtedness;

b. allow or suffer to exist any mortgage, lien, pledge, charge, security interest or other encumbrance upon or in any property or assets (including accounts and contract rights) owned by the Company or any of its Subsidiaries (collectively, "**Liens**") other than Permitted Liens;

c. redeem, defease, repurchase, repay or make any payments in respect of, by the payment of cash or cash equivalents (in whole or in part, whether by way of open market purchases, tender offers, private transactions or otherwise), all or any portion of any Indebtedness (excluding Permitted Indebtedness and for the avoidance of doubt, this Note and the Other Notes), whether by way of payment in respect of principal of (or premium, if any) or interest on, such Indebtedness if at the time such payment is due or is otherwise made or, after giving effect to such payment, an event constituting, or that with the passage of time and without being cured would constitute, an Event of Default has occurred and is continuing;

d. redeem, defease, repurchase, repay or make any payments in respect of, by the payment of cash or cash equivalents (in whole or in part, whether by way of open market purchases, tender offers, private transactions or otherwise), all or any portion of any Indebtedness (including, without limitation Permitted Indebtedness other than this Note and the Other Notes), by way of payment in respect of principal of (or premium, if any) such Indebtedness. For clarity, such restriction shall not preclude the payment of regularly scheduled interest payments which may accrue under Permitted Indebtedness secured by Permitted Liens (pursuant to clause (iv) of such definition);

e. redeem or repurchase any Equity Interest of the Company;

f. declare or pay any cash dividend or distribution on any Equity Interest of the Company or of its Subsidiaries other than wholly-owned Subsidiaries;

g. make, any material change in the nature of its business as described in the Company's most recent Quarterly Report filed on Form 10-Q with the SEC or modify its corporate structure or purpose; or

h. encumber, license or otherwise allow any Liens on any Intellectual Property Rights, including, without limitation, any claims for damage by way of any past, present, or future infringement of any of the foregoing, in each case, other than Permitted Liens;

i. enter into, renew, extend or be a party to, any transaction or series of related transactions (including, without limitation, the purchase, sale, lease, license, transfer or exchange of property or assets of any kind or the rendering of services of any kind) with any Affiliate, except in the ordinary course of business in a manner and to an extent consistent with past practice and necessary or desirable for the prudent operation of its business, for fair consideration and on terms no less favorable to it or its Subsidiaries than would be obtainable in a comparable arm's length transaction with a Person that is not an Affiliate thereof; or

j. issue any Notes or issue any other securities that would cause a breach or default under the Notes.

14. **AFFIRMATIVE COVENANTS**. Until all of the Notes have been redeemed or otherwise satisfied in full in accordance with their terms, the Company shall, and the Company shall cause each Subsidiary to, unless otherwise agreed to by the Required Holders, directly and indirectly:

a. maintain and preserve its existence, rights and privileges, and become or remain duly qualified and in good standing in each jurisdiction in which the character of the properties owned or leased by it or in which the transaction of its business makes such qualification necessary;

b. maintain and preserve all of its properties which are necessary or useful in the proper conduct of its business in good working order and condition, ordinary wear and tear excepted, and comply at all times with the provisions of all leases to which it is a party as lessee or under which it occupies property, so as to prevent any loss or forfeiture thereof or thereunder;

c. take all action necessary or advisable to maintain all of the Intellectual Property Rights that is necessary or material to the conduct of its business in full force and effect;

d. maintain current insurance policies, in such amounts and covering such risks as such policies currently cover; and

e. promptly, but in any event within one (1) Business Day, notify the Holder and the holders of the Other Notes in writing whenever an Event of Default (an "**Event of Default Notice**") occurs, and simultaneously with the delivery of such notice to the Holder and the holders of the Other Notes, file a Current Report on Form 8-K with the SEC to state such fact; and

15. **VOTE TO ISSUE, OR CHANGE THE TERMS OF, NOTES**. Any exchange, change or amendment or waiver of any provision to this Note or any of the Other Notes requires written consent of the Required Holders. Any exchange, change, amendment or waiver by the Company and the Required Holders shall be binding on the Holder of this Note and all holders of the Other Notes. The Holder hereby acknowledges and agrees that any action taken pursuant to this Section may result in, or be perceived to result in, a disproportionate impact on the Holder compared to the impact of such action on one or more holder(s) of Other Notes. This provision constitutes a separate right granted to each of the holders of Notes by the Company and shall not in any way be construed as such holders acting in concert or as a group with respect to the purchase, disposition or voting of securities or otherwise.

16. **TRANSFER**. This Note may be offered, sold, assigned or transferred by the Holder without the consent of the Company, subject only to the provisions of **Section 4.1** of the Securities Purchase Agreement.

17. **REISSUANCE OF THIS NOTE**.

a. Transfer. If this Note is to be transferred, the Holder shall surrender this Note to the Company, whereupon the Company will forthwith issue and deliver upon the order of the Holder a new Note (in accordance with **Section 17(d)** and subject to **Section 3(c)(iii)**), registered as the Holder may request, representing the outstanding Principal being transferred by the Holder and, if less than the entire outstanding Principal is being transferred, a new Note (in accordance with **Section 17(d)**) to the Holder representing the outstanding Principal not being transferred. The Holder and any assignee, by acceptance of this Note, acknowledge and agree that, by reason of the provisions of Section 3(c)(iii) following redemption of any portion of this Note, the outstanding Principal represented by this Note may be less than the Principal stated on the face of this Note.

b. Lost, Stolen or Mutilated Note. Upon receipt by the Company of evidence reasonably satisfactory to the Company of the loss, theft, destruction or mutilation of this Note, and, in the case of loss, theft or destruction, of any indemnification undertaking by the Holder to the Company in customary form (but without any obligation to post a surety or other bond) and, in the case of mutilation, upon surrender and cancellation of this Note, the Company shall execute and deliver to the Holder a new Note (in accordance with **Section 17(d)**) representing the outstanding Principal.

c. Note Exchangeable for Different Denominations. This Note is exchangeable, upon the surrender hereof by the Holder at the principal office of the Company, for a new Note or Notes (in accordance with **Section 17(d)**) representing in the aggregate the outstanding Principal of this Note, and each such new Note will represent such portion of such outstanding Principal as is designated by the Holder at the time of such surrender.

d. Issuance of New Notes. Whenever the Company is required to issue a new Note pursuant to the terms of this Note, such new Note (i) shall be of like tenor with this Note, (ii) shall represent, as indicated on the face of such new Note, the Principal remaining outstanding (or in the case of a new Note being issued pursuant to **Section 17(a)** or **Section 197(c),** the Principal designated by the Holder which, when added to the principal represented by the other new Notes issued in connection with such issuance, does not exceed the Principal remaining outstanding under this Note immediately prior to such issuance of new Notes), (iii) shall have an issuance date, as indicated on the face of such new Note, which is the same as the Issuance Date of this Note, (iv) shall have the same rights and conditions as this Note, and (v) shall represent accrued and unpaid Interest, if any, from the Issuance Date.

18. **REMEDIES, CHARACTERIZATIONS, OTHER OBLIGATIONS, BREACHES AND INJUNCTIVE RELIEF**. The remedies provided in this Note shall be cumulative and in addition to all other remedies available under this Note and any of the other Transaction Documents at law or in equity (including a decree of specific performance and/or other injunctive relief). No remedy contained herein shall be deemed a waiver of compliance with the provisions giving rise to such remedy. Nothing herein shall limit the Holder's right to pursue actual and consequential damages for any failure by the Company to comply with the terms of this Note. The Company covenants to the Holder that there shall be no characterization concerning this instrument other than as expressly provided herein. Amounts set forth or provided for herein with respect to payments, redemption and the like (and the computation thereof) shall be the amounts to be received by the Holder and shall not, except as expressly provided herein, be subject to any other obligation of the Company (or the performance thereof). The Company acknowledges that a breach by it of its obligations hereunder will cause irreparable harm to the Holder and that the remedy at law for any such breach may be inadequate. The Company therefore agrees that, in the event of any such breach or threatened breach, the Holder shall be entitled, in addition to all other available remedies, to an injunction restraining any breach, without the necessity of showing economic loss and without any bond or other security being required.

19. **PAYMENT OF COLLECTION, ENFORCEMENT AND OTHER COSTS**. If (a) this Note is placed in the hands of an attorney for collection or enforcement or is collected or enforced through any legal proceeding or the Holder otherwise takes action to collect amounts due under this Note or to enforce the provisions of this Note or (b) there occurs any bankruptcy, reorganization, receivership of the Company or other proceedings affecting Company creditors' rights and involving a claim under this Note, then the Company shall pay the costs incurred by the Holder for such collection, enforcement or action or in connection with such bankruptcy, reorganization, receivership or other proceeding, including, but not limited to, reasonable attorneys' fees and disbursements. The Company expressly acknowledges and agrees that no amounts due under this Note shall be affected, or limited, by the fact that the purchase price paid for this Note was less than the original Principal amount hereof.

20. **CONSTRUCTION; HEADINGS**. This Note shall be deemed to be jointly drafted by the Company and all the Purchasers and shall not be construed against any Person as the drafter hereof. The headings of this Note are for convenience of reference and shall not form part of, or affect the interpretation of, this Note.

21. **FAILURE OR INDULGENCE NOT WAIVER**. No failure or delay on the part of the Holder in the exercise of any power, right or privilege hereunder shall operate as a waiver thereof, nor shall any single or partial exercise of any such power, right or privilege preclude other or further exercise thereof or of any other right, power or privilege. No waiver shall be effective unless it is in writing and signed by an authorized representative of the waiving party.

22. **DISPUTE RESOLUTION**. In the case of a dispute as to the determination of any Redemption Price, the Company shall pay the applicable Redemption Price that is not disputed, and the Company shall submit the disputed determinations or arithmetic calculations via electronic mail within one (1) Business Day of receipt, or deemed receipt, of the Redemption Notice or other event giving rise to such dispute, as the case may be, to the Holder. If the Holder and the Company are unable to agree upon such determination or calculation within one (1) Business Day of such disputed determination or arithmetic calculation being submitted to the Holder, then the Company shall, within one (1) Business Day submit via electronic mail the disputed arithmetic calculation of any Redemption Price to an independent, outside accountant, selected by the Holder and approved by the Company, such approval not to be unreasonably withheld, conditioned or delayed. The Company, at the Company's expense, shall cause the accountant to perform the determinations or calculations and notify the Company and the Holder of the results no later than five (5) Business Days from the time it receives the disputed determinations or calculations. Such accountant's determination or calculation, as the case may be, shall be binding upon all parties absent demonstrable error.

23. **NOTICES; PAYMENTS**.

a. Notices. Whenever notice is required to be given under this Note, unless otherwise provided herein, such notice shall be given in accordance with **Section 5.4** of the Securities Purchase Agreement. The Company shall provide the Holder with prompt written notice of all actions taken pursuant to this Note, including in reasonable detail a description of such action and the reason therefor.

b. Payments. Whenever any payment of cash is to be made by the Company to any Holder pursuant to this Note, such payment shall be made in lawful money of the United States of America via wire transfer of immediately available funds to an account designated by the Holder; provided, that the Holder, upon written notice to the Company, may elect to receive a payment of cash in lawful money of the United States of America by a check drawn on the account of the Company and sent via overnight courier service to such Person at such address as previously provided to the Company in writing (which address, in the case of each of the Purchasers, shall initially be as set forth on the signature pages attached to the Securities Purchase Agreement). Whenever any amount expressed to be due by the terms of this Note is due on any day which is not a Business Day, the same shall instead be due on the next succeeding day which is a Business Day.

24. **CANCELLATION**. After all Principal, any accrued Interest and any other amounts at any time owed on this Note have been paid in full, this Note shall automatically be deemed canceled and shall not be reissued, sold or transferred.

25. **WAIVER OF NOTICE**. To the extent permitted by law, the Company hereby waives demand, notice, protest and all other demands and notices in connection with the delivery, acceptance, performance, default or enforcement of this Note and the Securities Purchase Agreement.

26. **GOVERNING LAW; JURISDICTION; JURY TRIAL**. This Note shall be governed by and construed and enforced in accordance with, and all questions concerning the construction, validity, interpretation and performance of this Note shall be governed by, the internal laws of the State of New York, without giving effect to any choice of law or conflict of law provision or rule (whether of the State of New York or any other jurisdictions) that would cause the application of the laws of any jurisdictions other than the State of New York. The Company hereby irrevocably submits to the exclusive jurisdiction of the state and federal courts sitting in The City of New York, Borough of Manhattan, for the adjudication of any dispute hereunder or in connection herewith or with any transaction contemplated hereby or discussed herein, and hereby irrevocably waives, and agrees not to assert in any suit, action or proceeding, any claim that it is not personally subject to the jurisdiction of any such court, that such suit, action or proceeding is brought in an inconvenient forum or that the venue of such suit, action or proceeding is improper. The Company hereby irrevocably waives personal service of process and consents to process being served in any such suit, action or proceeding by mailing a copy thereof to the Company at the address set forth on the Company's signature page to the Securities Purchase Agreement and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any manner permitted by law. Nothing contained herein shall be deemed or operate to preclude the Holder from bringing suit or taking other legal action against the Company in any other jurisdiction to collect on the Company's obligations to the Holder, to realize on any collateral or any other security for such obligations, or to enforce a judgment or other court ruling in favor of the Holder. **THE COMPANY HEREBY IRREVOCABLY WAIVES ANY RIGHT IT MAY HAVE TO, AND AGREES NOT TO REQUEST, A JURY TRIAL FOR THE ADJUDICATION OF ANY DISPUTE HEREUNDER OR IN CONNECTION WITH OR ARISING OUT OF THIS NOTE OR ANY TRANSACTION CONTEMPLATED HEREBY.**

27. **SEVERABILITY**. If any provision of this Note is prohibited by law or otherwise determined to be invalid or unenforceable by a court of competent jurisdiction, the provision that would otherwise be prohibited, invalid or unenforceable shall be deemed amended to apply to the broadest extent that it would be valid and enforceable, and the invalidity or unenforceability of such provision shall not affect the validity of the remaining provisions of this Note so long as this Note as so modified continues to express, without material change, the original intentions of the Company and the Holder as to the subject matter hereof and the prohibited nature, invalidity or unenforceability of the provision(s) in question does not substantially impair the respective expectations or reciprocal obligations of the Company or the Holder or the practical realization of the benefits that would otherwise be conferred upon the Company or the Holder. The Company and the Holder will endeavor in good faith negotiations to replace the prohibited, invalid or unenforceable provision(s) with a valid provision(s), the effect of which comes as close as possible to that of the prohibited, invalid or unenforceable provision(s).

28. **DISCLOSURE**. Upon receipt or delivery by the Company of any notice in accordance with the terms of this Note, unless the Company has in good faith determined that the matters relating to such notice do not constitute material, nonpublic information relating to the Company or its Subsidiaries, the Company shall contemporaneously with any such receipt or delivery publicly disclose such material, nonpublic information on a Current Report on Form 8-K or otherwise. In the event that the Company believes that a notice contains material, nonpublic information relating to the Company or its Subsidiaries, the Company so shall indicate to the Holder contemporaneously with delivery of such notice, and in the absence of any such indication, the Holder shall be allowed to presume that all matters relating to such notice do not constitute material, nonpublic information relating to the Company or its Subsidiaries.

29. **USURY**. This Note is subject to the express condition that at no time shall the Company be obligated or required to pay interest hereunder at a rate or in an amount which could subject the Holder to either civil or criminal liability as a result of being in excess of the maximum interest rate or amount which the Company is permitted by applicable law to contract or agree to pay. If by the terms of this Note, the Company is at any time required or obligated to pay interest hereunder, including by way of an original issue discount, at a rate or in an amount in excess of such maximum rate or amount, the rate or amount of interest under this Note shall be deemed to be immediately reduced to such maximum rate or amount and the interest payable shall be computed at such maximum rate or be in such maximum amount and all prior interest payments in excess of such maximum rate or amount shall be applied and shall be deemed to have been payments in reduction of the principal balance of this Note.

30. **CERTAIN DEFINITIONS**. For purposes of this Note, the following terms shall have the following meanings:

a. "**Affiliate**" shall have the meaning ascribed to such term in Rule 405 of the Securities Act.

b. "**Business Day**" means any day other than Saturday, Sunday or other day on which commercial banks in The City of New York are authorized or required by law to remain closed; provided, however, for clarification, commercial banks shall not be deemed to be authorized or required by law to remain closed due to "stay at home", "shelter-in-place", "non-essential employee" or any other similar orders or restrictions or the closure of any physical branch locations at the direction of any governmental authority so long as the electronic funds transfer systems (including for wire transfers) of commercial banks in The City of New York, New York generally are open for use by customers on such day.

c. "**Change of Control**" means any Fundamental Transaction other than (i) any reorganization, recapitalization or reclassification of the Common Stock in which holders of the Company's voting power immediately prior to such reorganization, recapitalization or reclassification continue after such reorganization, recapitalization or reclassification to hold publicly traded securities and, directly or indirectly, are the holders of a majority of the voting power of the surviving entity (or entities with the authority or voting power to elect the members of the board of directors (or their equivalent if other than a corporation) of such entity or entities) after such reorganization, recapitalization or reclassification or (ii) pursuant to a migratory merger effected solely for the purpose of changing the jurisdiction of incorporation of the Company.

d. "**Closing Date**" shall have the meaning set forth in the Securities Purchase Agreement, which date is the date the Company initially issued Notes pursuant to the terms of the Securities Purchase Agreement.

e. "**Common Stock**" means (i) the Company's shares of Common Stock, par value $0.00001 per share, and (ii) any capital stock into which such Common Stock shall be changed or any capital stock resulting from a reorganization, recapitalization or reclassification of such Common Stock.

f. "**Contingent Obligation**" means, as to any Person, any direct or indirect liability, contingent or otherwise, of that Person with respect to any Indebtedness, lease, dividend or other obligation of another Person if the primary purpose or intent of the Person incurring such liability, or the primary effect thereof, is to provide assurance to the obligee of such liability that such liability will be paid or discharged, or that any agreements relating thereto will be complied with, or that the holders of such liability will be protected (in whole or in part) against loss with respect thereto.

g. "**Convertible Securities**" means any stock or securities (other than Options) directly or indirectly convertible into or exercisable or exchangeable for shares of Common Stock.

h. "**Equity Interests**" means (a) all shares of capital stock (whether denominated as common capital stock or preferred capital stock), equity interests, beneficial, partnership or membership interests, joint venture interests, participations or other ownership or profit interests in or equivalents (regardless of how designated) of or in a Person (other than an individual), whether voting or non-voting and (b) all securities convertible into or exchangeable for any of the foregoing and all warrants, Options or other rights to purchase, subscribe for or otherwise acquire any of the foregoing, whether or not presently convertible, exchangeable or exercisable.

i. "**Exchange Act**" means the Securities Exchange Act of 1934, as amended.

j. "**Fundamental Transaction**" means (A) that the Company shall, directly or indirectly, including through Subsidiaries, Affiliates or otherwise, in one or more related transactions, (i) consolidate or merge with or into (whether or not the Company is the surviving corporation) another Subject Entity, or (ii) sell, assign, transfer, convey or otherwise dispose of all or substantially all of the properties or assets of the Company or any of its "significant subsidiaries" (as defined in Rule 1-02 of Regulation S-X) to one or more Subject Entities, or (iii) make, or allow one or more Subject Entities to make, or allow the Company to be subject to or have its Common Stock be subject to or party to one or more Subject Entities making, a purchase, tender or exchange offer that is accepted by the holders of at least either (x) 50% of the outstanding shares of Common Stock, (y) 50% of the outstanding shares of Common Stock calculated as if any shares of Common Stock held by all Subject Entities making or party to, or Affiliated with any Subject Entities making or party to, such purchase, tender or exchange offer were not outstanding; or (z) such number of shares of Common Stock such that all Subject Entities making or party to, or Affiliated with any Subject Entity making or party to, such purchase, tender or exchange offer, become collectively the beneficial owners (as defined in Rule 13d-3 under the Exchange Act) of at least 50% of the outstanding shares of Common Stock, or (iv) consummate a stock purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off or scheme of arrangement) with one or more Subject Entities whereby such Subject Entities, individually or in the aggregate, acquire, either (x) at least 50% of the outstanding shares of Common Stock, (y) at least 50% of the outstanding shares of Common Stock calculated as if any shares of Common Stock held by all the Subject Entities making or party to, or Affiliated with any Subject Entity making or party to, such stock purchase agreement or other business combination were not outstanding; or (z) such number of shares of Common Stock such that the Subject Entities become collectively the beneficial owners (as defined in Rule 13d-3 under the Exchange Act) of at least 50% of the outstanding shares of Common Stock, or (v) reorganize, recapitalize or reclassify its Common Stock, (B) that the Company shall, directly or indirectly, including through Subsidiaries, Affiliates or otherwise, in one or more related transactions allow any Subject Entity individually or the Subject Entities in the aggregate to be or become the "beneficial owner" (as defined in Rule 13d-3 under the Exchange Act), directly or indirectly, whether through acquisition, purchase, assignment, conveyance, tender, tender offer, exchange, reduction in outstanding shares of Common Stock, merger, consolidation, business combination, reorganization, recapitalization, spin-off, scheme of arrangement, reorganization, recapitalization or reclassification or otherwise in any manner whatsoever, of either (x) at least 50% of the aggregate ordinary voting power represented by issued and outstanding Common Stock, (y) at least 50% of the aggregate ordinary voting power represented by issued and outstanding Common Stock not held by all such Subject Entities as of the Subscription Date calculated as if any shares of Common Stock held by all such Subject Entities were not outstanding, or (z) a percentage of the aggregate ordinary voting power represented by issued and outstanding shares of Common Stock or other equity securities of the Company sufficient to allow such Subject Entities to effect a statutory short form merger or other transaction requiring other stockholders of the Company to surrender their shares of Common Stock without approval of the stockholders of the Company or (C) that the Company shall, directly or indirectly, including through Subsidiaries, Affiliates or otherwise, in one or more related transactions, the issuance of or the entering into any other instrument or transaction structured in a manner to circumvent, or that circumvents, the intent of this definition in which case this definition shall be construed and implemented in a manner otherwise than in strict conformity with the terms of this definition to the extent necessary to correct this definition or any portion of this definition which may be defective or inconsistent with the intended treatment of such instrument or transaction.

k. "**GAAP**" means United States generally accepted accounting principles, consistently applied during the periods involved.

l. "**Group**" means a "group" as that term is used in Section 13(d) of the Exchange Act and as defined in Rule 13d-5 thereunder.

m. "**Indebtedness**" of any Person means, without duplication (i) all indebtedness for borrowed money, (ii) all reimbursement or payment obligations with respect to letters of credit, surety bonds and other similar instruments, (iii) all obligations evidenced by notes, bonds, debentures or similar instruments, including obligations so evidenced incurred in connection with the acquisition of property, assets or businesses, (iv) all indebtedness created or arising under any conditional sale or other title retention agreement, or incurred as financing, in either case with respect to any property or assets acquired with the proceeds of such indebtedness (even though the rights and remedies of the seller or bank under such agreement in the event of default are limited to repossession or sale of such property), (v) all monetary obligations under any leasing or similar arrangement which, in connection with GAAP, is classified as a finance lease, (vi) all indebtedness referred to in clauses (i) through (v) above secured by (or for which the holder of such Indebtedness has an existing right, contingent or otherwise, to be secured by) any mortgage, deed of trust, lien, pledge, charge, security interest or other encumbrance of any nature whatsoever in or upon any property or assets (including accounts and contract rights) with respect to any asset or property owned by any Person, even though the Person which owns such assets or property has not assumed or become liable for the payment of such indebtedness, and (vii) all Contingent Obligations in respect of indebtedness or obligations of others of the kinds referred to in clauses (i) through (vii) above.

n. "**Intellectual Property Rights**" shall have the meaning ascribed to such term in the Securities Purchase Agreement.

o. "**Material Adverse Effect**" shall have the meaning ascribed to such term in the Securities Purchase Agreement.

p. "**Options**" means any rights, warrants or options to subscribe for or purchase (i) shares of Common Stock or (ii) Convertible Securities.

q. "**Permitted Indebtedness**" means (i) Indebtedness evidenced by this Note and the Other Notes, (ii) trade payables incurred in the ordinary course of business and consistent with past practice, (iii) unsecured Indebtedness incurred by the Company that is made expressly subordinate in right of payment to the Indebtedness evidenced by this Note, as reflected in a written agreement acceptable to the Required Holders and approved by the Required Holders in writing, and which Indebtedness (a) does not provide at any time for the payment, prepayment, repayment, repurchase or defeasance, directly or indirectly, of any principal or premium, if any, thereon until ninety-one (91) days after the Maturity Date or later and (b) includes terms and conditions acceptable to the Required Holders and (iv) Indebtedness, up to $50,000, in the aggregate, secured by Permitted Liens described in clauses (iv) of the definition of Permitted Liens.

r. "**Permitted Liens**" means (i) any Lien for taxes not yet due or delinquent or being contested in good faith by appropriate proceedings for which adequate reserves have been established in accordance with GAAP, (ii) any statutory Lien arising in the ordinary course of business by operation of law with respect to a liability that is not yet due or delinquent, (iii) any Lien created by operation of law, such as materialmen's liens, mechanics' liens and other similar liens, arising in the ordinary course of business with respect to a liability that is not yet due or delinquent or that are being contested in good faith by appropriate proceedings, (iv) Liens (A) upon or in any equipment acquired or held by the Company or any of its Subsidiaries to secure the purchase price of such equipment or Indebtedness incurred solely for the purpose of financing the acquisition or lease of such equipment, or (B) existing on such equipment at the time of its acquisition, provided that the Lien is confined solely to the property so acquired and improvements thereon, and the proceeds of such equipment, (v) Liens incurred in connection with the extension, renewal or refinancing of the Indebtedness secured by Liens of the type described in clause (iv) above, provided that any extension, renewal or replacement Lien shall be limited to the property encumbered by the existing Lien and the principal amount of the Indebtedness being extended, renewed or refinanced does not increase, (vi) leases or subleases and licenses and sublicenses granted to others in the ordinary course of the Company's business, not interfering in any material respect with the business of the Company and its Subsidiaries taken as a whole, (vii) Liens in favor of customs and revenue authorities arising as a matter of law to secure payments of custom duties in connection with the importation of goods and (viii) Liens arising from judgments, decrees or attachments in circumstances not constituting an Event of Default under Section 4(a)(ix).

s. "**Person**" means an individual, a limited liability company, a partnership, a joint venture, a corporation, a trust, an unincorporated organization, any other entity and any governmental entity or any department or agency thereof.

t. "**Purchaser**" shall have the meaning ascribed to such term in the Securities Purchase Agreement.

u. "**Redemption Dates**" means, collectively, the Event of Default Redemption Dates and the Change of Control Redemption Dates and the Optional Prepayment Date, as applicable, each of the foregoing, individually, a Redemption Date.

v. "**Redemption Notices**" means, collectively, the Event of Default Redemption Notices and the Change of Control Redemption Notices and the Optional Prepayment Notice, each of the foregoing, individually, a Redemption Notice.

w. "**Redemption Premium**" means 110%.

x. "**Redemption Prices**" means, collectively, the Event of Default Redemption Prices and the Change of Control Redemption Prices and the Note Amount being prepaid upon any Optional Prepayment, each of the foregoing, individually, a Redemption Price.

y. "**Related Fund**" means, with respect to any Person, a fund or account managed by such Person or an Affiliate of such Person.

z. "**Required Holders**" means the holders of Notes representing, in aggregate, at least a majority of the aggregate principal amount of the Notes then outstanding.

aa. "**SEC**" means the United States Securities and Exchange Commission.

bb. "**Securities Act**" means the Securities Act of 1933, as amended.

cc. "**Securities Purchase Agreement**" means that certain securities purchase agreement dated as of the date hereof by and among the Company and each purchaser identified on the signature pages attached thereto pursuant to which the Company issued the Notes and Shares, as may be amended, amended and restated, supplemented or otherwise modified from time to time.

dd. "**Shares**" shall have the meaning ascribed to such term in the Securities Purchase Agreement, and shall include all warrants issued in exchange therefor or replacement thereof.

ee. "**Subject Entity**" means any Person, Persons or Group or any Affiliate or associate of any such Person, Persons or Group.

ff. "**Subscription Date**" means the date hereof.

gg. "**Subsidiary**" shall have the meaning ascribed to such term in the Securities Purchase Agreement.

hh. "**Transaction Documents**" shall have the meaning ascribed to such term in the Securities Purchase Agreement.

[*Signature page follows*.]

IN WITNESS WHEREOF, the Company has caused this Note to be duly executed as of the Issuance Date set out above.

Oragenics, Inc.

By: _____
Name: _____
Title: _____

Exhibit 10.27

ORAGENICS, Inc. - Lock-up Agreement

March 13, 2025

Oragenics, Inc.
1990 Main Street, Suite 750
Sarasota, Florida 34236

Ladies and Gentlemen:

The undersigned understands that Oragenics, Inc., a Florida corporation (the "**Company**"), entered into a Securities Purchase Agreement (the "**SPA**") on March 13, 2025 with each purchaser (each, an "**Investor**", and collectively "**Investors**") identified on the signature pages of the SPA, providing for the private placement (the "**Transaction**") of senior secured notes and shares of Series G Mirroring Preferred Stock, par value $0.0001 per share, of the Company ("**Shares**").

To induce the Company to continue its efforts in connection with the Transaction, the undersigned hereby irrevocably enters into this Lock-Up Agreement (this "**Agreement**") and agrees that the undersigned will not, during the 90-day period commencing on the date hereof (such period, the "**Lock-Up Period**"), (1) offer, pledge, sell, contract to sell, grant, lend, or otherwise transfer or dispose of, directly or indirectly, any Shares or any securities convertible into or exercisable or exchangeable for Shares, whether now owned or hereafter acquired by the undersigned (or any Affiliate of the undersigned) or with respect to which the undersigned (or any Affiliate of the undersigned) has or hereafter acquires the power of disposition (collectively, the "**Lock-Up Securities**"); (2) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the Lock-Up Securities, whether any such transaction described in clause (1) or (2) above is to be settled by delivery of Lock-Up Securities, in cash or otherwise; (3) make any demand for or exercise any right with respect to the registration of any Lock-Up Securities; or (4) publicly disclose the intention to make any offer, sale, pledge or disposition, or to enter into any transaction, swap, hedge or other arrangement relating to any Lock-Up Securities.

Notwithstanding the foregoing, and subject to the conditions below, the undersigned may transfer Lock-Up Securities in connection with:

1. transfers of Lock-Up Securities as a *bona fide* gift, by will or intestacy or to a family member or trust for the benefit of the undersigned (for purposes of this lock-up agreement, "family member" means any relationship by blood, marriage or adoption, not more remote than first cousin) provided that the transferee agrees to sign and deliver a lock-up agreement substantially in the form of this lock-up agreement for the balance of the Lock-Up Period;

2. transfers of Lock-Up Securities to a charity or educational institution;

3. if the undersigned is a corporation, partnership, limited liability company or other business entity, (i) any transfers of Lock-Up Securities to another corporation, partnership or other business entity that controls, is controlled by or is under common control with the undersigned or (ii) distributions of Lock-Up Securities to members, partners, shareholders, subsidiaries or affiliates (as defined in Rule 405 promulgated under the Securities Act of 1933, as amended) of the undersigned as of the date of this Agreement, provided that the transferee agrees to sign and deliver a lock-up agreement substantially in the form of this lock-up agreement for the balance of the Lock-Up Period;

4. if the undersigned is a trust, to a trustee or beneficiary of the trust provided that in the case of any transfer pursuant to the foregoing clauses (b), (c) (d) or (e), (i) any such transfer shall not involve a disposition for value, (ii) each transferee shall sign and deliver to the Company a lock-up agreement substantially in the form of this lock-up agreement and (iii) no filing under Section 13 or Section 16 of the Securities Exchange Act of 1934, as amended (the "**Exchange Act**") or other public announcement shall be required or shall be voluntarily made during the Lock-Up Period;

5. the receipt by the undersigned from the Company of Shares upon the vesting of restricted stock awards or stock units or upon the exercise of options to purchase the Shares issued under an equity incentive plan of the Company or an employment arrangement (the "**Plan Shares**") or the transfer or withholding of Shares or any securities convertible into Shares to the Company upon a vesting event of the Company's securities or upon the exercise of options to purchase the Company's securities, in each case on a "cashless" or "net exercise" basis or to cover tax obligations of the undersigned in connection with such vesting or exercise provided that if the undersigned is required to file a report under Section 13 or Section 16 of the Exchange Act reporting a reduction in beneficial ownership of Shares during the Lock-Up Period, the undersigned shall include a statement in such schedule or report to the effect that the purpose of such transfer was to cover tax withholding obligations of the undersigned in connection with such vesting or exercise and, provided further that the Plan Shares shall be subject to the terms of this lock-up agreement;

6. the establishment of a trading plan pursuant to Rule 10b5-1 under the Exchange Act for the transfer of Lock-Up Securities provided that (i) such plan does not provide for the transfer of Lock-Up Securities during the Lock-Up Period and (ii) no filing under Section 13 or Section 16 of the Exchange Act or other public announcement shall be required or shall be voluntarily made during the Lock-Up Period;

7. the transfer of Lock-Up Securities that occurs by operation of law, such as pursuant to a qualified domestic order or in connection with a divorce settlement, provided that the transferee agrees to sign and deliver a lock-up agreement substantially in the form of this lock-up agreement for the balance of the Lock-Up Period, and provided further that any filing under Section 13 or Section 16 of the Exchange Act that is required to be made during the Lock-Up Period as a result of such transfer shall include a statement that such transfer has occurred by operation of law; and provided further that competent legal counsel for the Company shall have first advised that such transfer is a mandatory and not voluntary transfer; and

8. the transfer of Lock-Up Securities pursuant to a bona fide third party tender offer, merger, consolidation or other similar transaction made to all holders of the Shares involving a change of control (as defined below) of the Company after the closing of the Transaction and approved by the Company's board of directors; provided that in the event that the tender offer, merger, consolidation or other such transaction is not completed, the Lock-Up Securities owned by the undersigned shall remain subject to the restrictions contained in this lock-up agreement. For purposes of clause (i) above, "change of control" shall mean the consummation of any bona fide third party tender offer, merger, amalgamation, consolidation or other similar transaction the result of which is that any "person" (as defined in Section 13(d)(3) of the Exchange Act), or group of persons, becomes the beneficial owner (as defined in Rules 13d-3 and 13d-5 of the Exchange Act) of a majority of total voting power of the voting shares of the Company. The undersigned also agrees and consents to the entry of stop transfer instructions with the Company's transfer agent and registrar against the transfer of the undersigned's Lock-Up Securities except in compliance with this lock-up agreement.

This Agreement may not be amended or otherwise modified in any respect without the written consent of each of the Company and the undersigned. This Agreement shall be governed by and construed in accordance with the law of the State of New York. The undersigned hereby irrevocably submits to the exclusive jurisdiction of the United States District Court sitting in the Southern District of New York and the courts of the State of New York located in the City and County of New York, for the purposes of any suit, action or proceeding arising out of or relating to this Agreement, and hereby waives, and agrees not to assert in any such suit, action or proceeding, any claim that (i) it is not personally subject to the jurisdiction of such court, (ii) the suit, action or proceeding is brought in an inconvenient forum, or (iii) the venue of the suit, action or proceeding is improper. The undersigned hereby irrevocably waives personal service of process and consents to process being served in any such suit, action or proceeding by receiving a copy thereof sent to the Company at the address in effect for notices to it under the SPA and agrees that such service shall constitute good and sufficient service of process and notice thereof. The undersigned hereby waives any right to a trial by jury. Nothing contained herein shall be deemed to limit in any way any right to serve process in any manner permitted by law. The undersigned agrees and understands that this Agreement does not intend to create any relationship between the undersigned and any Purchaser and that no Purchaser is entitled to cast any votes on the matters herein contemplated and that no issuance or sale of the Securities is created or intended by virtue of this Agreement.

The undersigned understands that the Company is relying upon this lock-up agreement in proceeding toward consummation of the Transaction. The undersigned further understands that this lock-up agreement is irrevocable and shall be binding upon the undersigned's heirs, legal representative, successors and assigns. This Letter Agreement is intended for the benefit of the parties hereto and their respective successors and permitted assigns and is not for the benefit of, nor may any provisions hereof be enforced by, any of other person or entity.

The undersigned understands that, if the SPA is not executed by March 18, 2025 or if the SPA (other than the provisions thereof which survive termination) shall terminate or be terminated prior to payment for and delivery of the Shares to be sold thereunder, then this lock-up agreement shall be void and of no further force or effect.

Whether or not the Transaction actually occurs depends on a number of factors, including market conditions. Any Transaction will only be made pursuant to the SPA.

[Lock-Up Agreement Signature Page]

The undersigned has read and agrees to be bound by the terms of this Lock-Up Agreement dated as of the date first above written.

Very truly yours,

_____

(Signature)

_____

Name

Address: _____

_____

_____

_____

Email: _____

Exhibit 10.28

Execution Version

PLACEMENT AGENCY AGREEMENT

Dawson James Securities, Inc.
101 North Federal Highway
Suite 600
Boca Raton, FL 33432

March 13, 2025

Ladies and Gentlemen:

This letter (this "Agreement") constitutes the agreement between Oragenics, Inc., a Florida corporation (the "Company"), and Dawson James Securities, Inc. ("Dawson") pursuant to which Dawson shall serve as the placement agent (the "Placement Agent"), for the Company, on a reasonable "best efforts" basis, in connection with the proposed private offer and placement (the "Offering") by the Company of its Securities (as defined Section 3 of this Agreement) in reliance upon the exemption from securities registration afforded by Section 4(a)(2) of the Securities Act of 1933, as amended (the "Securities Act") and Rule 506(b) of Regulation D ("Regulation D") as promulgated by the United States Securities and Exchange Commission (the "Commission") under the Securities Act. The Company and Dawson hereby mutually agree to the terms of the Offering and the Securities, and nothing in this Agreement may be construed to suggest that Dawson would have the power or authority to bind the Company or an obligation for the Company to issue any Securities or complete the Offering. The Company expressly acknowledges and agrees that Dawson's obligations hereunder are on a reasonable "best efforts" basis only and that the execution of this Agreement does not constitute a commitment by Dawson to purchase the Securities and does not ensure the successful placement of the Securities or any portion thereof or the success of Dawson placing the Securities. The terms of the Offering and the Securities shall be mutually agreed upon by the Company and the Purchasers and nothing herein constitutes that the Placement Agent would have the power or authority to bind the Company or any Purchaser or an obligation for the Company to issue any Securities or complete the Offering. This Agreement and the documents, if any, executed and delivered by the Company and the Purchasers in connection with the Offering shall be collectively referred to herein as the "Transaction Documents."

1. Appointment of Dawson James Securities, Inc. as Exclusive Placement Agent.

On the basis of the representations, warranties, covenants and agreements of the Company herein contained, and subject to all the terms and conditions of this Agreement, the Company hereby appoints the Placement Agent as its exclusive placement agent in connection with the Offering. The Offering documents shall consist of a Securities Purchase Agreement, form of Note, form of Certificate of Designation, form of Lock-Up Agreement, and all exhibits attached thereto (collectively, the foregoing are referred to as the "Subscription Documents"). Pursuant to this appointment, the Placement Agent will solicit offers for the purchase of or attempt to place all or part of the Securities of the Company in the proposed Offering. Until the final Closing (as defined below) or earlier upon termination of this Agreement pursuant to Section 5 hereof, the Company shall not, without the prior written consent of the Placement Agent, solicit or accept offers to purchase the Securities other than through the Placement Agent. The Company acknowledges that the Placement Agent will act as an agent of the Company and use its reasonable "best efforts" to solicit offers to purchase the Securities from the Company on the terms, and subject to the conditions, set forth in the Subscription Documents. The Placement Agent shall use commercially reasonable efforts to assist the Company in obtaining performance by each Purchaser whose offer to purchase Securities has been solicited by the Placement Agent, but the Placement Agent shall not, except as otherwise provided in this Agreement, be obligated to disclose the identity of any potential purchaser or have any liability to the Company in the event any such purchase is not consummated for any reason. Under no circumstances will the Placement Agent be obligated to underwrite or purchase any Securities for its own account and, in soliciting purchases of the Securities, the Placement Agent shall act solely as an agent of the Company. The Services provided pursuant to this Agreement shall be on an "agency" basis and not on a "principal" basis.

The Placement Agent will solicit offers for the purchase of the Securities in the Offering at such times and in such amounts as the Placement Agent deems advisable. The Company shall have the sole right to accept offers to purchase Securities and may reject any such offer, in whole or in part. The Placement Agent may retain other brokers or dealers to act as sub-agents on its behalf in connection with the Offering and may pay any sub-agent a solicitation fee with respect to any Securities placed by it. The Company and Placement Agent shall negotiate the timing and terms of the Offering and acknowledge that the Offering and the provision of Placement Agent services related to the Offering are subject to market conditions and the receipt of all required related clearances and approvals.

2. Fees; Expenses; Other Arrangements.

A. Placement Agent's Fee. As compensation for services rendered, the Company shall pay to the Placement Agent in cash by wire transfer in immediately available funds to an account or accounts designated by the Placement Agent an amount (the "Placement Fee") equal to seven percent (7.0%) of the aggregate gross proceeds received by the Company from the sale of the Securities in the Offering, at the closing (the "Closing" and the date on which the Closing occurs, the "Closing Date"). The Placement Agent may deduct from the net proceeds of the Offering payable to the Company on the Closing Date the Placement Fee set forth herein to be paid by the Company to the Placement Agent.

B. Reserved.

C. Offering Expenses. The Company will be responsible for and will pay all expenses relating to the Offering, including, without limitation, (a) all filing fees and expenses relating to the registration of the Securities with the Commission; (b) all FINRA Public Offering filing fees; (c) all fees and expenses relating to the listing of the Company's common stock on the NYSE American; (d) all fees, expenses and disbursements relating to the registration or qualification of the Securities under the "blue sky" securities laws of such states and other jurisdictions as Dawson may reasonably designate (including, without limitation, all filing and registration fees, and the reasonable fees and disbursements of "blue sky" counsel, which will be Placement Agent's counsel); (e) all fees, expenses and disbursements relating to the registration, qualification or exemption of the Securities under the securities laws of such foreign jurisdictions as Dawson may reasonably designate; (f) the costs of all mailing and printing of the Offering documents; (g) transfer and/or stamp taxes, if any, payable upon the transfer of Securities from the Company to Investors; (h) the fees and expenses of the Company's accountants; and (i) "road show" expenses, diligence expenses, and reasonable legal fees of Dawson's counsel and not to exceed in the aggregate $75,000.

D. Tail Financing. If the Offering results in the Company receiving at least $2,000,000 in gross proceeds, the Placement Agent shall be entitled to fees per Section 2.A. of this Agreement with respect to any public or private offering or other financing or capital-raising transaction of any kind ("Tail Financing") to the extent that (i) such Tail Financing is provided to the Company by any investors that the Placement Agent has contacted or introduced to the Company during the term of the Placement Agent's engagement for this Offering and (ii) such Tail Financing is consummated at any time within the three month period following the Closing Date.

3. Description of the Offering.

The Securities to be offered directly to various investors (each, an "Investor" or "Purchaser" and, collectively, the "Investors" or the "Purchasers") in the Offering shall consist of [__]% original issue discount senior notes in the aggregate principal amount of $3,000,000 (the "Notes") and 1,000,000 shares of Series G Mirroring Preferred Stock of the Company (the "Shares" and together with the Notes, the "Securities"). If the Company shall default in its obligations to deliver Securities to a Purchaser whose offer it has accepted and who has tendered payment, the Company shall indemnify and hold the Placement Agent harmless against any loss, claim, damage or expense arising from or as a result of such default by the Company under this Agreement.

4. Delivery and Payment; Closing.

Settlement of the Securities purchased by an Investor shall be made as set forth in the Securities Purchase Agreement. On the Closing Date, the Securities to which the Closing relates shall be delivered through such means as the parties to the Securities Purchase Agreement may hereafter agree. The Securities shall be registered in such name or names and in such authorized denominations as set forth in the Securities Purchase Agreement. The term "Business Day" means any day other than a Saturday, a Sunday or a legal holiday or a day on which banking institutions are authorized or obligated by law to close in New York, New York.

5. Term and Termination of Agreement.

The term of this Agreement will commence upon the execution of this Agreement and will automatically terminate at the earlier of the Closing of the Offering or 11:59 p.m. (New York Time) on March 21, 2025. Notwithstanding anything to the contrary contained herein, any provision in this Agreement concerning or relating to confidentiality, indemnification, contribution, advancement, the Company's representations and warranties and the Company's obligations to pay fees and reimburse expenses will survive any expiration or termination of this Agreement. If any condition specified in Section 8 is not satisfied when and as required to be satisfied, this Agreement may be terminated by the Placement Agent by notice to the Company at any time on or prior to a Closing Date, which termination shall be without liability on the part of any party to any other party, except that those portions of this Agreement specified in Section 19 shall at all times be effective and shall survive such termination.

6. Permitted Acts.

Nothing in this Agreement shall be construed to limit the ability of the Placement Agent, its officers, directors, employees, agents, associated persons and any individual or entity "controlling," controlled by," or "under common control" with the Placement Agent (as those terms are defined in Rule 405 under the Securities Act) to conduct its business including without limitation the ability to pursue, investigate, analyze, invest in, or engage in investment banking, financial advisory or any other business relationship with any individual or corporation, partnership, trust, incorporated or unincorporated association, joint venture, limited liability company, joint stock company, government (or an agency or subdivision thereof) or other entity of any kind.

7. Representations, Warranties and Covenants of the Company.

As of the date and time of the execution of this Agreement and the Closing Date, the Company (i) makes such representations represents, warrants and covenants to the Placement Agent as the Company makes to the Investors pursuant to the Securities Purchase Agreement, and (ii) further represents, warrants and covenants to the Placement Agent that:

A. Validity and Binding Effect of Agreements. This Agreement and the Transaction Documents have been duly and validly authorized by the Company, and, when executed and delivered, will constitute, the valid and binding agreements of the Company, enforceable against the Company in accordance with its respective terms, except: (i) as such enforceability may be limited by bankruptcy, insolvency, reorganization or similar laws affecting creditors' rights generally; (ii) as enforceability of any indemnification or contribution provision may be limited under the federal and state securities laws; and (iii) that the remedy of specific performance and injunctive and other forms of equitable relief may be subject to the equitable defenses and to the discretion of the court before which any proceeding therefor may be brought.

B. No Conflicts, etc. The execution, delivery and performance by the Company of this Agreement, the Transaction Documents and all ancillary documents, the consummation by the Company of the transactions herein and therein contemplated and the compliance by the Company with the terms hereof and thereof do not and will not, with or without the giving of notice or the lapse of time or both: (i) result in a material breach of, or conflict with any of the terms and provisions of, or constitute a material default under, or result in the creation, modification, termination or imposition of any lien, charge or encumbrance upon any property or assets of the Company pursuant to the terms of any agreement or instrument to which the Company is a party; (ii) result in any violation of the provisions of the Company's Certificate of Incorporation (as the same may be amended or restated from time to time, the "Charter") or the by-laws of the Company (as the same may be amended or restated from time to time, the "Bylaws"); or (iii) violate any existing applicable law, rule, regulation, judgment, order or decree of any Governmental Entity as of the date hereof.

C. No Defaults; Violations. No material default exists in the due performance and observance of any term, covenant or condition of any material license, contract, indenture, mortgage, deed of trust, note, loan or credit agreement, or any other agreement or instrument evidencing an obligation for borrowed money, or any other material agreement or instrument to which the Company is a party or by which the Company may be bound or to which any of the properties or assets of the Company is subject. The Company is not (i) in violation of any term or provision of its Charter or Bylaws, or (ii) in violation of any franchise, license, permit, applicable law, rule, regulation, judgment or decree of any Governmental Entity applicable to the Company.

D. Corporate Power; Licenses; Consents. The Company has all corporate power and authority to enter into this Agreement and to carry out the provisions and conditions hereof, and all consents, authorizations, approvals and orders required in connection therewith have been obtained. No consent, authorization or order of, and no filing with, any court, government agency or other body is required for the valid issuance, sale and delivery of the Securities, and the consummation of the transactions and agreements contemplated by this Agreement and as contemplated by the Subscription Documents, except with respect to applicable federal and state securities laws and the rules and regulations of the Financial Industry Regulatory Authority, Inc. ("FINRA").

E. Officers' Certificate. Any certificate signed by any duly authorized officer of the Company and delivered to you or to Placement Agent Counsel shall be deemed a representation and warranty by the Company to the Placement Agent as to the matters covered thereby.

F. FDA. As to each product subject to the jurisdiction of the U.S. Food and Drug Administration ("FDA") under the Federal Food, Drug and Cosmetic Act, as amended, and the regulations thereunder ("FDCA") that is manufactured, packaged, labeled, tested, distributed, sold, and/or marketed by the Company or any of its subsidiaries (each such product, a "Pharmaceutical Product"), such Pharmaceutical Product is being manufactured, packaged, labeled, tested, distributed, sold and/or marketed by the Company in compliance with all applicable requirements under FDCA and similar laws, rules and regulations relating to registration, investigational use, premarket clearance, licensure, or application approval, good manufacturing practices, good laboratory practices, good clinical practices, product listing, quotas, labeling, advertising, record keeping and filing of reports, except where the failure to be in compliance would not have a Material Adverse Effect. There is no pending, completed or, to the Company's knowledge, threatened, action (including any lawsuit, arbitration, or legal or administrative or regulatory proceeding, charge, complaint, or investigation) against the Company or any of its subsidiaries, and none of the Company or any of its subsidiaries has received any notice, warning letter or other communication from the FDA or any other governmental entity, which (i) contests the premarket clearance, licensure, registration, or approval of, the uses of, the distribution of, the manufacturing or packaging of, the testing of, the sale of, or the labeling and promotion of any Pharmaceutical Product, (ii) withdraws its approval of, requests the recall, suspension, or seizure of, or withdraws or orders the withdrawal of advertising or sales promotional materials relating to, any Pharmaceutical Product, (iii) imposes a clinical hold on any clinical investigation by the Company or any of its subsidiaries, (iv) enjoins production at any facility of the Company or any of its subsidiaries, (v) enters or proposes to enter into a consent decree of permanent injunction with the Company or any of its subsidiaries, or (vi) otherwise alleges any violation of any laws, rules or regulations by the Company or any of its subsidiaries, and which, either individually or in the aggregate, would have a Material Adverse Effect. The properties, business and operations of the Company have been and are being conducted in all material respects in accordance with all applicable laws, rules and regulations of the FDA. The Company has not been informed by the FDA that the FDA will prohibit the marketing, sale, license or use in the United States of any product proposed to be developed, produced or marketed by the Company nor has the FDA expressed any concern as to approving or clearing for marketing any product being developed or proposed to be developed by the Company.

G. Integration. Neither the Company, nor any of its affiliates, nor any person acting on its or their behalf has, directly or indirectly, made any offers or sales of any security or solicited any offers to buy any security, under circumstances that would cause the Offering to be integrated with prior offerings by the Company for purposes of the Securities Act that would require the registration of any such securities under the Securities Act.

H. Restriction on Sales of Capital Stock. The Company, on behalf of itself and any successor entity, agrees that it will not, for a period of 120 days after the date of this Agreement, without the prior written consent of the Placement Agent (i) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, any shares of capital stock of the Company or any securities convertible into or exercisable or exchangeable for shares of capital stock of the Company; (ii) file or cause to be filed any registration statement with the Commission relating to the offering of any shares of capital stock of the Company or any securities convertible into or exercisable or exchangeable for shares of capital stock of the Company, other than pursuant to a registration statement on Form S-8 for employee benefit plans, whether any such transaction described in clause (i) or (ii) above is to be settled by delivery of shares of capital stock of the Company or such other securities, in cash or otherwise; or (iii) publicly announce an intention to effect any transaction specified in clause (i) or (ii). The restrictions contained in this section shall not apply to (i) the issuance by the Company of common stock upon the exercise of stock options, warrants or the conversion of a security, in each case, that is outstanding on the date hereof, (ii) the grant by the Company of stock options or other stock-based awards, or the issuance of shares of capital stock of the Company under any stock compensation plan of the Company in effect on the date hereof, or (iii) the utilization or undertaking of any At-the-Market (ATM) offering or registration statement.

I. Lock-Up Agreements. The Company has caused each of its officers and directors to deliver to the Placement Agent an executed Lock-Up Agreement, in such form as approved by the Placement Agent (the "Lock-Up Agreement"), prior to the execution of this Agreement.

8. Conditions of the Obligations of the Placement Agent.

The obligations of the Placement Agent hereunder shall be subject to the accuracy of the representations and warranties on the part of the Company set forth in Section 7 hereof, in each case as of the date hereof and as of the Closing Date as though then made, to the timely performance by each of the Company of its covenants and other obligations hereunder on and as of such dates, and to each of the following additional conditions:

A. Form D and Blue Sky. The Company shall file a Form D with respect to the Securities as required under Regulation D and to provide a copy thereof to Placement Agent promptly after such filing. The Company shall, on or before the Closing Date, take such action as the Company shall reasonably determine is necessary in order to obtain an exemption for, or to, qualify the Securities for sale to the Investors at the Closing pursuant to this Agreement under applicable securities or "blue sky" laws of the states of the United States (or to obtain an exemption from such qualification), and shall provide evidence of any such action so taken to the Placement Agent on or prior to the Closing Date. Without limiting any other obligation of the Company under this Agreement, the Company shall timely make all filings and reports relating to the offer and sale of the Securities required under all applicable securities laws (including, without limitation, all applicable federal securities laws and all applicable "blue sky" laws), and the Company shall comply with all applicable federal, state, local and foreign laws, statutes, rules, regulations and the like relating to the offering and sale of the Securities to the Investors.

B. Company Counsel Matters.

i. On the Closing Date, the Placement Agent shall have received the favorable opinion of Shumaker, Loop & Kendrick, LLP, outside counsel for the Company, dated the Closing Date and addressed to the Placement Agent, substantially in form and substance reasonably satisfactory to the Placement Agent.

C. Officers' Certificates.

i. Officers' Certificate. The Company shall have furnished to the Placement Agent a certificate, dated the Closing Date, of its Chief Executive Officer and its Chief Financial Officer stating that to their knowledge after reasonable investigation, as of the Closing Date, the representations and warranties of the Company in this Agreement are true and correct, and the Company has complied with all agreements and satisfied all conditions on its part to be performed or satisfied hereunder at or prior to the Closing Date.

ii. Secretary's Certificate. As of the Closing Date the Placement Agent shall have received a certificate of the Company signed by the Secretary of the Company, dated the Closing Date, certifying: (i) that each of the Company's Charter and Bylaws is true and complete, has not been modified and is in full force and effect; (ii) that the resolutions of the Company's Board of Directors relating to the Offering are in full force and effect and have not been modified; and (iii) the good standing of the Company and its U.S. subsidiaries. The documents referred to in such certificate, including a certified copy of the Certificate of Designations relating to the Shares, shall be attached to such certificate.

D. Delivery of Agreements.

(i) Lock-Up Agreements. On or before the date of this Agreement, the Company shall have delivered to the Placement Agent executed copies of the Lock-Up Agreements from each of the Company and its officers and directors.

E. Additional Documents. At the Closing Date, Placement Agent Counsel shall have been furnished with such documents and opinions as they may reasonably require in order to evidence the accuracy of any of the representations or warranties, or the fulfillment of any of the conditions, herein contained; and all proceedings taken by the Company in connection with the issuance and sale of the Securities as herein contemplated shall be satisfactory in form and substance to the Placement Agent and Placement Agent Counsel.

9. Indemnification and Contribution; Procedures.

A. Indemnification of the Placement Agent. The Company agrees to indemnify and hold harmless the Placement Agent, its affiliates and each person controlling such Placement Agent (within the meaning of Section 15 of the Securities Act), and the directors, officers, agents and employees of the Placement Agent, its affiliates and each such controlling person (the Placement Agent, and each such entity or person hereafter is referred to as an "Indemnified Person") from and against any losses, claims, damages, judgments, assessments, costs and other liabilities (collectively, the "Liabilities"), and shall reimburse each Indemnified Person for all fees and expenses (including the reasonable fees and expenses of counsel for the Indemnified Persons, except as otherwise expressly provided in this Agreement) (collectively, the "Expenses") and agrees to advance payment of such Expenses as they are incurred by an Indemnified Person in investigating, preparing, pursuing or defending any actions, whether or not any Indemnified Person is a party thereto, arising out of or based upon any untrue statement or alleged untrue statement of a material fact contained in (i) the Subscription Documents; (ii) any materials or information provided to investors by, or with the approval of, the Company in connection with the marketing of the Offering, including any "road show" or investor presentations made to investors by the Company (whether in person or electronically); or (iii) any application or other document or written communication (in this Section 9, collectively called "application") executed by the Company or based upon written information furnished by the Company in any jurisdiction in order to qualify the Securities under the securities laws thereof or filed with the Commission, any state securities commission or agency, any national securities exchange; or the omission or alleged omission therefrom of a material fact required to be stated therein or necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading, unless such statement or omission was made in reliance upon, and in conformity with, the Placement Agent's information. The Company also agrees to reimburse each Indemnified Person for all Expenses as they are reasonably incurred in connection with such Indemnified Person's enforcement of his or its rights under this Agreement. Each Indemnified Person is an intended third party beneficiary with the same rights to enforce the indemnification that each Indemnified Person would have if he was a party to this Agreement.

B. Procedure. Upon receipt by an Indemnified Person of actual notice of an action against such Indemnified Person with respect to which indemnity, contribution or advancement of expenses may reasonably be expected to be sought under this Agreement, such Indemnified Person shall promptly notify the Company in writing; provided that failure by any Indemnified Person so to notify the Company shall not relieve the Company from any obligation or liability which the Company may have on account of this Section 9 or otherwise to such Indemnified Person, except to the extent (and only to the extent) that its ability to assume the defense is actually impaired by such failure or delay. The Company shall, if requested by the Placement Agent, assume the defense of any such action (including the employment of counsel and reasonably satisfactory to the Placement Agent). Any Indemnified Person shall have the right to employ separate counsel in any such action and participate in the defense thereof, but the fees and expenses of such counsel shall be at the expense of such Indemnified Person unless: (i) the Company has failed promptly to assume the defense and employ counsel for the benefit of the Placement Agent and the other Indemnified Persons or (ii) such Indemnified Person shall have been advised that in the opinion of counsel that there is an actual or potential conflict of interest that prevents (or makes it imprudent for) the counsel engaged by the Company for the purpose of representing the Indemnified Person, to represent both such Indemnified Person and any other person represented or proposed to be represented by such counsel, it being understood, however, that the Company shall not be liable for the expenses of more than one separate counsel (together with local counsel), representing the Placement Agent and all Indemnified persons who are parties to such action. The Company shall not be liable for any settlement of any action effected without its written consent (which shall not be unreasonably withheld). In addition, the Company shall not, without the prior written consent of the Placement Agent, settle, compromise or consent to the entry of any judgment in or otherwise seek to terminate any pending or threatened action in respect of which advancement, reimbursement, indemnification or contribution may be sought hereunder (whether or not such Indemnified Person is a party thereto) unless such settlement, compromise, consent or termination (i) includes an unconditional release of each Indemnified Person, acceptable to such Indemnified Party, from all Liabilities arising out of such action for which indemnification or contribution may be sought hereunder and (ii) does not include a statement as to or an admission of fault, culpability or a failure to act, by or on behalf of any Indemnified Person. The advancement, reimbursement, indemnification and contribution obligations of the Company required hereby shall be made by periodic payments of the amount thereof during the course of the investigation or defense, as every Liability and Expense is incurred and is due and payable, and in such amounts as fully satisfy each and every Liability and Expense as it is incurred (and in no event later than 30 days following the date of any invoice therefor).

C. Indemnification of the Company. The Placement Agent agrees to indemnify and hold harmless the Company, its directors, its officers who signed the Subscription Documents and persons who control the Company within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act against any and all Liabilities, but only with respect to untrue statements or omissions, or alleged untrue statements or omissions made in the Subscription Documents or any amendment or supplement thereto, in reliance upon, and in strict conformity with, the Placement Agent's Information. In case any action shall be brought against the Company or any other person so indemnified based on any Subscription Documents or any amendment or supplement thereto, and in respect of which indemnity may be sought against the Placement Agent, the Placement Agent shall have the rights and duties given to the Company, and the Company and each other person so indemnified shall have the rights and duties given to the Placement Agent by the provisions of Section 9.B. The Company agrees promptly to notify the Placement Agent of the commencement of any litigation or proceedings against the Company or any of its officers, directors or any person, if any, who controls the Company within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act, in connection with the issuance and sale of the Securities or in connection with the Subscription Documents, provided, that failure by the Company so to notify the Placement Agent shall not relieve the Placement Agent from any obligation or liability which the Placement Agent may have on account of this Section 9.C. or otherwise to the Company, except to the extent the Placement Agent is materially prejudiced as a proximate result of such failure..

D. Contribution. In the event that a court of competent jurisdiction makes a finding that indemnity is unavailable to any indemnified person, then each indemnifying party shall contribute to the Liabilities and Expenses paid or payable by such indemnified person in such proportion as is appropriate to reflect (i) the relative benefits to the Company, on the one hand, and to the Placement Agent and any other Indemnified Person, on the other hand, of the matters contemplated by this Agreement or (ii) if the allocation provided by the immediately preceding clause is not permitted by applicable law, not only such relative benefits but also the relative fault of the Company, on the one hand, and the Placement Agent and any other Indemnified Person, on the other hand, in connection with the matters as to which such Liabilities or Expenses relate, as well as any other relevant equitable considerations; provided that in no event shall the Company contribute less than the amount necessary to ensure that all Indemnified Persons, in the aggregate, are not liable for any Liabilities and Expenses in excess of the amount of commissions actually received by the Placement Agent pursuant to this Agreement. The relative fault shall be determined by reference to, among other things, whether the untrue or alleged untrue statement of a material fact or the omission or alleged omission to state a material fact relates to information supplied by the Company on the one hand or the Placement Agent on the other and the parties' relative intent, knowledge, access to information and opportunity to correct or prevent such statement or omission. The Company and the Placement Agent agree that it would not be just and equitable if contributions pursuant to this subsection (D) were determined by pro rata allocation or by any other method of allocation which does not take account of the equitable considerations referred to above in this subsection (D). For purposes of this paragraph, the relative benefits to the Company, on the one hand, and to the Placement Agent on the other hand, of the matters contemplated by this Agreement shall be deemed to be in the same proportion as: (a) the total value received by the Company in the Offering, whether or not such Offering is consummated, bears to (b) the commissions paid to the Placement Agent under this Agreement. Notwithstanding the above, no person guilty of fraudulent misrepresentation within the meaning of Section 11(f) of the Securities Act shall be entitled to contribution from a party who was not guilty of fraudulent misrepresentation.

E. Limitation. The Company also agrees that no Indemnified Person shall have any liability (whether direct or indirect, in contract or tort or otherwise) to the Company for or in connection with advice or services rendered or to be rendered by any Indemnified Person pursuant to this Agreement, the transactions contemplated thereby or any Indemnified Person's actions or inactions in connection with any such advice, services or transactions, except to the extent that a court of competent jurisdiction has made a finding that Liabilities (and related Expenses) of the Company have resulted primarily from such Indemnified Person's gross negligence or willful misconduct in connection with any such advice, actions, inactions or services.

F. Survival. The advancement, reimbursement, indemnity and contribution obligations set forth in this Section 9 shall remain in full force and effect regardless of any termination of, or the completion of any Indemnified Person's services under or in connection with, this Agreement. Each Indemnified Person is an intended third-party beneficiary of this Section 9, and has the right to enforce the provisions of Section 9 as if he/she/it was a party to this Agreement.

10. Limitation of the Placement Agent's Liability to the Company.

The Placement Agent and the Company further agree that neither the Placement Agent nor any of its affiliates or any of their respective officers, directors, controlling persons (within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act), employees or agents shall have any liability to the Company, its security holders or creditors, or any person asserting claims on behalf of or in the right of the Company (whether direct or indirect, in contract or tort, for an act of negligence or otherwise) for any losses, fees, damages, liabilities, costs, expenses or equitable relief arising out of or relating to this Agreement or the Services rendered hereunder, except for losses, fees, damages, liabilities, costs or expenses that arise out of or are based on any action of or failure to act by the Placement Agent and that are finally judicially determined to have resulted solely from the gross negligence or willful misconduct of the Placement Agent.

11. Limitation of Engagement to the Company.

The Company acknowledges that the Placement Agent has been retained only by the Company, that the Placement Agent is providing services hereunder as an independent contractor (and not in any fiduciary or agency capacity) and that the Company's engagement of the Placement Agent is not deemed to be on behalf of, and is not intended to confer rights upon, any shareholder, owner or partner of the Company or any other person not a party hereto as against the Placement Agent or any of its affiliates, or any of its or their respective officers, directors, controlling persons (within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act), employees or agents. Unless otherwise expressly agreed in writing by the Placement Agent, no one other than the Company is authorized to rely upon any statement or conduct of the Placement Agent in connection with this Agreement. The Company acknowledges that any recommendation or advice, written or oral, given by the Placement Agent to the Company in connection with the Placement Agent's engagement is intended solely for the benefit and use of the Company's management and directors in considering a possible Offering, and any such recommendation or advice is not on behalf of, and shall not confer any rights or remedies upon, any other person or be used or relied upon for any other purpose. The Placement Agent shall not have the authority to make any commitment binding on the Company. The Company, in its sole discretion, shall have the right to reject any investor introduced to it by the Placement Agent. If any purchase agreement and/or related transaction documents are entered into between the Company and the investors in the Offering, the Placement Agent will be entitled to rely on the representations, warranties, agreements and covenants of the Company contained in any such purchase agreement and related transaction documents as if such representations, warranties, agreements and covenants were made directly to the Placement Agent by the Company.

12. Amendments and Waivers.

No supplement, modification or waiver of this Agreement shall be binding unless executed in writing by the party to be bound thereby. The failure of a party to exercise any right or remedy shall not be deemed or constitute a waiver of such right or remedy in the future. No waiver of any of the provisions of this Agreement shall be deemed or shall constitute a waiver of any other provision hereof (regardless of whether similar), nor shall any such waiver be deemed or constitute a continuing waiver unless otherwise expressly provided.

13. Confidentiality.

In the event of the consummation or public announcement of any Offering, the Placement Agent shall have the right to disclose its participation in such Offering, including, without limitation, the placement at its cost of "tombstone" advertisements in financial and other newspapers and journals. the Placement Agent agrees not to use any confidential information concerning the Company provided to the Placement Agent by the Company for any purposes other than those contemplated under this Agreement.

14. Headings.

The headings of the various sections of this Agreement have been inserted for convenience of reference only and will not be deemed to be part of this Agreement.

15. Counterparts.

This Agreement may be executed in one or more counterparts and, if executed in more than one counterpart, the executed counterparts shall each be deemed to be an original and all such counterparts shall together constitute one and the same instrument.

16. Severability.

In case any provision contained in this Agreement should be invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions contained herein will not in any way be affected or impaired thereby.

17. Use of Information.

The Company will furnish the Placement Agent such written information as the Placement Agent reasonably requests in connection with the performance of its services hereunder. The Company understands, acknowledges and agrees that, in performing its services hereunder, the Placement Agent will use and rely entirely upon such information as well as publicly available information regarding the Company and other potential parties to an Offering and that the Placement Agent does not assume responsibility for independent verification of the accuracy or completeness of any information, whether publicly available or otherwise furnished to it, concerning the Company or otherwise relevant to an Offering, including, without limitation, any financial information, forecasts or projections considered by the Placement Agent in connection with the provision of its services.

18. Absence of Fiduciary Relationship.

The Company acknowledges and agrees that: (a) the Placement Agent has been retained solely to act as Placement Agent in connection with the sale of the Securities and that no fiduciary, advisory or agency relationship between the Company and the Placement Agent has been created in respect of any of the transactions contemplated by this Agreement, irrespective of whether the Placement Agent has advised or is advising the Company on other matters; (b) the terms of the Securities set forth in this Agreement were established by the Company following discussions and arms-length negotiations with the Placement Agent and the Company is capable of evaluating and understanding and understands and accepts the terms, risks and conditions of the transactions contemplated by this Agreement; (c) it has been advised that the Placement Agent and its affiliates are engaged in a broad range of transactions that may involve interests that differ from those of the Company and that the Placement Agent has no obligation to disclose such interest and transactions to the Company by virtue of any fiduciary, advisory or agency relationship; and (d) it has been advised that the Placement Agent is acting, in respect of the transactions contemplated by this Agreement, solely for the benefit of the Placement Agent, and not on behalf of the Company and that the Placement Agents may have interests that differ from those of the Company. The Company waives to the full extent permitted by applicable law any claims it may have against the Placement Agent arising from an alleged breach of fiduciary duty in connection with the Offering.

19. Survival Of Indemnities, Representations, Warranties, Etc.

The respective indemnities, covenants, agreements, representations, warranties and other statements of the Company and Placement Agent, as set forth in this Agreement or made by them respectively, pursuant to this Agreement, shall remain in full force and effect, regardless of any investigation made by or on behalf of the Placement Agent, the Company, the Purchasers or any person controlling any of them and shall survive delivery of and payment for the Securities. Notwithstanding any termination of this Agreement, including without limitation any termination pursuant to Section 5, the payment, reimbursement, indemnity, contribution and advancement agreements contained in Sections 2, 9, 10, and 11, respectively, and the Company's covenants, representations, and warranties set forth in this Agreement shall not terminate and shall remain in full force and effect at all times. The indemnity and contribution provisions contained in Section 9 and the covenants, warranties and representations of the Company contained in this Agreement shall remain operative and in full force and effect regardless of (i) any termination of this Agreement, (ii) any investigation made by or on behalf of any Placement Agent, any person who controls any Placement Agent within the meaning of either Section 15 of the Securities Act or Section 20 of the Exchange Act or any affiliate of any Placement Agent, or by or on behalf of the Company, its directors or officers or any person who controls the Company within the meaning of either Section 15 of the Securities Act or Section 20 of the Exchange Act, and (iii) the issuance and delivery of the Securities.

20. Governing Law.

This Agreement shall be governed by and construed in accordance with the laws of the State of New York applicable to agreements made and to be fully performed therein. Any disputes that arise under this Agreement, even after the termination of this Agreement, will be heard only in the state or federal courts located in the City of New York, State of New York. The parties hereto expressly agree to submit themselves to the jurisdiction of the foregoing courts in the City of New York, State of New York. The parties hereto expressly waive any rights they may have to contest the jurisdiction, venue or authority of any court sitting in the City and State of New York.

21. Notices.

All communications hereunder shall be in writing and shall be mailed or hand delivered and confirmed to the parties hereto as follows:

If to the Company:

Oragenics, Inc.
1990 Main Street, Suite 750
Sarasota, FL 34236
Attention: Chief Financial Officer

If to the Placement Agent:

Dawson James Securities, Inc.
101 North Federal Highway
Suite 600
Boca Raton, FL 33432
Attention: Chief Executive Officer

Any party hereto may change the address for receipt of communications by giving written notice to the others.

22. Miscellaneous.

This Agreement shall not be modified or amended except in writing signed by the Placement Agent and the Company. This Agreement constitutes the entire agreement of the Placement Agent and the Company, and supersedes any prior agreements, with respect to the subject matter hereof. If any provision of this Agreement is determined to be invalid or unenforceable in any respect, such determination will not affect such provision in any other respect, and the remainder of this Agreement shall remain in full force and effect. This Agreement may be executed in counterparts (including facsimile or .pdf counterparts), each of which shall be deemed an original but all of which together shall constitute one and the same instrument.

23. Successors.

This Agreement will inure to the benefit of and be binding upon the parties hereto, and to the benefit of the employees, officers and directors and controlling persons referred to in Section 9 hereof, and to their respective successors, and personal representative, and, except as set forth in Section 9 of this Agreement, no other person will have any right or obligation hereunder.

24. Partial Unenforceability.

The invalidity or unenforceability of any section, paragraph or provision of this Agreement shall not affect the validity or enforceability of any other section, paragraph or provision hereof. If any Section, paragraph or provision of this Agreement is for any reason determined to be invalid or unenforceable, there shall be deemed to be made such minor changes (and only such minor changes) as are necessary to make it valid and enforceable.

[SIGNATURE PAGE TO FOLLOW]

In acknowledgment that the foregoing correctly sets forth the understanding reached by the Placement Agent and the Company, and intending to be legally bound, please sign in the space provided below, whereupon this letter shall constitute a binding Agreement as of the date executed.

Very truly yours,

ORAGENICS, INC.

By: /s/ Janet Huffman
Name: Janet Huffman
Title: Chief Financial Officer

Confirmed as of the date first written above:

DAWSON JAMES SECURITIES, INC.

By: /s/ Robert D. Keyser, Jr.
Name: Robert D. Keyser, Jr.
Title: Chief Executive Officer

SCHEDULE I

Issuer General Use Free Writing Prospectuses

None.

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We hereby consent to the incorporation by reference in the Registration Statements on Form S-1 (333-224498, 333-224950 and 333-226150), Form S-3 (333-213321, 333-230422, 333-238789 and 333-269225)), and Form S-8 (333-184588, 333-223088, 333-225894, 333-23230, 333-263821, 333-276460 and 333-283841) of the report dated March XX, 2025 included in this Annual Report on Form 10-K of Oragenics, Inc. (the "Company"), relating to the consolidated financial statements of the Company and its subsidiaries as of and for the year ended December 31, 2024 (collectively referred to as, "Audit Report on the 2023 Form 10-K") and inclusion therein of the Audit Report on the 2024 Form 10-K filed March XX, 2025 with the Securities Exchange Commission.

/s/ Cherry Bekaert, LLP.

Tampa, Florida

March 14, 2025

Exhibit 31.1

CERTIFICATION

I, Janet Huffman certify that:

1. I have reviewed this Annual Report on Form 10-K of Oragenics, 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 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;

(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;

(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 that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer 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:

(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.

Dated this day of March 14, 2025

By: */s/ Janet Huffman*
Janet Huffman
Chief Financial Officer, Interim Chief Executive Officer, President

Exhibit 31.2

CERTIFICATION

I, Janet Huffman, certify that:

1. I have reviewed this Annual Report on Form 10-K of Oragenics, 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 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;

(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;

(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 that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer 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:

(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.

Dated this day of March 14, 2025

By:*/s/ Janet Huffman*
Janet Huffman
Chief Financial Officer

Exhibit 32.1

Certification of Principal Executive Officer

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. Section 1350)

In connection with the Annual Report on Form 10-K for the period ended December 31, 2024 (the "Report") of Oragenics, Inc. (the "Registrant"), as filed with the Securities and Exchange Commission on the date hereof, I, Janet Huffman, hereby certify, to the best of my knowledge, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Registrant.

/s/ Janet Huffman

Name: Janet Huffman
Interim Principal Executive Officer

Date: March 14, 2025

Exhibit 32.2

Certification of Principal Financial Officer

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. Section 1350)

In connection with the Annual Report on Form 10-K for the period ended December 31, 2024 (the "Report") of Oragenics, Inc. (the "Registrant"), as filed with the Securities and Exchange Commission on the date hereof, I, Janet Huffman, hereby certify, to the best of my knowledge, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Registrant.

/s/ Janet Huffman
Name: Janet Huffman
Principal Financial Officer

Date: March 14, 2025