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

FORM 10-K

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

For the fiscal year ended December 31, 2025

☐ **TRANSITION REPORT PURSUANT TO 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.)**
9015 Town Center Parkway, Suite 143, Lakewood Ranch, FL	**34202**
(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 $3,126,135 computed based upon a last sales price of $3.82 as reported by the NYSE American as of June 30, 2025, the last business day of the registrant's most recently completed second fiscal quarter.

As of March 13, 2026, there were 4,336,029 shares of the registrant's Common stock outstanding.

Note Regarding Reverse Stock Split

On June 3, 2025, the Company effected a 1-for-30 reverse stock split of its outstanding common stock. All share and per share amounts in these consolidated financial statements and related footnotes have been retroactively adjusted to reflect the reverse stock split for all periods presented in the accompanying financial statements, unless otherwise indicated (the "Reverse Stock Split").

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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 compliance with the continued listing requirements of 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 biopharmaceutical company dedicated to the research and development of nasal delivery pharmaceutical therapies targeting neurological conditions and infectious diseases. The Company is currently focused on advancing the development and commercialization of its lead product candidate, ONP-002. Our lead product, ONP-002, is a fully synthetic, non-naturally occurring neurosteroid, is lipophilic, and we believe it can cross the blood-brain barrier with the goal of rapidly eliminating swelling, oxidative stress and inflammation while restoring proper blood flow through gene amplification.

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

Our lead product and focus are on the development and commercialization of ONP-002 for the treatment of mild traumatic brain injury ("mTBI" or "Concussion").

ONP-002, together with our other neurology assets, are referred to herein as the Neurology Assets. To date, ONP-002 has been shown to be stable up to 104 degrees for 18 months. The drug candidate is manufactured into a powder and filled into a 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 is designed 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 effectively 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 clinical trial	Phase 2a clinical trial	US based clinical trial	Phase 3 clinical trial
Complete	Complete	Q1 2026 Start	Estimated Q1 2027 start	Estimated Q1 2028 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 have 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 and Philippines. A bundle of patents under the European Patent Convention have also been granted, namely, France, Germany, Ireland, Italy, Spain, Switzerland and UK.
    - 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 and/or, minimize 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 have 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, *inter alia*, 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 (entProgesterone) and Progesterone induce the PXR receptor. Receptor binding studies have been performed showing ONP-002 does not activate the classical Progesterone Receptor.

ONP-002 Animal Studies

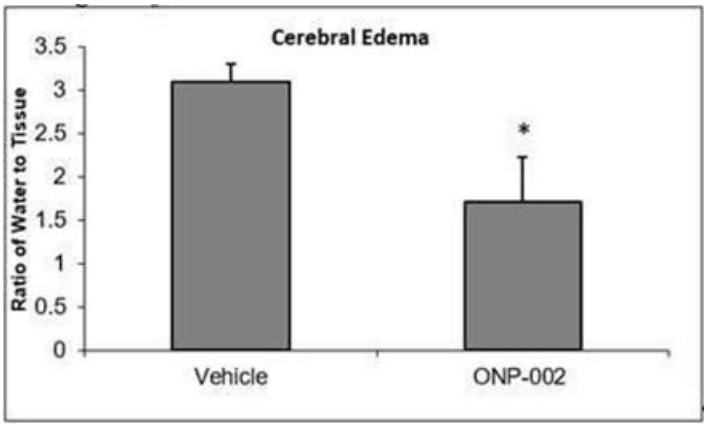
All surgical animals (male Sprague-Dawley rats weighing approximately 250 grams) were anesthetized with an initial isoflurane induction for 4 minutes, the minimum time necessary to sedate the animal. The scalp was shaved and cleaned with isopropanol and betadine. During the stereotaxic surgery, anesthesia 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.

After a delay due to a large hospital merger in Australia that included our lead site, we anticipate launching our Phase 2a clinical trials in Australia in the first quarter of 2026. Phase 2a clinical trials are focused on feasibility metrics and we anticipate that this data will be important in our clinical trial design and strategy for future U.S. based clinical trials.

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. Additional non-clinical studies are planned for 2026 as part of our IND submission strategy.

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

We are currently focused on applying intranasal drug delivery to the development of therapies for neurological conditions, including mild traumatic brain injury ("mTBI" or concussion). We believe the treatment of concussion represents a significant unmet medical need, as there are currently no FDA-approved pharmacological therapies specifically indicated for the treatment of concussion.

We believe intranasal delivery may offer certain advantages compared to systemic administration, including non-invasive administration and the potential for more rapid central nervous system exposure. Systemic administration can present challenges in achieving efficient delivery of certain therapies to the central nervous system, which we believe present an opportunity for intranasal drug delivery approaches.

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 preclinical 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 act 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 products 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 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 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 prohibit 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 nutraceuticals, 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 patents 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 or have rights to 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, exporting, and/or importing our products and methods may depend on the extent to which we have rights under valid and enforceable patents and/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 using and/or manufacturing the same, or will be held invalid, unenforceable or not infringed.

Patents

We attempt to protect our technology, innovations, and products through patents, patent applications, and trade secrets and know-how. 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 right to multiple patent applications that have 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 and Philippines. A bundle of patents under the European Patent Convention have also been granted, namely, France, Germany, Ireland, Italy, Spain, Switzerland and UK.
    - 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 and/or, minimize 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, *inter alia*, 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.

The effect of issued patents is that they provide patent protection for the claims covered by the patents. While the expiration of a product or method patent may result 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, (xiii) nasal devices in combination with pharmaceuticals, and (xiv) 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, the ability to establish bio equivalency, safety and effectiveness of third parties, 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 and information, 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 may obtain patents that we would require us to license or design around. If existing or future patents held by third parties and containing broad claims that cover our technology that may infringe, and if such patents were upheld by a court or other authority of competent jurisdiction as valid and infringed, the holders of such patents could require us to obtain licenses to use such technology or require us to cease from using such infringing technology until their infringed patents expire.

Trademarks

Our trademarks are important to our business. We currently use the following unregistered trademarks: SMaRT Replacement Therapy™, MU1140™, and LPT3-04™. In November 2025, the USPTO issued a Notice of Allowance in connection with our application for registration of the mark of ORAGENICS™ for therapeutic products, namely, anti-infectives and vaccine products in the nature of antibiotics for medical or veterinary use and vaccines for medical or veterinary use. 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. Also pending in different classes in the USPTO is our mark ORAGENICS™ for therapeutic goods, namely, neurotherapeutic products, for medical, pharmaceutical, or veterinary use, namely, neurosteroid compounds and preparations; Therapeutic goods, namely, neurotherapeutic products, for medical, pharmaceutical, or veterinary use, namely, nasal devices for medical or pharmaceutical use, namely, nasal devices for delivering drug compounds to the nasal cavity, sold filled with neurosteroid compounds and preparations; and therapeutic goods, namely, neurotherapeutic products, for medical, pharmaceutical, or veterinary use, namely, nasal devices for medical or pharmaceutical use, namely, nasal devices for delivering drug compounds to the nasal cavity, sold empty. 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

As of December 31, 2025, we had three full-time and part-time employees. We believe our relations with our employees are good. None of our employees are represented by a 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 who support our research and development and regulatory activities. These consultants provide expertise in areas including neurology, clinical development, manufacturing, and regulatory affairs.

We retain consultants pursuant to written consulting agreements under which we pay consulting fees and reimburse out-of-pocket expenses incurred in performing services for us. In addition, certain consultants have been granted options to purchase shares of our common stock pursuant to separate equity award agreements, subject to applicable vesting requirements. Our consultants may be employed by other entities or provide services to other companies and, as a result, may have commitments that could 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 9015 Town Center Parkway, Suite 143, Lakewood Ranch, Florida 34202.

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 8K 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 summary below 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 summary risks below 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 and will not be able to develop our product candidates or operate our business if we are unable to secure additional funding.
- Our independent registered public accounting firm has included an explanatory paragraph in its audit report expressing substantial doubt about our ability to continue as a going concern, and although recent financing activities have improved our liquidity position, we will require additional capital to fund operations beyond our current planning horizon.
- Although we have regained compliance with the continued listing standards of the NYSE American, we may not be able to maintain compliance in the future and our common stock could be delisted.
- 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 $9.9 million and $10.6 million for the years ended December 31, 2025, and 2024, respectively. As of December 31, 2025, our accumulated deficit was approximately $226 million. We have devoted, and expect to continue to devote, a significant portion of our financial resources to research and development activities, including nonclinical development and planned clinical trials related to ONP-002.

Although we completed a financing transaction in July 2025 that improved our liquidity position, we expect to continue to incur substantial operating losses and negative cash flows for the foreseeable future as we advance the development of ONP-002, including anticipated Phase 2 clinical activities. Based on our lack of revenues, anticipated uses of cash and historical recurring cash losses from operating activity, and cash and cash equivalents as of December 31, 2025, we anticipate that we will be able to fund our operating expenses and capital expenditure requirements through the third quarter of 2026, depending on the timing and scope of our development activities and other strategic decisions. These factors raise substantial doubt regarding our ability to continue as a going concern.

As a result of the numerous risks and uncertainties associated with product development, clinical trials, regulatory approval, and commercialization, we are unable to predict the timing or amount of future expenses or whether, or when, we will be able to generate revenues sufficient to achieve or sustain profitability. If we are unable to raise additional capital on acceptable terms, or at all, we may be required to delay, reduce, or eliminate development programs or otherwise curtail operations, which raises substantial double about our ability to continue as a going concern.

We will require additional capital to complete the development of ONP-002 and to operate our business, and we may not be able to obtain such capital on acceptable terms, or at all.

The development and potential commercialization of biopharmaceutical products is capital intensive and subject to significant uncertainty. Although we completed a financing transaction in July 2025 that improved our liquidity position, we do not expect to generate revenues sufficient to fund our operations for the foreseeable future. As a result, we will need to obtain additional capital to continue nonclinical and clinical development activities for ONP-002, including planned Phase 2 clinical trials, manufacturing activities, regulatory interactions, and general corporate operations.

Our future capital requirements will depend on numerous factors, including the scope and timing of clinical development activities, regulatory requirements, manufacturing activities, and general corporate expenses. We may seek additional funding through equity offerings, debt financing, grants, collaborations, and licensing arrangements, or other strategic transactions. Such financing may not be available on acceptable terms, or at all, and may result in dilution to existing stockholders or impose restrictive covenants on our operations. Additionally, as discussed below, our Series H Preferred Stock contains anti-dilution provisions that will result in further dilution to existing shareholders if we issue securities for less than the Conversion Price of our Series H Preferred Stock, which in turn may make it more difficult for us to raise capital.

If we are unable to obtain additional capital when required, we may be forced to delay, reduce, or eliminate development programs, curtail operations, or take other actions that could materially adversely affect our business, financial condition, and prospects.

There is substantial doubt regarding our ability to continue as a going concern, absent additional capital beyond our current operating horizon.

We have incurred operating losses, have an accumulated deficit, and have historically generated negative cash flows from operations. These conditions initially raised substantial doubt regarding our ability to continue as a going concern.

In July 2025, we completed a financing transaction that improved our liquidity position. Based on our lack of revenues, anticipated uses of cash and historical recurring cash losses from operating activity, and cash and cash equivalents as of December 31, 2025, we anticipate that we will be able to fund our operating expenses and capital expenditure requirements through the third quarter of 2026, depending on the timing and scope of our development activities and other strategic decisions. Our ability to continue as a going concern beyond that period is dependent on our ability to raise additional capital.

Our independent registered public accounting firm included an explanatory paragraph in its audit report for the year ended December 31, 2025, related to these conditions. Our consolidated financial statements do not include any adjustments that might result if we were unable to continue as a going concern.

The Certificate of Designation for our Series H Convertible Preferred Stock (the "Series H Preferred Stock") contains anti-dilution provisions that may result in the reduction of the Conversion Price for the Series H Preferred Stock in the future. This feature may result in an indeterminate number of shares of Common Stock being issued upon conversion.

The Certificate of Designation for our Series H Preferred Stock contains anti-dilution provisions, which provisions require the lowering of the current $2.50 Conversion Price on any unconverted Series H Preferred Stock to the price of future issuances by us (subject to certain exclusions). If in the future we issue securities for less than the Conversion Price of our Series H Preferred Stock, we will be required to reduce the relevant Conversion Price of any unconverted Series H Preferred Stock, which will result in a greater number of shares of Common Stock being issuable upon conversion, which in turn will have a greater dilutive effect on our shareholders. In addition, as there is no floor price on the Conversion Price, we cannot determine the total number of shares issuable upon conversion. As such, it is possible that we will not have sufficient available shares to satisfy the conversion of the Series H Preferred Stock if we enter into a future transaction that results in the reduction of the Conversion Price. If we do not have sufficient available shares for any Series H Preferred Stock conversions, we will be required to increase our authorized shares, which may not be possible and will be time consuming and expensive. The potential for such Conversion Price adjustments may depress the price of our Common Stock regardless of our business performance, and, as a result, we may find it more difficult to raise additional equity capital while our Series H Preferred Stock is outstanding. Effective as of March 14, 2025, as a result of the Company's issuance of shares of Common Stock to Dawson James in payment of advisory fees pursuant to an Engagement Agreement dated as of March 14, 2025, at a price of $1.00 per share, the Conversion Price of the Series H Preferred Stock was reduced to $1.00.

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. Our current cash, cash equivalents and short-term investments are not sufficient to fully implement our business strategy and sustain our operations. Our auditor has expressed substantial doubt about our ability to continue as a going concern. We anticipate we will need to raise additional capital in the future to complete the development and commercialization of our product candidates and operate our business. 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. However, our recently completed Series H Preferred Stock offering and the anti-dilution protection contained in the Series H Preferred Stock's Certificate of Designation, as well as our auditor's substantial doubt about our ability to continue as a going concern, may depress the price of our Common Stock regardless of our business performance and may make it more difficult for us to raise or obtain additional financing. Furthermore, even if we are able to obtain additional financing, it may not be on favorable terms and, if such financing is undertaken at a price below the Conversion Price of our Series H Preferred Stock, it will trigger the anti-dilution protection in our Series H Preferred Stock's Certificate of Designation, as discussed above, which in turn may result in a greater number of shares of Common Stock being issued upon conversion of our Series H Preferred Stock, which in turn will have a greater dilutive effect on our shareholders and may make it more difficult to raise additional capital. 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, and, absent sufficient additional financing, we may be unable to remain a going concern.

The market price of our Common Stock may never exceed the Conversion Price of the Series H Preferred Stock.

The warrants we issued in connection with the Series H Preferred Stock offering (the "Series H Warrants") become exercisable upon issuance and will expire five years from the date of issuance. The exercise price of the Series H Warrants is $25 per share of Series H Preferred Stock. Upon exercise, a holder will be required to pay us the exercise price per share in cash and in exchange will receive shares of our Series H Preferred Stock with a stated value of $25. Such shares of Preferred Stock are convertible into shares of Common Stock at the Conversion Price of $2.50, subject to adjustment pursuant to the terms of the Series H Preferred Stock. The number of shares of Common Stock into which each share of Preferred Stock is convertible into is determined by dividing the Offering Price by the Conversion Price. Thus, if the Conversion Price is $2.50, each share of Series H Preferred Stock, exclusive of dividends, is convertible into approximately 10 shares of Common Stock. If the market price of our Common Stock is below the Conversion Price, the holder of the Warrant may elect not to exercise the Warrant until the market price of our Common Stock increases. However, the market price of our Common Stock may never exceed the Conversion Price prior to the expiration of the Warrants. As a result, the holders of our Warrants may elect not to ever exercise their Warrants. We will not receive any additional proceeds in connection with unexercised Warrants, which likely will result in our needing to raise additional capital sooner than if some or all of the Warrants are exercised, of which there can be no assurances. Any Warrants not exercised by their date of expiration will expire worthless and we will be under no further obligation to the Warrant holder.

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.

Future sales of our Common Stock in the public market could cause our stock price to fall.

Sales of a substantial number of shares of our 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 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 shareholders may experience substantial dilution and a reduction in the price that they are able to obtain upon 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. The exercise and conversion of such securities will cause additional dilution. Additionally, if we make one or more significant acquisitions in which the consideration includes stock or other securities, our shareholders' holdings may be significantly diluted. In addition, shareholders' 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.

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 ONP001 (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 approval. 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 results 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 vendors upon whom we rely for the supply of ONP-002 are our sole source of supply, and the loss of these suppliers could significantly harm our business.

We do not manufacture or have the capacity to manufacture any of our drug candidates and have two manufacturers as our current partners in the development of synthetic chemistry and manufacturing of the ONP-002. Our ability to successfully develop our ONP-002 product candidates, and to ultimately supply our commercial products in sufficient quantities 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.

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 substances 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 replacement suppliers 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.

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 involve 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 healthcare 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 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.

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 expertise of the 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 noncompetitive 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 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 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 people, and we may be unable to replace key people if they leave, in addition it may not be possible to fill new positions requiring key people 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 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 claims 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 produce 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, 2025, we had U.S. federal and state net operating loss carryforwards of approximately $164,834,118 and $138,451,933, respectively.

Federal and Florida tax net operating loss carryforwards generated prior to December 31, 2017, will expire through 2038 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 80% deduction limitation based upon pre-NOL deduction taxable income 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 $3,959,813, of which are included as an uncertain tax position. The federal tax credit carryforward will expire beginning in 2022 and continuing through 2044 unless utilized.

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 ("NOLs") 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. We have experienced significant equity issuances in recent years, and future transactions in our stock could result in one or more ownership change. 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 licensor's 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 implemented 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 has developed 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 and Canada. 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 certain 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 either do not have patent protection or have insufficient patent protection 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 in such countries 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 or even permit third parties to produce or use our patented products or processes without our consent as the patent owner. The application of compulsory licensing varies greatly between countries and enforcement is in accordance with each country's licensing laws in which a patent is granted. 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 but only for older patent applications filed before March 16, 2023 (pre-AIA), or in a derivation proceeding to determine ownership of invention for patent applications filed on or after March 16, 2023. The Leahy-Smith America Invents Act (AIA) replaced interference practice with derivation proceedings.

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 initiation of a patent infringement litigation by us in response to a Paragraph IV notice under 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 or we are successful in a Paragraph IV litigation. In the event that a court decides we are determined to be infringing the third party's patents, such court may order us to cease the activities covered by those infringed patents. In addition, there is a risk that a court could order us to pay for such third-party damages for having violated their 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 or other agreements 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 (but only for older patent applications filed before March 16, 2023 (pre-AIA)), derivation, reexamination 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 several issues, including:

- Infringement and other intellectual property claim 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 up to treble damages. In addition, the court may award attorneys' fees to the third party if the court deems the case to be "exceptional" under 35 U.S.C § 285;
- 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 in the United States;
- 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 expenditure 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 may have agreed to indemnify certain third-party licensors and partners against claims of infringement caused by our proprietary technologies, and/or we may have entered or may enter into cost-sharing agreements with some of 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 as filing a Paragraph IV litigation against one or more generic companies to prevent premature genericization of our FDA approved drug product(s). 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, ownership, 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 or other results discussed herein throughout 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, patent applications filed by us, licensors, or potential partners 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 to take necessary steps to protect these rights, in part, through confidentiality and proprietary information agreements and internal policies. These agreements and policies may not provide meaningful protection or adequate remedies for violation of our rights in the event of unauthorized use, misappropriation, or unauthorized disclosure of confidential and proprietary information. Failure of these efforts 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 on 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 non-clinical 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 non-clinical 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. Although the Company is currently in compliance with NYSE continued listing requirements there can be no assurances that the Company will be able to maintain compliance with current or proposed new NYSE continued listing requirements. 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.

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

The conversion of our Series F and Series H Preferred stock, and the exercise of currently outstanding warrants, could result in significant dilution to the holders of our common stock. Holders of our Series F Preferred Stock and Series H Preferred Stock have the right to convert their shares into shares of our common stock in accordance with the applicable certificates of designation. As of December 31, 2025, we had 7,488,692 shares of Series F Preferred Stock outstanding. Following the 1-for-30 reverse stock split effected on June 3, 2025, the conversion terms of the Series F Preferred Stock was proportionally adjusted. As a result, the Series F Preferred Stock is convertible into an aggregate of approximately 249,624 shares of our common stock on a split-adjusted basis. As of December 31, 2025, we had 429,291 shares of Series H Preferred Stock outstanding, which are convertible into 6,224,720 shares of common stock on a one-to-fourteen and a half basis rounded up to the nearest one basis. In addition, as of December 31, 2025, we had outstanding warrants primarily issued in connection with our July 2025 financing transaction, which was exercisable to purchase 660,000 shares of Series H Preferred Stock with rights to convert their shares into an aggregate of approximately 9,570,000 of our common stock.

The conversion of our outstanding preferred stock and the exercise of these warrants would increase the number of shares of our common stock outstanding and could result in a significant dilution to existing common shareholders. Such issuances could adversely affect the market price of our common stock and impair our ability to raise additional capital through future equity financings.

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 depend 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 $12.30 and a low price of $0.75 in the 52-week period ended December 31, 2025. Furthermore, our stock traded within a range of a high volume of 15,488,500 and a low volume of 2,127 per share for the period of January 1, 2025, through December 31, 2025. 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 lease office space located at 9015 Town Center Parkway, Suite 143, Lakewood Ranch, Florida, which serves as our principal executive offices. We believe that our current facilities are adequate for our present needs.

ITEM 3. LEGAL PROCEEDINGS.

On December 7, 2022, the Company entered into an investment-banking engagement letter with Ladenburg Thalmann & Co. Inc. (“Ladenburg”), which was subsequently amended several times (collectively, the “Engagement Letter”). The Company terminated the Engagement Letter effective August 15, 2023. Following the termination, Ladenburg asserted that it was entitled to a fee in connection with the Company’s purchase of assets from Odyssey Health, Inc., and issued an invoice for $2,500,000 to the Company. The Company disputed that no such fee is owed. Related proceedings were also filed in the United States District Court for the Southern District of Florida. On October 16, 2025, the Company and Ladenburg executed a Settlement Agreement (the “Settlement Agreement”) resolving all claims between the parties. Under the terms of the Settlement Agreement, the Company agreed to pay $700,000, which was wired on October 17, 2025, in full satisfaction of the matter.

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 13, 2026, was $0.88 per share and 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, 2025.

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 biopharmaceutical company dedicated to the research and development of nasal delivery pharmaceutical therapies targeting neurological conditions and infectious diseases. The Company is currently focused on advancing the development and commercialization of its lead product candidate, ONP-002. Our lead product, ONP-002, is a fully synthetic, non-naturally occurring neurosteroid, is lipophilic, and we believe it can cross the blood-brain barrier with the goal of rapidly eliminating swelling, oxidative stress and inflammation while restoring proper blood flow through gene amplification.

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

Our lead product and focus are on the development and commercialization of ONP-002 for the treatment of mild traumatic brain injury ("mTBI" or "Concussion").

ONP-002, together with our other neurology assets, are referred to herein as the Neurology Assets. To date, ONP-002 has been shown to be stable up to 104 degrees for 18 months. The drug candidate is manufactured into a powder and filled into a 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 is designed 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 effectively 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 clinical trial	Phase 2a clinical trial	US based clinical trial	Phase 3 clinical trial
Complete	Complete	Q1 2026 Start	Estimated Q1 2027 start	Estimated Q1 2028 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

Stock Sale

In February 2025, we sold 258,849 shares pursuant to our ATM Agreement with Dawson James for net proceeds of $2.6 million. See Note 7 of Notes to Consolidated Financial Statements.

On July 2, 2025, we completed a public offering of 660,000 shares of Series H Convertible Preferred Stock and 660,000 common stock warrants to purchase additional shares of Series H Convertible Preferred Stock, resulting in net proceeds of approximately $15 million. See Note 7 of Notes to Consolidated Financial Statements.

Promissory Note

In March 2025, we issued a $3.0 million promissory note at a 17% original issue discount. After expenses, we received net proceeds of $2.2 million.

On July 2, 2025, the Company repaid in full the $3.0 million promissory note. The repayment was made using a portion of the net proceeds from the Company's July 2, 2025, public offering of Series H Preferred Shares and warrants. See Note 6 of Notes to Consolidated Financial Statements.

Going Concern

We have incurred significant net losses and negative cash flow in each year since our inception, including net losses of $9.8 million and $10.6 million for the years ended December 31, 2025, and 2024 respectively. As of December 31, 2025, our accumulated deficit was $226.6 million. We expect to continue to incur operating losses and negative cash flows for the foreseeable future as we advance the development of our product candidates.

Our operating plan requires significant expenditures related to research and development activities, including nonclinical studies and planned Phase 2 clinical trials for ONP-002, as well as general and administrative costs necessary to support our operations. In addition, certain of our license agreements require the payment of ongoing and milestone-based royalties, which may further impact our liquidity.

These conditions raised substantial doubt about our ability to continue as a going concern within one year after the date that the consolidated financial statements included in this Annual report are issued.

Management's plans to address these conditions include pursuing additional sources of capital, which may consist of equity or debt financings, strategic collaborations, licensing agreements, or other funding alternatives. However, there can be no assurance that such financing will be available on acceptable terms, or at all.

If we are unable to obtain sufficient additional funding when needed, we may be required to delay, reduce, or eliminate certain research and development programs or curtail operations. The consolidated financial statements do not include any adjustments that might result from outcome of this uncertainty.

Future Capital Requirements

Our capital requirements for 2025 and beyond will depend on numerous factors, including the success of our research and development efforts, the progress of our ONP-002 program, and our ability to secure strategic partnerships or licensing arrangements to support our pipeline.

We expect to incur substantial expenditures to further develop our neurology assets, including increased cost related to research, nonclinical testing, clinical trials, regulatory submissions, and the ongoing requirements of being a public company. Subject to our ability to raise additional capital, we plan to continue advancing the ONP-002 toward Phase II clinical trials and further IND-enabling work.

To support these activities, we may seek additional equity and debt financings, as well as strategic alliances, joint ventures, licensing agreements, or other business arrangements that could generate sufficient capital to sustain our operations.

As of December 31, 2025, we had $8.4 million in cash and cash equivalents. We believe this capital will allow us to fund our current operating plan through the third quarter of 2026, depending on the timing and scope of our development activities and other strategic decisions.

Additional capital will still be required to complete planned clinical trials, regulatory filings, and any future commercialization efforts. There can be no assurance that such funding will be available on favorable terms, or at all. If we are unable to secure sufficient capital, we may be forced to delay, scale back, or eliminate certain development programs, which would adversely impact our business and strategic objectives.

The sale of additional equity or convertible securities could result in significant dilution to our existing shareholders. If we raise funds through debt or preferred stock, these instruments may have rights senior to our common stock and could impose restrictive covenants on our operations.

Due to uncertainties associated with clinical development, regulatory approval timelines, and partnership negotiations, we cannot precisely estimate our future capital requirements. However, our needs will depend on many factors, including but not limited to:

- Conducting Phase II trials and filing an IND for ONP-002, including potential Phase III Trial planning;
- Identification and preparation of clinical sites;
- The number and development paths of product candidates we pursue;
- The scope, cost, and results of our preclinical and clinical programs;
- Timing and cost of obtaining regulatory approvals;
- Our ability to secure and maintain strategic partnerships and licensing deals;
- Our performance under existing agreements, including potential milestone or royalty payments;
- Patent prosecution, enforcement, and potential litigation; and
- The timing and revenue, if any, from future product sales and royalties.

We have based these forward-looking statements on assumptions we believe are reasonable; however, actual results and funding needs may differ materially from our current expectations.

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. 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 are not certain that our current source suppliers will be able to meet our demand, either because of the nature of our agreement with the suppliers, our limited experience with the suppliers or our relative importance as a customer to the suppliers. It may be difficult for us to assess their ability to timely meet our demand in the future based on past performance. While our suppliers have 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;
- 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) consists primarily of income, interest expense, and gains and losses related to foreign currency transactions with vendors. Interest income is earned on our cash and cash equivalents, which are invested in accordance with our investment policy focused on capital preservation. Interest expense consists primarily of interest and related costs associated with our outstanding indebtedness. To a lesser extent, other income (expense) may include certain non-operating items, such as local business taxes.

Income Taxes

At December 31, 2025, the Company has federal and state tax net operating loss carry forwards of $164,834,118 and $138,451,933, respectively.

Federal and Florida tax net operating loss carryforwards generated prior to December 31, 2017, will expire through 2038 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 80% deduction limitation based upon pre-NOL deduction taxable income 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 $3,959,813, of which are included as an uncertain tax position. The federal tax credit carryforward will expire beginning in 2022 and continuing through 2044 unless utilized.

In assessing the realization of deferred tax assets, management considers whether it is more likely than not that some portion or all the deferred income tax assets will not be realized. The ultimate realization of deferred income 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 income tax liabilities, projected future taxable income, and tax planning strategies in making this assessment. Based on consideration of these items, management has determined that a full valuation allowance is required as of December 31, 2025, and 2024.

The utilization of the Company's net operating loss carryforwards could be subject to annual limitations under Section 382 and 383 of the Internal Revenue Code of 1986, as amended (the "Code"), and similar state tax provisions, due to ownership change limitations that may have occurred previously or that could occur in the future. These ownership changes limit the amount of net operating loss carryforwards and other deferred tax assets that can be utilized to offset future taxable income and tax, respectively. In general, an ownership change, as defined by Section 382 and 383 of the Code, results from transactions increasing ownership of certain stockholders or public groups in the stock of the corporation by more than 50 percent points over a three-year period. The Company has not completed an analysis of an ownership change under Section 382 of the Code. To the extent that a study is completed and an ownership change is deemed to occur, the Company's net operating losses and tax credits could be limited.

On July 4, 2025, the One Big Beautiful Bill Act ("OBBBA") was enacted in the U.S. The OBBBA includes significant provisions, such as the permanent extension of certain expiring provision of the Tax Cuts and Jobs Act, modification to the international tax framework and the restoration of favorable tax treatment for certain business provisions. The legislation has multiple effective dates, with certain provisions effective in 2025 and other implemented through 2027. The bill does not materially impact the Company's 2025 income tax provision.

For the years ended December 31, 2025, and 2024, 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.

Critical Accounting Estimates and Policies

Our discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with the accounting principles generally accepted in the United States ("U.S. GAAP"). The preparation of these financial statements requires management to make estimates, assumptions, and judgements that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period.

We define critical accounting estimates as those estimates that require the use of assumptions or judgements that are inherently uncertain and that could have a material impact on our financial condition or results of operations if actual results differ from those estimates.

While our significant accounting policies are described in the notes to the consolidated financial statements, we believe the following accounting estimates involve a higher degree of judgment and complexity and are therefore considered critical to the preparation of our financial statements:

- Stock-based compensation, which requires the estimation of fair value of equity awards and assumptions related to volatility, expected term, and forfeitures;
- Income taxes, including the assessment of realizability of deferred tax assets and the establishment of valuation allowances; and
- Going concern, which requires management to evaluate whether conditions or events raise substantial doubt about our ability to continue as a going concern and to consider management's plans to address such conditions.

Actual results could differ from management's estimates, and such differences could be material to our consolidated financial statement. Management evaluates its estimates and assumptions on an ongoing basis and adjusts them when facts and circumstances change.

Stock-Based Compensation

We account for stock-based compensation in accordance with U.S. Generally Accepted Accounting Principles ("U.S. GAAP"), which require share-based payment transactions with employees and non-employees to be recognized in the financial statements based on the grant-date fair value of the equity awards. The fair value of stock options is typically estimated using the Black-Scholes option-pricing model.

Stock-based compensation expense is recognized over the requisite service period during which the employee or non-employee is required to provide service, unless the award vests immediately. Compensation expense related to stock-based awards is classified within research and development expense or general and administrative expense in the consolidated statements of operations, based on the nature of services provided.

For stock options and other equity awards that include service-based vesting conditions, compensation expense is recognized on a straight-line basis over the vesting period. For performance-based awards that do not include market-based conditions, we recognize compensation expense only when achievement of the applicable performance condition is considered probable. Management uses both quantitative and qualitative factors to assess the probability of achieving such performance conditions.

For awards that include market-based performance conditions, the grant-date fair value is recognized over the derived service period, regardless of whether the market-based condition is ultimately satisfied.

We account for forfeitures of stock-based awards as they occur and record forfeitures as a reduction of stock-based compensation expense.

New Accounting Pronouncements

Income Taxes

In December 2023, the Financial Accounting Standard Board ("FASB") issued Accounting Standard Update ("ASU") 2023-09, Income Taxes (Topic 740): *Improvements to Income Tax Disclosures*, which enhances income tax disclosure requirements by requiring greater disaggregation of information in the effective tax rate reconciliation and disclosures of income taxes paid. The guidance is effective for annual periods beginning after December 15, 2024, with early adoption permitted. The Company adopted this guidance for the year ended December 31, 2025, and the adoption did not have a material impact on the Company's consolidated financial statements or elated disclosures.

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

Results of Operations

	Year Ended December 31,		Increase	Percentage
	2025	2024	(Decrease)	Change
Research and development	$ 2,392,658	$ 4,114,434	$ (1,721,776)	(41.85)%
General and administrative	6,969,845	6,444,381	525,464	8.15%
Total operating expenses	9,362,503	10,558,815	(1,196,312)	(11.33)%
Loss from operations	(9,362,503)	(10,558,815)	1,196,312	11.33%
Other income (expense):				
Interest income	182,229	45,897	136,332	297.04%
Interest expense	(785,930)	(29,828)	(756,102)	2,534.87%
Foreign currency exchange, net	(13,193)	(25,172)	11,979	(47.59)%
Total other (expenses) income, net	(616,894)	(9,103)	(607,791)	6,676.82%
Loss before income taxes	(9,979,397)	(10,567,918)	588,521	(5.57)%
Income tax benefit	136,910	-	136,910	100.00%
Net loss	$ (9,842,487)	$ (10,567,918)	$ 725,431	(6.86)%

Research and Development

Research and development expenses were $2.4 million for the year ended December 31, 2025, compared to $4.1 million for the year ended December 31, 2024, representing a decrease of $1.7 million or 41.8%.

The decrease was primarily attributable to reduced nonclinical and contract research activity compared to 2024, which included higher levels of external development work and program wind-down costs associated with discontinued vaccine and antibiotic programs. During 2025, the Company focused on its research and development efforts on advancing ONP-002, which expenditures primarily related to regulatory preparation, manufacturing readiness, and consulting services. While ONP-002 activities continued during 2025, overall laboratory, formulation, and preclinical spending was lower than the prior year. The Company expects research and development expenses to increase in future periods as clinical trial activities advance, and manufacturing of additional ONP-002 clinical material expands.

General and Administrative

General and administrative expenses were $7 million for the year ended December 31, 2025, compared to $6.4 million for the year ended December 31, 2024, representing an increase of $525,464 or 8.1%.

The increase was primarily attributable to a $616,580 increase in patent expenses, as patent-related costs in 2025 were classified within general and administrative expenses whereas a significant portion of such costs had been recorded within research and development in 2024. Investor relations expense increased by $265,004 due to expanded shareholder engagement and capital market activities. Legal and professional fees increased by $146,279 reflecting higher corporate, regulatory, and financing-related costs. These increases were partially offset by a $443,664 decrease in salaries and benefits due to lower headcount, a $38,206 decrease in board compensation, and a $33,285 decrease in public company expenses. Other expenses decreased by $72,711 primarily due to the reclassification of certain costs to travel expense. Insurance and software expenses increased modestly, while travel expense increased by $61,389 reflecting increased business development and investor-related activity.

Other Income (Expense)

For the year ended December 31, 2025, total other expenses, net was $616,894, compared to total other expenses, net of $9,103 for the year ended December 31, 2024. The increase in net other expenses was primarily attributable to higher interest expense related to the $3.0 million short-term promissory note issued in March 2025, including amortization of debt discount and associated financing costs. This increase was partially offset by higher interest income earned on cash balances during 2025 following capital raises completed during the year.

Interest income increased to $182,229 for the year ended December 31, 2025, compared to $45,897 in 2024, reflecting higher average cash balances and prevailing interest rates. Interest expense increased to $785,930 in 2025 from $29,828 in 2024, primarily due to debt-related costs associated with the March 2025 note, which was repaid in July 2025. Foreign currency exchange losses were $13,193 in 2025 compared to $25,172 in 2024, reflecting normal fluctuations in exchange rates related to vendor activity denominated in foreign currencies.

The Company conducts research and development activities in Australia through its wholly owned subsidiary Oragenics Australia Pty Ltd. Under Australian tax law, the Company is eligible to receive refundable research and development tax incentives. For the year ended December 31, 2025, the Company recorded $274,200 Australian income tax expense related to transfer pricing markup of 6% and $411,110 of refundable Australian R&D tax incentive benefit resulting in a net income tax benefit of $136,910.

Liquidity and Capital Resources

See “Recent Funding” above for our discussion of our July 2025 public offering of Series H Preferred Stock and warrants.

Since our inception, we have funded our operations primarily through the sale of equity securities in public and private offerings, debt financing, and warrants exercises. As of December 31, 2025, we had an accumulated deficit of $226.6 million and have not yet achieved profitability. We incurred a net loss of $9.8 million for the twelve-months ended December 31, 2025, and $10.5 million for the year ended December 31, 2024. We expect to continue incurring significant operating losses as we advance the development of our Neurology Assets, including ONP-002, through regulatory and clinical stages toward potential commercialization.

Based on our lack of revenues, anticipated uses of cash and historical recurring cash losses from operating activity, and cash and cash equivalents as of December 31, 2025, we anticipate that we will be able to fund our operating expenses and capital expenditure requirements through the third quarter of 2026, depending on the timing and scope of our development activities and other strategic decisions. These factors raise substantial doubt regarding our ability to continue as a going concern.

The following table sets forth our primary sources and uses of cash:

	Year Ended December 31,	
	2025	2024
Net cash used in operating activities	$ (9,246,387)	$ (8,597,382)
Net cash provided by financing activities	16,781,273	5,978,721
Net increase (decrease) in cash and cash equivalents	$ 7,534,886	$ (2,618,661)

Operating Activities

Cash used in operating activities for the years ended December 31, 2025, and 2024, was $9.2 million and $8.6 million, respectively. In both periods, cash used in operations primarily reflected the Company's net losses adjusted for non-cash charges and changes in working capital accounts.

For the year ended December 31, 2025, significant non-cash items affecting the operating cash flows included in $771,437 of amortization of debt discount and closing costs associated with the March 2025 short-term promissory note, $642,364 of stock-based compensation expense, $86,617 stock-based compensation recapture adjustment, and $126,140 of common stock issued for services. Changes in operating assets and liabilities also contributed to the net cash outflow, including a $1,007,286 decrease in prepaid expenses and other current assets, $53,082 decrease in interest receivable from a 6-month certificate of deposit, and a $203,144 increase in accounts payable and accrued expenses, primarily reflecting the timing of vendor payments and ongoing ONP-002 program activities.

For the year ended December 31, 2024, non-cash adjustments included $516,049 of stock-based compensation expense. Working capital changes included a $1.5 million increase in prepaid expenses and other current assets and a $119,800 decrease in accounts payable and accrued expenses.

The increase in operating cash used year-over-year primarily reflects higher working capital utilization and debt-related non-cash charges in 2025, partially offset by lower overall expenses compared to 2024.

Financing Activities

Net cash provided by financial activities was $16.8 million for the year ended December 31, 2025, compared to $6 million for the year ended December 31, 2024.

Financing activities in 2025 were primarily driven by $15.0 million in net proceeds from the July 2025 issuance of Series H Preferred Stock and warrants, $2.6 million in net proceeds from issuance of common stock, and $2.5 million in borrowings under short-term notes payable. These inflows were partially offset by $3.3 million in repayment of short-term notes payable.

In comparison, financing activities for the year ended December 31, 2024, consisted primarily of $6.7 million in net proceeds from the issuance of common stock, partially offset by $0.7 million in repayments of short-term notes payables.

Short-Term Notes Payable

On March 13, 2025, we issued a $3.0 million promissory note (the "Note") to a single investor at an original issue discount of 17%. Net proceeds to us were approximately $2.2 million after placement agent fees of $175,000 and legal expenses of $98,437.

The Note was a non-interesting bearing unless an event of a default occurred, at which time interest would accrue at a rate of 20% per annum. The Note was scheduled to mature on the earlier of July 14, 2025, or the closing of any subsequent offering with net proceeds equal to or exceeding all amounts due under the Note.

In connection with the issuance of the Note, we designated and issued 1,000,000 shares of our authorized but unissued Series G Mirroring Preferred Stock. For a description of the Series G terms, see Note 8. We used the net proceeds for working capital and general corporate purposes. Subsequently, in connection with the Reverse Stock Split the shares of Series G Preferred Stock were cancelled. See Note 8.

On July 2, 2025, the Company repaid in full the $3.0 million promissory note issued on March 13, 2025. The repayment was made using a portion of the net proceeds from the Company's July 2, 2025, public offering of Series H Preferred Stock and warrants to purchase additional shares of Series H Preferred Stock.

Short-term notes payable consisted of the following:

	December 31, 2025	December 31, 2024
Insurance premium financing of $506,190, due in monthly installments of $58,314, which includes principal and annual interest at 8.75% through April 2026	$ 227,348	$ —
Insurance premium financing of $636,972, due in monthly installments of $67,277, which include principal and annual interest at 9.55% through May 2025	—	328,528
Total short-term notes payable	$ 227,348	$ 328,528

Inflation

Inflation may impact the cost of services and supplies used in our operations, including professional services, insurance premiums, and research-related vendor agreements. Increases in wages, employee benefits, and regulatory compliance costs may continue to exert upward pressure on operating expenses. However, because we are currently in the development stage and do not maintain significant manufacturing operations or large-scale procurement of raw materials, we have not experienced material inflationary effect on our operating results. For the fiscal year ended December 31, 2025, and 2024, inflation has not had a material impact on our results of operations.

Off Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

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

We are a smaller reporting company and are not required to provide information under this item.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

The Financial Statements are incorporated herein by reference to pages F-1 to F-19 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.

Evaluation of Disclosure Controls and Procedures

Management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2025. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives. Based on the evaluation of our disclosure controls and procedures as of December 31, 2025, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective.

Changes in Internal Controls over Financial Reporting

There have been no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the period covered by this Annual Report on Form 10-K that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on the Effectiveness of Controls

Our management, including our 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, 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 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 Rule 13a-15(f) under the Securities Exchange Act of 1934. Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America.

Our 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 Company's assets; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. GAAP, and that receipts and expenditures are made only in accordance with authorizations of management and directors; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Even effective internal controls can provide only reasonable assurance with respect to financial statement preparation and may become inadequate due to changes in conditions and deterioration in compliance.

Management, under the supervision of the Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of the Company's internal control over financial reporting as of December 31, 2025, using the criteria set forth in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). Based on this evaluation, management concluded that no material weaknesses in internal control over financial reporting were identified as of December 31, 2025.

This Annual Report does not include an attestation report of the Company's registered public accounting firm regarding internal control over financial reporting, as the Company is a non-accelerated filer and is not required to provide such attestation.

ITEM 9B. OTHER INFORMATION.

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

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*	73	Director
Robert C. Koski	66	Director
Dr. Frederick W. Telling, Ph.D.	73	Director
Dr. Alan W. Dunton, M.D.	71	Director
John Gandolfo	65	Director
Natasha Giordano	65	Director
Janet Huffman	53	Chief Executive Officer & Chief Financial Officer

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 Nonexecutive 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.

Natasha Giordano. Ms. Giordano, since July 2, 2025, has served as the Board Chair for Incora Health and, since August 2024, has served on the Compensation Committee and on the Board of Directors of Afaxys Inc. She also is presently serving as a strategic advisor to Aqtual, Inc. and Omeza. Previously, Ms. Giordano served on the Board of Matinas BioPharma (NYSE:MTNB) from September 2020 through February 2025. Ms. Giordano served as President and Chief Executive Officer of PLx Pharma Inc. (NASDAQ:

PLXP), a late-stage specialty pharmaceutical company, from January 2016 through July 2023, and served as a member of the board of PLx. Previously, Ms. Giordano served as Chief Executive Officer of ClearPoint Learning, Inc., a privately held learning and training platform company, from May 2015 through November 2015. She also served on the ClearPoint board of directors from December 2009 through November 2015. Previously, Ms. Giordano served as the Chief Executive Officer of Healthcare Corporation of America (NYSE: HCA), a leading healthcare provider, from January 2014 through August 2014. From June 2009 to August 2012, Ms. Giordano served as Chief Operating Officer and then as Chief Executive Officer, President and a member of the board of directors of Xanodyne Pharmaceuticals, Inc., a privately-held branded specialty pharmaceutical company with development and commercial capabilities focused on pain management and women's health. Prior to that, she served as President, Americas, for Cegedim Dendrite (formerly Dendrite International Inc.), a global technology services company, from 2007 to 2008 and as Senior Vice President of the Global Customer Business Unit of Cegedim Dendrite from 2004 to 2007. Ms. Giordano holds a Bachelor of Science degree in nursing from Wagner College.

Effective September 1, 2025, the board of directors (the "Board") of Oragenics, Inc. (the "Company") appointed Ms. Natasha Giordano to the Company's Board. Ms. Giordano was chosen to serve as a member of our Board due to her experience in commercialization of pharmaceuticals, her general management knowledge and her knowledge of the Pharmaceutical and healthcare industries.

Executive Management

Janet Huffman. Ms. Huffman has served as our Chief Executive Officer since May 2, 2025, and served as our Chief Financial Officer since March 8, 2023. 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 2025, 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 directors to attend the annual shareholders' meeting. However, all members of the Board attended our 2025 annual shareholders' meeting.

Independence of Directors

Our common stock is listed on the NYSE American. Accordingly, the independence of our directors is determined in accordance with the listing standards of the NYSE American, as well as applicable rules and regulations of the Securities and Exchange Commission, including Section 301 of the Sarbanes-Oxley Act of 2002 and Rule 10A-3 under the Securities Exchange Act of 1934 with respect to Audit Committee independence.

The NYSE American listing standards generally define an "independent director" as a person who is not an officer or employee of the company and who does not have a relationship that, in the opinion of the Board of Directors, would interfere with the exercise of independent judgment.

The Board of Directors has affirmatively determined that the following directors are independent within the meaning of the NYSE American listing standards and that they constitute a majority of the Board:

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

In making these determinations, the Board considered both the objective independence criteria set forth in the NYSE American listing standards and made subjective determination that no relationships exist that would interfere with the exercise of independent judgment by these directors.

Audit Committee and Audit Committee Financial Expert

As of December 31, 2025, the Audit Committee members currently consist of Mr. Charles Pope (Chairman), Dr. Frederick Telling, Mr. John Gandolfo 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. 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, officers, 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 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 directors, executive officers, and 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 the year ended December 31, 2025.

The Company's insider trading policy prohibits all employees, including our executive officers, and non-employee directors from engaging in short sales, transactions in put or call options, hedging transactions, using margin accounts, pledges, or other inherently speculative transactions involving the Company's securities.

ITEM 11. EXECUTIVE COMPENSATION.

Compensation Discussion and Analysis

This section describes the objectives of our executive compensation program, and the compensation decisions made with respect to our named executive officer for the fiscal year ended December 31, 2025. Our named executive officer during 2025 was Janet Huffman who also serves as the Chief Financial Officer.

The Compensation Committee of the Board of Director is responsible for establishing, reviewing, and overseeing the Company's executive compensation policies and practices. The Compensation Committee reviews and recommends to the Board of Directors the compensation of the Chief Executive Officer and approves the compensation of other executive officers. In carrying out its responsibilities, the Compensation Committee seeks to ensure that executive compensation is aligned with the Company's business objectives, financial condition, and long-term stockholder interests.

The Company has conducted advisory votes on executives' compensation at prior annual meetings of stockholders. The Compensation Committee considers the results of such advisory votes, along with other relevant actors when evaluating executive compensation decisions.

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 preclinical 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 themselves, 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 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, 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 2025.

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 2025, 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 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.

2025 Bonus Plan

The Company established performance-based bonus targets for its named executive officers in 2025 (the "2025 Bonus Plan"). The percentages were weighted for purposes of determining bonuses, if any, for the Company's executive officers with respect to 2025 performance. Under such a cash bonus program, Ms. Huffman, was eligible for cash bonuses of up to 50% of base salary, or $162,500, ("Bonus Target").

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

i. Up to 40% of the Bonus Target for overseeing the Company's capital raising efforts;
ii. Up to 5% of the Bonus Target for strategic talent acquisition in the Company's finance department;
iii. Up to 15% of the Bonus Target for the Company's clinical trial milestones; and
iv. Up to 40% of the Bonus Target for the Company's strategic planning initiatives.

The executive officers' actual bonuses for fiscal year 2025 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 2025 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 incentives 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 2025, we had employment agreements in effect with Ms. Huffman. 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.

Named Executive Officer Compensation Decisions

We believe that the total compensation paid to our named executive officers for the fiscal year ended December 31, 2025, achieved the overall objectives of our executive compensation program. In accordance with our overall objectives, we believe executive compensation for 2025 was competitive with other similarly sized companies. The Compensation Committee took the following key compensation actions in 2025:

Base Salaries

During 2025, we made the following changes in annual base salary for named Executive Officers and key employees.

Name	Annual Salary For 2024	Increase	Annual Salary For 2025
Janet Huffman	$ 250,000	$ 75,000	$ 325,000

Determination of Cash Bonus-2025

Our Board of Directors determined that Ms. Huffman's 2025 performance-based cash bonus award earned to be $110,500, which was paid in December 2025.

Determination of Equity Awards

On December 11, 2025, Ms. Huffman received a stock option grant pursuant to our 2021 Equity Incentive Plan (the "2021 Plan") to purchase 250,000 shares of our common stock at an exercise price of $0.93 per share, the closing price of our common stock on the grant date. This award vests over three years

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

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

Employment Agreements—Ms. Huffman, Chief Financial Officer and 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 received an annual base salary of $250,000 and was 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 was 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.

On May 2, 2025, the Board appointed Janet Huffman, to serve as the Company's Chief Executive Officer, in addition to continuing to serve as its Chief Financial Officer, and in connection therewith, the Board determined that, effective May 2, 2025, Ms. Huffman's employment agreement would be modified to (i) include her new title of Chief Executive Officer (ii) increase her base salary to $325,000; (iii) include bonus target of fifty percent (50%) of her base compensation.

In the event the Company terminates the Employment Agreement without cause, as defined in the Employment Agreement, Ms. Huffman will be entitled to receive severance pay equal to six (6) months of her annual base salary, at the rate in effect on the date of termination and any performance bonus that, as of the date of termination, has been earned by Ms. Huffman but has not yet been paid by the Company. If Ms. Huffman's employment with the Company is terminated by the Company without cause during the period of thirty (30) days following a Change in Control of the Company (as defined in the Employment Agreement), in lieu of the severance payments above, Ms. Huffman will be entitled to receive a severance payment equal to the sum of: (i) six (6) months of her annual base salary, at the higher of the base salary rate in effect on the termination date or the base salary rate in effect immediately before the effective date of the Change of Control, and (ii) her performance bonus for the year which includes the effective date of the Change in Control, payable at the target level of performance. In addition, Ms. Huffman also will be entitled to receive the amount of any performance bonus that, as of the date of termination, has been earned by Ms. Huffman but has not yet been paid by the Company to Ms. Huffman. The Employment Agreement contains customary confidentiality, non-competition and non-solicitation provisions.

In connection with Ms. Huffman's employment in March 2023, she was awarded stock options to acquire 233 shares of our common stock under our 2021 Plan, at an exercise price of $120.00 per share, which was our closing price on the grant date. The options vested as follows: 58 options vested on the grant date, 58 options vested on September 6, 2023, 58 options vested on March 6, 2024, 58 options vested on September 6, 2024, and 59 options vested on March 6, 2025, in each case Ms. Huffman 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 paid or accrued for the fiscal years ended December 31, 2025, and 2024 to our most highly compensated executive officer who earned more than $100,000 in total compensation during 2025, as well as two former executive officers (collectively, 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	2025	$ -	$ -	$ -	$ -	$ -	$ -
Former Chief Executive Officer and President	2024	$ 53,750	$ -	$ -	$ 10,562	$ 216,612	$ 280,924
Janet Huffman	2025	$ 285,801	$ 110,500	$ -	$ 201,700	$ 11,156	$ 609,157
Chief Financial Officer, Chief Executive Officer	2024	$ 250,000	$ 75,000	$ -	$ 31,200	$ 7,500	$ 363,700
Joseph Redmond	2025	$ -	$ -	$ -	$ -	$ 198,000	$ 198,000
Former President and Interim Principal Executive Officer	2024	$ 397,126	$ -	$ -	$ 39,000	$ 28,015	$ 464,141

(1) The amounts reported in this column represent performance-based bonuses earned pursuant to the Company's bonus plans. Amounts earned for 2024 were paid in February 2025. Amounts earned for 2025 were paid in December 2025.

(2) The amounts reported in this column represent the aggregate grant-date fair value of stock awards computed in accordance with Financial Accounting Standards Board Accounting Standards Codification Topic 718, *Compensation—Stock Compensation* ("ASC 718"). See Notes 2 and 8 to the Consolidated Financial Statements for additional information. On December 11, 2025, Ms. Huffman received incentive stock option awards under the Company's 2021 Equity Incentive Plan covering 25,000 shares at an exercise price of $0.80 per share, vesting over three years.

(3) Amounts reported in this column for Ms. Huffman represent Company matching contributions under the Company's SIMPLE IRA retirement plan. Amounts reported for Mr. Redmond in 2025 represent severance payments totaling $198,000.

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, 2025:

	Number of securities underlying unexercised options (#) exercisable (1)	Number of securities underlying unexercised options (#) unexercisable (2)	Option exercise price(s)	Option expiration date
Janet Huffman Chief Executive Officer and Chief Financial Officer	250,000	-	$ 0.93	12/11/2035
Janet Huffman	2,667	-	14.40	9/19/2034
Janet Huffman	187	47	$ 120.00	3/7/2033

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.

Director Compensation

The Director Compensation program for 2025 consisted of the following:

Cash Compensation. The Director compensation program for 2025 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 will 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 December 2025, the Board considered and granted stock options to non-employee Directors. Directors Pope, Koski, Telling, Gandolfo, Dunton, and Giordano received 125,000 options at a grant price of $0.93 per share. Messrs. 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 for the year ended December 31,2025.

Non-Employee Director Compensation

Name	Fees earned or paid in cash (1)	Option awards (2)	Total
Dr. Frederick W. Telling	$ 72,500	$ 96,400	$ 168,900
Robert C. Koski	$ 50,000	$ 96,400	$ 146,400
Charles L. Pope	$ 112,500	$ 96,400	$ 208,900
Dr. Alan W. Dunton	$ 75,000	$ 96,400	$ 171,400
John Gandolfo	$ 62,500	$ 96,400	$ 158,900
Natasha Giordano	$ 15,000	$ 96,400	$ 111,400

(1) Amounts represent cash compensation earned by our Non-employee Directors during 2025 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 December 11, 2025, Director. Pope, Koski, Telling, Gandolfo, Dunton and Giordano received 125,000 options at a grant price of $0.93 per share. According to the terms of the grants, the options vested immediately.

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 12, 2026 (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)
Five Percent Holders:		
Sabby Volatility Warrant Master Fund, Ltd. (3)	412,654	9.6%
Directors and officers:		
Robert C. Koski (4)	129,479	2.6%
Charles L. Pope (5)	129,784	2.6%
Dr. Alan Dunton (6)	128,622	2.6%
Dr. Frederick W. Telling (7)	128,768	2.5%
Natasha Giordano (8)	163,320	3.2%
Janet Huffman (9)	3,401	*
John Gandolfo (10)	126,671	2.6%
(All Directors and officers as a group 6 persons)	810,045	16.10%

* *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.**,** 9015 Town Center Parkway, Suite 143, Lakewood Ranch, FL 34202.

(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 12, 2026, 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 4,286,029 shares of common stock outstanding as of March 12, 2026, an admission of beneficial ownership of those shares.

(3) The securities are held by Sabby Volatility Warrant Master Fund, Ltd. ("Sabby Volatility"), Sabby Management, LLC ("Sabby Management") and Hal Mintz, Sabby Management is the investment manager of Sabby Volatility. Hal Mintz is the Manager of Sabby Management and in such capacity has the right to vote and dispose of the securities held by Sabby Management. The address of Sabby Volatility is c/o Captiva (Cayman) Ltd Governors Square, Bldg. 4, 2nd Floor 23 Lime Tree Bay Avenue P.O. Box 32315 Grand Cayman KY1-1209 Cayman Islands. The address of Sabby Management is1011 Links Dr. Miami Beach, FL 33109. The address of Hal Mintz is c/o Sabby Management, 1011 Links Dr. Miami Beach, FL 33109. As of the record date, Sabby Volatility held of record 412,654 warrants. The Company does not have any information with respect to shares of common stock that Sabby Volatility that may be held in street name. On January 21, 2026, Sabby Volatility filed a Schedule 13G with the SEC reporting beneficial ownership of 412,654 shares, representing 9.90% of the Company's outstanding shares as of such date.

(4) Includes: 128,935 shares able to be acquired pursuant to stock options.

(5) Includes: 127,768 shares able to be acquired pursuant to stock options.

(6) Includes: 127,820 shares able to be acquired pursuant to stock options.

(7) Includes: 127,820 shares able to be acquired upon the exercise of stock options.

(8) Includes 163,320 shares able to be acquired upon the exercise of stock options.

(9) Includes: 500 shares owned directly by Ms. Huffman; and 2,901 shares able to be acquired upon the exercise of stock options.

(10) Represents 126,671 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, 2025, 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)	1,076,332	$ 4.41	2,090,335
Equity compensation plans not approved by stockholders	-	-	-
Total:	1,076,332	$ 4.41	2,090,335

(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.

Applicable rules of the U.S. Securities and Exchange Commission require disclosure of any transaction, arrangement, or relationship in which the company was or is to be participant, the amount involved exceed the lesser of $120,000 or one percent (1%) of the average of the Company's total assets at year-end for the last two completed fiscal years, and in which any related person had or will have a direct or indirect material interest.

A "related person" includes any executive officer, director, nominee for director, holder of more than five percent (5%) of the Company's common stock, or any immediate family member of any of the foregoing persons.

The Audit Committee of the Board of Directors is responsible for reviewing and approving all related-party transactions between the Company and any executive officer or director, or any entity in which such executive officer or director has a material interest. Any such transactions must be conducted on terms no less favorable to the Company than those that could be obtained in comparable arm's length transactions with 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	2025	2024
Audit Fees (1)	$ —	$ 176,956
Audit-Related Fees (2)	—	—
Tax Fees (3)	—	—
All Other Fees (4)	—	—
	$ —	$ 176,956

Cherry Bekaert Fees

Services Rendered	2025	2024
Audit Fees (1)	$ 154,350	$ 231,513
Audit-Related Fees (2)	33,023	—
Tax Fees (3)	27,963	11,223
All Other Fees (4)	—	—
	$ 215,336	$ 242,736

(1) *Audit Fees*. This category includes fees for professional services provided in conjunction with the audit of the Company's financial statements, 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-19.

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 annual report to be signed on its behalf by the undersigned, thereunto duly authorized.

Dated: March 16, 2026

ORAGENICS, INC.

By: */s/ Janet Huffman*
Janet Huffman
Chief Financial Officer
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, Chief Executive Officer (Principal Accounting and Financial Officer)	March 16, 2026
/s/ Robert. C. Koski Robert C. Koski	Director	March 16, 2026
/s/ Charles L. Pope Charles L. Pope	Director	March 16, 2026
/s/ Frederick W. Telling Frederick W. Telling	Director	March 16, 2026
/s/ Alan W. Dunton Alan W. Dunton	Director	March 16, 2026
/s/ John Gandolfo John Gandolfo	Director	March 16, 2026
/s/ Natasha Giordano Natasha Giordano	Director	March 16, 2026

Oragenics, Inc.

Consolidated Financial Statements

Years Ended December 31, 2025, and 2024

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
Oragenics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Oragenics, Inc. (the "Company") as of December 31, 2025, and 2024, the related consolidated statements of operations, stockholders' equity (deficit), and cash flows for the years 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, 2025, and 2024, and the results of its operations and its cash flows for the years 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 audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

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

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

Critical Audit Matters

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

/s/ Cherry Bekaert LLP

We have served as the Company's auditor since 2023
Tampa, Florida
March 16, 2026

Oragenics, Inc.
Consolidated Balance Sheets

	December 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 4,399,726	$ 864,840
Short-term investments	4,000,000	-
Interest receivable	53,082	-
Prepaid expenses and other current assets	1,614,956	607,670
Total current assets	10,067,764	1,472,510
Total assets	$ 10,067,764	$ 1,472,510
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable and accrued expenses	$ 1,559,011	$ 1,355,867
Short-term notes payable, net of debt issuance costs	227,348	328,528
Total liabilities	1,786,359	1,684,395
Stockholders' equity (deficit):		
Preferred stock, no par value; 50,000,000 shares authorized; 429,291 Series H and 7,488,692 Series F outstanding at December 31, 2025, and 0 Series H and 7,488,692 Series F outstanding at December 31, 2024.	-	-
Common stock, $0.001 par value; 350,000,000 shares authorized; 4,271,529 and 419,003 shares issued and outstanding at December 31, 2025, and December 31, 2024, respectively	4,271	419
Additional paid-in capital	234,905,793	216,573,868
Accumulated deficit	(226,628,659)	(216,786,172)
Total stockholders' equity (deficit)	8,281,405	(211,885)
Total liabilities and stockholders' equity (deficit)	$ 10,067,764	$ 1,472,510

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

Oragenics, Inc.
Consolidated Statements of Operations

	Year Ended December 31,	
	2025	**2024**
Operating expenses:		
Research and development	$ 2,392,658	$ 4,114,434
General and administrative	6,969,845	6,444,381
Total operating expenses	9,362,503	10,558,815
Loss from operations	(9,362,503)	(10,558,815)
Other income (expense):		
Interest income	182,229	45,897
Interest expense	(785,930)	(29,828)
Foreign currency exchange, net	(13,193)	(25,172)
Total other income (expense), net	(616,894)	(9,103)
Loss before income taxes	(9,979,397)	(10,567,918)
Income tax benefit	136,910	-
Net loss	$ (9,842,487)	$ (10,567,918)
Basic and diluted net loss per share	$ (4.56)	$ (47.88)
Weight average shares outstanding, basic and diluted	2,157,076	220,731

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 Stockholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	(Deficit) Equity
Balances at December 31, 2023	102,690	$ 103	16,955,197	$ 1,592,723	$ 207,793,582	$ (206,218,254)	$ 3,168,154
Compensation expense relating to option issuances	—	—	—	—	516,049	—	516,049
Sale of common stock	185,946	186	—	—	6,669,674	—	6,669,860
Conversion of Series A and B preferred stock to common stock	750	—	(9,467,000)	(1,592,723)	1,592,723	—	—
Conversion of prefunded warrants to common stock	129,617	130	—	—	1,840	—	1,970
Net loss	—	—	—	—	—	(10,567,918)	(10,567,918)
Balances at December 31, 2024	419,003	$ 419	7,488,197	$ —	$ 216,573,868	$ (216,786,172)	$ (211,885)
Reverse split fractional shares issued	107,085	107	—	—	(107)	—	—
Compensation expense relating to options	—	—	—	—	642,364	—	642,364
Compensation expense recapture relating to options	—	—	—	—	(86,617)	—	(86,617)
Common stock issued for services	103,306	103	—	—	124,897	—	125,000
Sale of common stock	258,849	259	—	—	2,633,931	—	2,634,190
Sale of Series H preferred stock	—	—	660,000	—	15,019,700	—	15,019,700
Conversion of Series H Preferred Shares into Common Stock	3,345,296	3,345	(230,709)	—	(3,345)	—	—
Conversion of prefunded warrants to common stock	37,990	38	—	—	1,102	—	1,140
Issuance of Series G Preferred Stock	—	—	1,000,000	—	—	—	—
Cancellation of Series G Preferred Stock	—	—	(1,000,000)	—	—	—	—
Net loss	—	—	—	—	—	(9,842,487)	(9,842,487)
Balances at December 31, 2025	4,271,529	$ 4,271	7,917,488	$ —	$ 234,905,793	$ (226,628,659)	$ 8,281,405

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,	
	2025	**2024**
Cash flows from operating activities:		
Net loss	$ (9,842,487)	$ (10,567,918)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization of debt discount and closing costs	771,437	-
Stock-based compensation expense	642,364	516,049
Stock-based compensation recapture expense	(86,617)	-
Common stock for services rendered	126,140	-
Changes in operating assets and liabilities:		
Other receivables	(53,082)	-
Prepaid expenses and other current assets	(1,007,286)	1,574,287
Operating lease right of use assets	-	9,811
Accounts payable and accrued expenses	203,144	(119,800)
Change in operating lease liabilities	-	(9,811)
Net cash used in operating activities	(9,246,387)	(8,597,382)
Cash flows from financing activities:		
Borrowings on short-term notes payable	2,455,911	-
Payments on short-term notes payable	(3,328,528)	(693,109)
Net proceeds from issuance of preferred stock and warrants	15,019,700	-
Net proceeds from issuance of common stock	2,634,190	6,671,830
Net cash provided by financing activities	16,781,273	5,978,721
Net increase (decrease) in cash and cash equivalents	7,534,886	(2,618,661)
Cash and cash equivalents at beginning of period	864,840	3,483,501
Cash and cash equivalents at end of year	$ 8,399,726	$ 864,840
Supplemental disclosure of cash flow information:		
Interest paid	$ 22,353	$ 29,828

The accompanying notes to the consolidated financial statements are an integral part of these 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 ONP002 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 of America ("U.S. GAAP") and the rules and regulations of the U.S. Securities and Exchange Commission applicable to annual financial reporting.

The consolidated financial statements include the accounts of Oragenics, Inc. and its wholly owned subsidiaries, Noachis Terra Inc. and Oragenics Australia Pty Ltd (collectively, the "Company"). All intercompany balances and transactions have been eliminated in consolidation.

The consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the settlement of liabilities in the normal course of business. As discussed in Note 1 Going Concern Consideration, the Company has incurred recurring losses and negative cash flows from operations, which raise substantial doubt about the Company's ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

On June 3, 2025, the Company effected a 1-for-30 reverse stock split of its outstanding common stock. All share and per-share amounts in the consolidated financial statements and accompanying notes have been retroactively adjusted to reflect the reverse stock split for all periods presented, unless otherwise indicated.

Going Concern Consideration

In light of the Company's recurring losses, accumulated deficit, and negative cash flows from operations, the report of the Company's independent registered public accounting firm on the consolidated financial statements for the year ended December 31, 2025, includes an explanatory paragraph raising substantial doubt about the Company's ability to continue as a going concern.

The Company has incurred losses and negative cash flows from operations since inception and has not generated significant revenues from operations. For the year ended December 31, 2025, the Company incurred a net loss of approximately $9.8 million and used approximately $9.2 million of cash in operating activities. As of December 31, 2025, the Company had an accumulated deficit of approximately $226.6 million.

Historically, the Company's primary sources of liquidity have consisted of proceeds from public and private equity financings, debt financings, warrant exercises, grant income, and interest income. During the twelve months ending December 31, 2025, we raised approximately $2.6 million in net proceeds from private placements and sales of our common stock, $15 million in net proceeds from the issuance of Series H preferred stock and warrants and received approximately $2.2 million in net proceeds from the issuance of debt. We believe that this financing meaningfully extends our ability to execute on our near-term operating objectives, including continued development of ONP-002. Based on these financings, management believes that the Company's available cash resources will be sufficient to fund planned operations through the third quarter of 2026.

The Company expects to continue to incur operating losses and negative cash flows as it advances the development of ONP-002 and supports ongoing general and administrative activities. However, based on the financing transactions completed in February, March, and July 2025, management believes the Company has sufficient liquidity to support its planned research and development activities and general corporate operations through the third quarter of 2026.

These conditions raise substantial doubt about the Company's ability to continue as a going concern for a period of one year from the date that these consolidated financial statements are issued. The Company's ability to continue operations beyond its current liquidity horizon is dependent upon its ability to obtain additional financing or achieve profitable operations, neither of which can be assured. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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 in consolidation.

New Accounting Standards

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. The Company adopted ASU 2023-07 for the year ended December 31, 2024. The adoption resulted in expanded disclosure requirements but did not have a material impact on the Company's consolidated financial statements.

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. The Company adopted this pronouncement for the year ended December 31, 2025. Aside from the expanded disclosure requirements, the adoption did not have a material impact on the Company's consolidated 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 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 because the estimate involves matters that were highly uncertain at the time the estimate was made; 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 highly liquid overnight repurchase agreements that qualify as cash equivalents. At times, deposits are in excess of federally insured limits.

Business Segments

We operate in a single reportable segment, which includes all activities related to the development of our lead product candidate, ONP-002, for the treatment of mild traumatic brain injury (concussion). This determination is consistent with how financial information is reviewed and evaluated by our Chief Operation Decision Maker ("CODM") for purposes of performance assessment, resource allocation, and planning.

Our CODM is currently our Chief Executive Officer and Chief Financial Officer, who regularly reviews consolidated net loss and total assets as key measures in operating decision-making. We do not separately evaluate results by geographic region or product line.

For the years ended December 31, 2025, and 2024, we did not generate any revenue. Our segment asset measure is reported on the consolidated balance sheet and total assets.

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 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. Awards that do not vest at the grant date 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. Recoverability is assessed based on a comparison of the carrying amount of the asset to the sum of the undiscounted cash flows expected to result from the use and eventual disposition of the asset. There was no impairment losses recorded during the years ended December 31, 2025, and 2024.

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 and are expensed to research and development as the related services are performed or the goods are delivered.

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 income tax expense 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 U.S. 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. The Company recognizes interest and penalties related to uncertain tax positions in income tax expense.

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. Management monitors the creditworthiness of the financial institutions in which it deposits cash and cash equivalents. As of December 31, 2025, and 2024, the uninsured portion of this balance was $3.9 million and $0.6 million, respectively.

Grant Revenue

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. No grant revenue was recognized during the years ended December 31, 2025, or 2024.

Leases

The Company determines whether an arrangement contains a lease at inception. The Company has elected the short-term lease exemption for leases with a term of twelve months or less and does not record right-of-use assets or lease liabilities for such leases. Lease payments under short-term leases are recognized as lease expense on a straight-line basis over the lease term.

3. Property and Equipment, net

We do not own any properties. The company leases office space under a short-term lease arrangement that qualifies for the short-term lease exemption under ASC 842.

4. Prepaid Expenses - Current and Long-Term

Prepaid expenses and other current assets were $1.6 million as of December 31, 2025, compared to $0.6 million as of December 31, 2024. The increase was primarily due to the timing of insurance premiums from financing our new policy renewals and advance payments related to research and development service agreements associated with the ONP-002 program.

The Company's prepaid balances typically consist of insurance premiums, research and development service agreements, and other vendor advances aligned with ongoing clinical, manufacturing, and regulatory activities.

5. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses totaled $1.6 million as of December 31, 2025, compared to $1.4 million as of December 31, 2024. The decrease was primarily attributable to the timing of vendor invoicing and payments. The Company maintains a vacation policy under which employee vacation benefits do not vest, do not accumulate, and expire at the end of each calendar year if unused. Accordingly, the Company does not record an accrued vacation liability at year-end.

6. Short-Term Notes Payable

On March 13, 2025, we issued a $3.0 million promissory note (the "Note") to a single investor at an original issue discount of 17%. Net proceeds to us were approximately $2.2 million after placement agent fees of $175,000 and legal expenses of $98,437. The Note was non-interest-bearing unless an event of a default occurred, at which time interest would accrue at a rate of 20% per annum. The Note was scheduled to mature on the earlier of July 14, 2025, or the closing of any subsequent offering with net proceeds equal to or exceeding all amounts due under the Note.

In connection with the issuance of the Note, we designated and issued 1,000,000 shares of our authorized but unissued Series G Mirroring Preferred Stock. For a description of the Series G terms, see Note 7. We used the net proceeds for working capital and general corporate purposes. Subsequently, in connection with the Reverse Stock Split the shares of Series G Preferred Stock were cancelled. See Note 7.

On July 2, 2025, the Company repaid in full the $3.0 million promissory note issued on March 13, 2025. The repayment was made using a portion of the net proceeds from the Company's July 2, 2025, public offering of Series H Preferred Stock and warrants to purchase additional shares of Series H Preferred Stock. See Note 7.

We had the following short-term notes payable as of December 31, 2025, and 2024:

	December 31, 2025	December 31, 2024
Insurance premium financing of $506,190, due in monthly installments of $58,314, which includes principal and annual interest at 8.75% through April 2026	$ 227,348	$ —
Insurance premium financing of $636,972, due in monthly installments of $67,277, which include principal and annual interest at 9.55% through May 2025	—	328,528
Total short-term notes payable	$ 227,348	$ 328,528

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, 2025, and 2024, respectively we had 4,271,529 and 419,003 shares of common shares issued.

Series F Convertible Preferred Stock

In December 2023, we issued 8,000,000 shares of our Series F Convertible Preferred Stock in connection with our purchase of assets from Odyssey Health, Inc. ("Odyssey"). The Series F Convertible Preferred Stock is convertible into shares of our common stock in accordance with the Certificate of Designation for the Series F Convertible Preferred Stock. Upon issuance, 511,308 shares of Series F Convertible Preferred Stock were converted to 17,044 shares of our common stock. As of December 31, 2025, 7,488,692 shares of Series F Convertible Preferred Stock remain outstanding. Currently, such 7,488,692 shares of Series F preferred stock are convertible into 249,624 shares of our common stock, subject to the provisions and limitations contained in the Certificate of Designation for the Series F Convertible Preferred Stock, which provide that the following Subsequent Conversion Conditions must occur before such shares can be converted: (i) the Company must have applied for and been approved for initial listing on the NYSE American or another national exchange or shall have been delisted from the NYSE American, and (ii) if required by the rules of the NYSE American, the Corporation's shareholder shall have approved any change of control that could be deemed to occur upon the conversion of the Series F Convertible Preferred Stock into Common Stock, based on the facts and circumstances existing at such time.

Series G Mirroring Preferred Stock

In March 2025, in connection with our issuance of a $3.0 million promissory note (see Note 6), we designated and issued 1,000,000 shares of our authorized but unissued shares of preferred stock as Series G Mirroring preferred stock, no par value and a stated value of $0.10 per share. On May 2, 2025, upon our shareholders' approval, at our annual shareholders meeting, of 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"), in accordance with the Certificate of Designation creating the Series G Mirroring Preferred Stock, all of the shares of Series G Mirroring Preferred Stock were automatically transferred to the Company and cancelled and such shares have resumed the status of authorized but unissued shares of preferred stock and are no longer designated as Series G Preferred Stock.

Series H Preferred Stock and Warrants

On July 2, 2025, the Company completed a public offering of Series H Convertible Preferred Stock and warrants to purchase additional shares of Series H Convertible Preferred Stock, resulting in gross proceeds of approximately $16.5 million and net proceeds of approximately $15.2 million, after deducting placement agent fees and offering expenses. In connection with the offering, the Company issued 660,000 shares of Series H Preferred Stock, each with a stated value of $25.00, and 660,000 warrants to purchase an equal number of Series H Preferred Shares at an exercise price of $25.00 per warrant. Each share of Series H Preferred Stock is convertible into Common Stock at an initial conversion price of $2.50 per share, subject to adjustment pursuant to the terms of the Series H Preferred Stock. Effective March 14, 2026, the conversion price was lowered to $1.00. See Note 12. The warrants are exercisable immediately and expire on July 2, 2030.

The Series H Preferred Stock has a stated value of $25.00 per share and is convertible at the option of the holder into shares of the Company's common stock at a conversion price of $2.50 per share, subject to adjustments pursuant to the terms of the Series H Preferred Stock, including for stock splits, combinations, dividends, and similar events. The Series H Preferred Stock does not accrue dividends, except that holders are entitled to participate on an as-converted basis if dividends are declared on the common stock. The shares rank "pari passu" with Company's common stock with respect to rights upon liquidation, dissolution, or winding-up and do not carry voting rights, except as required under Florida law. The shares may be automatically converted into common stock upon certain events specified in the Certification of Designation, such as the effectiveness of a registration statement covering the underlying common shares or at the Company's election if the specified trading-price and volume conditions are met. The Series H Preferred Stock is non-redeemable by the Company, except as provided in the Certificate of Designation.

For the year ended December 31, 2025, 429,291 shares of Series H Preferred Stock remained outstanding, and 230,709 shares had been converted into 3,345,296 shares of common stock. All conversions were made in accordance with the stated conversion terms, and no additional Series H warrants had been exercised as of the reporting date.

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 we 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 affected 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.

In February 2025, we sold 258,849 shares pursuant to the ATM Agreement for net proceeds of $2.6 million after commissions and legal expenses totaling $0.11 million.

Public Offering of Common Stock

On March 1, 2024, we sold 46,667 shares of our common stock at a price of $45.00 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 7,000 shares of our common stock solely for the purpose of covering overallotments, 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 $56.25 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 36,667 shares of our common stock for $30.00 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 1,833 shares of our common stock, which represented 5% of the aggregate number of securities sold in this offering, with an exercise price of $37.50 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 270,219 shares of our common stock at $16.50 per share or pre-funded warrants to purchase shares of our common stock ("Pre-Funded Warrants") in lieu thereof at $16.47 per Pre-Funded Warrant, which is equal to the offering price per share of the common stock less the $0.03 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 102,613 shares of our common stock and Pre-Funded Warrants to purchase 167,607 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 13,511 shares of our common stock, which represented 5% of the aggregate number of securities sold in the Offering, with an exercise price of $20.63 per share and exercisable commencing 6 months from the closing of the offering and for five years thereafter.

Warrants

On July 2, 2025, the Company completed a public offering of Series H Convertible Preferred Stock and warrants to purchase additional shares of Series H Convertible Preferred Stock. In connection with the offering, the Company issued 660,000 shares of Series H Preferred Stock, each with a stated value of $25.00, and 660,000 warrants to purchase an equal number of Series H Preferred Shares at an exercise price of $25.00 per warrant. For the year ended December 31, 2025, 6,875 warrants expired in accordance with their original terms. These expirations included warrants held by institutional and accredited investors, as well as a limited number of board members and other holders. No warrants were exercised or cancelled during the period. All outstanding warrants are classified as equity on our Consolidated Balance Sheets.

Outstanding and exercisable warrants as of December 31, 2025, are presented below:

Warrants Outstanding		Exercise Price	Expiration Date
2,341	$	56.25	2/27/29
1,834	$	37.50	6/29/29
13,512	$	20.70	9/4/29
660,000	$	25.00	7/2/30
677,687			

8. Stock-Based Compensation

2021 Incentive Plan

Our 2021 Equity Incentive Plan (the "2021 Plan") authorizes the grant of stock options (incentive and non-statutory), stock appreciation rights and restricted stock covering a total of 3,166,667 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, 2025, 1,076,332 shares were reserved for issuance related to the 2021 Plan and 2,090,335 shares of our common stock remain 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 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	1.03	0.86	0.93
Market Price	0.93	0.86	0.92
Volatility	117.87%	117.79%	117.87%
Dividend Yield	0.00%	0.00%	0.00%
Expected Life	6.00 yrs	5.00 yrs	5.25 yrs
Risk Free Rate	3.82%	3.72%	3.74%

Unrecognized Stock-Based Compensation Costs

Total stock-based compensation related to stock options was $555,747 and $516,049 for the years ended December 31, 2025, and 2024, respectively. As of December 31, 2025, there was $208,004 of unrecognized stock-based compensation related to stock options, which is expected to be recognized over a weighted average period of three years.

Stock Option Activity

Stock option activity for the year ended December 31, 2025, 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, 2024	33,150	$ 142.71	6.72	$ —
Granted	1,052,320	0.93	5.25	—
Forfeited	(9,138)	105.90	—	—
Outstanding at December 31, 2025	1,076,332	4.41	9.89	$ —
Exercisable at December 31, 2025	812,332	5.54	9.87	—

(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, 2025, and 2024, respectively

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

	2025	2024
Weighted average grant date fair value of stock options granted per share	$ 0.77	$ 11.46
Grant date fair value of stock options that vested	$ 819,842	$ 305,632

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, 2025, and 2024 were $11,156 and $27,325 respectively.

10. Income Taxes

Our income before provision for (benefit from) income taxes for the years ended December 31, 2025, and 2024 was as follows:

	2025	2024
Domestic	$ (9,999,086)	$ (10,594,939)
Australia	19,689	27,021
Loss before taxes	$ (9,979,397)	$ (10,567,918)

Income taxes are provided for the tax effects of transactions reported in the financial statements and consist of taxes currently due. Deferred taxes relate to differences between the basis of assets and liabilities for financial and income tax reporting which will be either taxable or deductible when the assets or liabilities are recovered or settled.

The components of the provision for income taxes for the years ended December 31, 2025, and 2024 are as follows:

	2025	2024
Current - Australia	$ (136,910)	$ —
Deferred - Federal	2,010,443	(1,408,287)
Valuation Allowance	(2,010,443)	1,408,287
Total provision (deferred benefit) for income taxes	$ (136,910)	$ —

The Company is subject to taxation in the United States at both the federal level and within Florida. The company is not currently under any audit examination. The federal and state statute of limitations is still open to the extent of the net operating losses generated within each particular year. Generally, U.S. and Florida tax years beginning in 2022 and forward remain open to examination, while Australian Taxation Office review periods remain open for 2024 and subsequent tax years.

The Company had an effective tax rate of 1.37% and 0.00% for the years ended December 31, 2025, and 2024, respectively.

Beginning in 2025 annual reporting, we adopted ASU 2023-09 prospectively. See Note 1 - Summary of Significant Accounting Policies - Recently Adopted Accounting Pronouncements for additional details on the adoption of ASU 2023-09. A reconciliation of the U.S. federal statutory income tax rate to our effective tax rate pursuant to the disclosure requirements of ASU 2023-09 for the year ended December 31, 2025, is as follows (in thousands, except for percentages):

	For the year ended December 31, 2025	
U.S. federal statutory income tax rate	(2,096)	21.00%
State taxes[1], net of federal	0	0.00%
Australia		
Statutory tax rate difference between Australia and United States	1	-0.05%
R&D tax incentive expenditure addback	112	-1.13%
FY24 tax provision true up	(78)	0.78%
Australian R&D incentive offset	(176)	1.76%
Change in valuation allowance	1,042	-10.42%
Expiring NOLS	742	-7.42%
Deferred only stock-based compensation adjustment	300	-3.00%
Other deferred only adjustments	14	-0.14%
Nontaxable or nondeductible items	2	-0.02%
Effective Tax Rate	(137)	1.36%

	December 31, 2024
U.S. statutory rate	21.00%
Australia Tax	0.59%
State taxes, net of federal	3.80%
Change in valuation allowance	-19.29%
Nontaxable or nondeductible items	0.00%
Stock-based compensation	-0.47%
Issuance Costs	0.00%
Other permanent items, net	-0.01%
Change in tax rate	-5.62%
Effective Tax Rate	0.00%

[1]Florida accounts for 100% of the tax effect in this category.

The Company did not make any income tax payments or receive any income tax refunds requiring disclosure under ASU 2023-09 for the year ended December 31, 2025.

The table below presents the effects of temporary differences that gave rise to significant portions of deferred tax assets and liabilities as of December 31, 2025, and 2024:

	2025	2024
Deferred tax assets (liabilities):		
Net operating loss carryforward	$ 40,114,803	$ 41,070,043
Accrued vacation	799	13,421
Non-qualified stock compensation	940,759	1,228,004
Capitalized Research & Development costs	2,940,435	3,694,354

In-process research and development	2,081,681	2,360,913
Intangibles	234,049	—
Total deferred tax assets	46,312,526	48,366,735
Less valuation allowance	(46,312,526)	(48,366,735)
Total net deferred tax asset, net of valuation allowance	$ —	$ —

At December 31, 2025, the Company has federal and state tax net operating loss carry forwards of $164,834,118 and $138,451,933, respectively.

Federal and Florida tax net operating loss carryforwards generated prior to December 31, 2017, will expire through 2038 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 80% deduction limitation based upon pre-NOL deduction taxable income 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 $3,959,813, of which are included as an uncertain tax position. The federal tax credit carryforward will expire beginning in 2022 and continuing through 2044 unless utilized.

In assessing the realization of deferred tax assets, management considers whether it is more likely than not that some portion or all the deferred income tax assets will not be realized. The ultimate realization of deferred income 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 income tax liabilities, projected future taxable income, and tax planning strategies in making this assessment. Based on consideration of these items, management has determined that a full valuation allowance is required as of December 31, 2025, and 2024.

The utilization of the Company's net operating loss carryforwards could be subject to annual limitations under Section 382 and 383 of the Internal Revenue Code of 1986, as amended (the "Code"), and similar state tax provisions, due to ownership change limitations that may have occurred previously or that could occur in the future. These ownership changes limit the amount of net operating loss carryforwards and other deferred tax assets that can be utilized to offset future taxable income and tax, respectively. In general, an ownership change, as defined by Section 382 and 383 of the Code, results from transactions increasing ownership of certain stockholders or public groups in the stock of the corporation by more than 50 percent points over a three-year period. The Company has not completed an analysis of an ownership change under Section 382 of the Code. To the extent that a study is completed and an ownership change is deemed to occur, the Company's net operating losses and tax credits could be limited.

On July 4, 2025, the One Big Beautiful Bill Act ("OBBBA") was enacted in the U.S. The OBBBA includes significant provisions, such as the permanent extension of certain expiring provision of the Tax Cuts and Jobs Act, modification to the international tax framework and the restoration of favorable tax treatment for certain business provisions. The legislation has multiple effective dates, with certain provisions effective in 2025 and other implemented through 2027. The bill does not materially impact the Company's 2025 income tax provision.

For the years ended December 31, 2025, and 2024, 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.

A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows:

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
Additions based on tax positions related to the current year	—
Reductions for the tax positions of prior years	—
Expired Tax Credits due to 20-year life	(81,881)
Balance as of December 31, 2025	$ 3,959,813

Included in the balance at December 31, 2025, and 2024, are $3,959,813 and $4,041,694, 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.

The Company's policy is to recognize interest and penalties associated with uncertain tax benefits as part of the income tax provision and include accrued interest and penalties with the related income tax liability on the Company's Condensed Consolidated Balance Sheets. During the years 2025, and 2024, 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, the Company entered into an investment-banking engagement letter with Ladenburg Thalmann & Co. Inc. ("Ladenburg"), which was subsequently amended several times (collectively, the "Engagement Letter"). The Company terminated the Engagement Letter effective August 15, 2023. Following termination, Ladenburg asserted that it was entitled to a fee in connection with the Company's purchase of assets from Odyssey Health, Inc., and issued an invoice for $2,500,000. The Company disputed that no such fee was due. Related proceedings were also filed in the United States District Court for the Southern District of Florida.

On October 16, 2025, the Company and Ladenburg executed a Settlement Agreement resolving all claims between the parties. Under the terms of the Settlement Agreement, the Company agreed to pay $700,000, which was wired on October 17, 2025, in full satisfaction of the matter.

No other material legal proceedings are pending or known to be threatened against the Company as of the date of these financial statements.

12. Subsequent Events

Dissolution of Noachis Terra, Inc

Subsequent to December 31, 2025, the Company completed the dissolution of Noachis Terra, Inc., its wholly owned Delaware subsidiary in February 2026. Noachis Terra, Inc. had no material assets or operations as of December 31, 2025, and the dissolution did not have material impact on the Company's consolidated financial statements.

Adjustment to Conversion Price of Series H Preferred Stock

The outstanding shares of Series H Preferred Stock are convertible into the number of shares of our common stock obtained by dividing the Stated Price of the shares to be converted by the Conversion Price. The Certificate of Designation for our Series H Preferred Stock contains anti-dilution provisions, which provisions require the lowering of the current $2.50 Conversion Price on any unconverted Series H Preferred Stock to the price of future issuances by us (subject to certain exclusions). Effective as of March 14, 2025, as a result of the Company's issuance of shares of Common Stock to Dawson James in payment of advisory fees pursuant to an Engagement Agreement dated as of March 14, 2025, at a price of $1.00 per share, the Conversion Price of the Series H Preferred Stock was reduced to $1.00.

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 H Preferred Stock	8-K	001-32188	3.1	7/2/2025	
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	Form of Representative's Warrants.	8-K	001-32188	4.1	3/1/24	
4.3	Form of Placement Agent Warrant.	8-K	001-32188	4.1	6/26/24	
4.4	Form of Placement Agent Warrant.	8-K	001-32188	4.2	9/5/24	
4.5	Form of Series H Preferred Warrant	8-K	001-32188	4.1	7/2/25	
4.6	Warrant Agency Agreement	8-K	001-32188	4.2	7/2/25	
4.7	Description of the Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934					X
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	Executive Employment Agreement between the Company and Janet Huffman dated effective March 8, 2023. +	8-K			3/8/23	

10.8	Amendment to Executive Employment Agreement between the Company and Janet Huffman dated effective January 16, 2025+	8-K	001-32188	10.2	1/17/25	
10.9	Executive Employment Agreement for Mr. Redmond dated December 28, 2023+	8-K	001-32188	10.1	12/29/23	
10.10	2021 Equity Incentive Plan+	8-K	001-3288	10.1	2/28/22	
10.11	First Amendment to 2021 Equity Incentive Plan. +	8-K	001-32188	4.2	12/15/23	
10.12	Second Amendment to 2021 Equity Incentive Plan+	8-K	001-32188	4.3	12/16/24	
10.13	Form Stock Option Award Agreement (Directors)+	8-K	001-3288	10.2	2/28/22	
10.14	Form Stock Option Award Agreement (Employees)+	8-K	001-3288	10.3	2/28/22	
10.15	Form Stock Option Award Agreement (Consultants)+	8-K	001-3288	10.4	2/28/22	
10.16	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	
10.17	Placement Agency Agreement dated, September 4, 2024, between Oragenics, Inc. and Dawson James Securities, Inc.	8-K	001-32188	1.1	9/5/24	
10.18	Placement Agency Agreement dated June 25, 2024 between Oragenics, Inc. and Dawson James Securities, Inc.	8-K	001-32188	1.1	6/26/24	
10.19	Form of Securities Purchase Agreement	8-K	001-32188	10.1	7/2/25	
10.20	Placement Agency Agreement dated, July 1, 2025, between Oragenics, Inc. and Dawson James Securities, Inc.	8-K	001-32188	1.1	7/2/25	
19.1	Insider Trading Policy					X

21.1	Subsidiaries of Registrant					X
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-K), irrespective of any general incorporation language contained in such filing.

Exhibit 4.7

DESCRIPTION OF THE REGISTRANT'S SECURITIES
REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES
EXCHANGE ACT OF 1934

Oragenics, Inc. ("Oragenics," "we," "our," or "us") has one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended: our common stock.

DESCRIPTION OF CAPITAL STOCK

The following descriptions are summaries of the material terms that are included in our amended and restated articles of incorporation (as amended) and our bylaws (as amended) as well as the specific agreements such descriptions relate to. This summary is qualified in its entirety by the specific terms and provisions contained in our restated articles of incorporation, bylaws and the specific agreements described herein, copies of which we have filed as exhibits to our Annual Report on Form 10-K and are incorporated herein by reference.

Overview

Authorized Capital Stock

Our authorized capital stock consists of 350,000,000 shares of common stock, par value $0.001, and 50,000,000 shares of preferred stock, without par value.

Listing of Common Stock

Our common stock is currently listed on the NYSE American under the trading symbol "OGEN."

Common Stock

Voting

The holders of our common stock are entitled to one vote for each share held of record on all matters submitted to a vote of the shareholders. Approval of an amendment of our articles of incorporation, a merger, a share exchange, a sale of all our property or dissolution must be approved by a majority of all votes entitled to be cast. Such votes may be cast in person or by proxy as provided in Article I Section 8 of our bylaws. One third of our shares entitled to vote constitute a quorum for purposes of a meeting of our shareholders.

Dividends

Subject to preferences that may be applicable to any outstanding preferred stock, the holders of our common stock are entitled to receive ratably all dividends, if any, as may be declared from time to time by our Board of Directors out of the funds legally available.

In the event of the liquidation, dissolution or winding up of the Company, the holders of our common stock are entitled to share ratably in all assets remaining after payment of liabilities, subject to prior distribution rights of preferred stock, if any, then outstanding. The common stock has no preemptive or conversion rights. There are no redemption or sinking fund provisions applicable to the common stock. All outstanding shares of common stock are fully paid and non-assessable.

Rights upon Liquidation

Upon our liquidation, dissolution or winding-up, after payment in full of our liabilities and the amounts required to be paid to holders of any outstanding shares of preferred stock, if any, all holders of our common stock, along with the holders of our Series F Convertible Preferred Stock and Series H Convertible Preferred Stock on an "as if" converted basis, will be entitled to receive a pro rata distribution of all of our assets and funds legally available for distribution.

Redemption and Pre-Emptive Rights

No shares of our common stock are subject to redemption or have preemptive rights to purchase additional shares of our common stock or any of our other securities.

Fully Paid and Non-assessable

All of our outstanding shares of common stock are, and the shares of common stock to be issued in this offering, will be fully paid and non-assessable.

Preferred Stock

Our Board of Directors has the authority, without action by our shareholders, to designate and issue up to 50,000,000 shares of preferred stock in one or more series or classes and to designate the rights, preferences and privileges of each series or class, which may be greater than the rights of our common stock. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, redemption rights, liquidation preferences, the number of shares constituting any class or series and the designation of the class or series. Terms selected by our Board of Directors in the future could decrease the amount of earnings and assets available for distribution to holders of shares of common stock or adversely affect the rights and powers, including voting rights, of the holders of shares of common stock without any further vote or action by the stockholders. As a result, the rights of holders of our common stock will be subject to, and may be adversely affected by, the rights of the holders of the Series F Convertible Preferred Stock, and Series H Convertible Preferred Stock or any other preferred stock that may be issued by us in the future, which could have the effect of decreasing the market price of our common stock.

Series A Convertible Preferred Stock

On May 10, 2017, and on July 25, 2017, we issued an aggregate of 12,000,000 shares of convertible preferred stock, designated as the Series A Convertible Preferred Stock pursuant to the certificate of designation and rights filed by us with the Secretary of State of the State of Florida, with an aggregate original purchase price and initial liquidation preference of $3.0 million. Each share of Series A Convertible Preferred Stock was issued for an amount equal to $0.25 per share, which we refer to as the original purchase price. Prior to the end of 2024, all shares of Series A Preferred Stock were converted to common stock and as such, the Company no longer has any Series A Preferred Stock outstanding.

Series B Convertible Preferred Stock

On November 8, 2017, we issued 6,600,000 shares of convertible preferred stock, designated as the Series B Convertible Preferred Stock pursuant to the certificate of designation and rights filed by us with the Secretary of State of the State of Florida, with an aggregate original purchase price and initial liquidation preference of $3.3 million. Each share of Series B Convertible Preferred Stock was issued for an amount equal to $0.50 per share, which we refer to as the original purchase price. Prior to the end of 2024, all shares of Series B Preferred Stock were converted to common stock and as such, the Company no longer has any Series B Preferred Stock outstanding.

Series C Non-Voting*, *Non-Convertible Preferred Stock

On November 8, 2017, we issued to a single holder 100 shares of non-convertible preferred stock, designated as the Series C Non-Voting, Non-Convertible Preferred Stock pursuant to the certificate of designation and rights filed with the Secretary of State of the State of Florida, with a stated value and liquidation preference equal to $33,847.9874 per share, which we refer to as the Stated Value. The shares of Series C Non-Voting, Non-Convertible Preferred Stock were entitled to payment-in-kind ("PIK") dividends thereon at the annual rate of twelve percent (12%) (the "Initial Rate") of its Stated Value, payable by issuing additional shares of Series C Non-Voting, Non-Convertible Preferred Stock within thirty days after the end of each calendar year, pro-rata for partial years. During the three months ended March 31, 2021, the Company provided a notice of redemption, to the holder of the Company's Series C Preferred Stock to redeem all outstanding Series C Preferred Stock (which included the dividend of 26.697 shares paid on January 28, 2021, and any accrued dividends due through the redemption date of March 13, 2021). The Series C Preferred Stock redemption amount of approximately $5.6 million was paid on March 15, 2021, and all outstanding shares of Series C Preferred Stock were cancelled.

Series D Preferred Stock-Converted to Common Stock

On July 13, 2018, our board of directors designated 9,364,000 shares of our preferred stock as Series D Convertible Preferred Stock ("Series D Preferred Stock"), which were subsequently issued on July 17, 2018, none of which are currently issued and outstanding. The preferences and rights of the Series D Preferred Stock was set forth in a Certificate of Designation (the "Series D Certificate of Designation"). Pursuant to a transfer agency agreement between us and Continental Stock Transfer & Trust Company, as transfer agent, the Series D Preferred Stock was issued in book-entry form and represented only by one or more global certificates deposited with The Depository Trust Company, or DTC, and registered in the name of Cede & Co., a nominee of DTC, or as otherwise directed by DTC. Prior to the end of 2018, all of 9,364,000 shares of Series D Preferred Stock converted to common stock and as such, the Company no longer has any Series D Preferred Stock outstanding.

Series E Mirroring Preferred Stock-Cancelled

On July 10, 2023, our board of directors designated 404,728 shares of our preferred stock as Series E Mirroring Preferred Stock ("Series E Preferred Stock"), which were issued on August 4, 2023 and subsequently cancelled. There currently are no issued and outstanding shares of Series E Preferred Stock. The preferences and rights of the Series E Preferred Stock was set forth in a Certificate of Designation (the "Series E Certificate of Designation"). Pursuant to the terms of the Series E Certificate of Designation, upon effectiveness of the Amendment to the Amended and Restated Articles of Incorporation, in connection with the Company's annual meeting of shareholders, to effect an increase in the shares of Common Stock the Company was authorized to issue from 4,166,666 shares of Common Stock to 350,000,000 shares of Common Stock (the "Amendment"), each share of Series E Preferred Stock would be automatically transferred to the Company and cancelled for no consideration with no action on behalf of the holders of Series E Preferred Stock. The Company's shareholders approved the Amendment on December 14, 2023. Such shares resumed the status of authorized but unissued preferred stock and are no longer designated as Series E Preferred Stock.

Series F Convertible Preferred Stock

On December 28, 2023, we issued 8,000,000 shares of convertible preferred stock, designated as the Series F Convertible Preferred Stock ("Series F Preferred Stock") pursuant to the certificate of designation and rights filed by the Company with the Secretary of State of the State of Florida ("Series F Certificate of Designation"), as partial consideration for the purchase of certain assets of Odyssey Health, Inc. On December 28, 2023 and pursuant to the Series F Certificate of Designation, 511,308 shares of Series F Preferred were converted to common stock and, as a result of such conversion, 7,488,692 shares of Series F Convertible Preferred Stock remain outstanding.

The following description is a summary of the material provisions of the Series F Convertible Preferred Stock.

*Liquidation Preference***.** The Series F Preferred Stock is economically equivalent to the Company's common stock. Upon liquidation, it is at parity with the common stock and junior to the Company's outstanding Class A and B Preferred Stock and any other class or series of capital stock of the Corporation created specifically ranking by its terms senior to the Series F Preferred Stock.

*Dividends***.** No dividends shall be paid on shares of the Series F Preferred Stock.

*Voting***.** The Series F Preferred Stock has no voting rights, except as required by applicable law and except for limited protective voting rights specifically set forth in Certificate of Designation.

Conversion. The Series F Preferred Stock is convertible commencing with the date of its issuance into Common Stock on a 1 for 1 basis (subject to customary adjustments). However, pursuant to the Series F Certificate of Designation, the holder of the Series F Preferred Stock cannot convert shares of Series F Preferred Stock into more than 19.9% of the Company's Common Stock outstanding as of October 4, 2023 until (i) the Company 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, and (ii) if required by the rules of the NYSE American, the Company's 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 facts and circumstances existing at such time.

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

Redemption. The Series F Preferred Stock is not redeemable by the Company.

Trading Market. There is no established trading market for any of the Series F Preferred Stock, and the Company does not expect a market to develop. The Company does not intend to apply for a listing for any of the Series F Preferred Stock on any securities exchange or other nationally recognized trading system.

Series G Mirroring Preferred Stock-Cancelled

On March 13, 2025, our board of directors designated 1,000,000 shares of our preferred stock as Series G Mirroring Preferred Stock ("Series G Preferred Stock"), which were issued on March 14, 2025, and subsequently cancelled. There currently are no issued and outstanding shares of Series G Preferred Stock. The preferences and rights of the Series G Preferred Stock was set forth in a Certificate of Designation (the "Series G Certificate of Designation"). Pursuant to the terms of the Series G Certificate of Designation, upon effectiveness of the Amendment to the Amended and Restated Articles of Incorporation, in connection with the Company's annual meeting of shareholders, the shareholders authorized the Board of Directors to enact a reverse stock split, in its sole discretion at any time within one year after shareholder approval is obtained, to effect a reverse stock split (the "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-fifty (1:50) (the "Reverse Stock Split Proposal") and to approve an amendment to the Company's Articles of Incorporation, as amended, to increase the Company's authorized shares of common stock to 350,000,000 in the event a Reverse Stock Split of Common Stock is effectuated prior to approval of the Reverse Stock Split (the "Amendment"). Each share of Series G Preferred Stock would be automatically transferred to the Company and cancelled for no consideration with no action on behalf of the holders of Series E Preferred Stock. The Company's shareholders approved the Reverse Stock Split and Amendment on May 2, 2025. Such shares resumed the status of authorized but unissued preferred stock and are no longer designated as Series G Preferred Stock.

Series H Convertible Preferred Stock

On July 2, 2025 (the "Issuance Date"), we issued 660,000 shares of convertible preferred stock, designated as the Series H Convertible Preferred Stock pursuant to the certificate of designation and rights filed by us with the Secretary of State of the State of Florida. The Series H Convertible Preferred Stock has no par value and a stated value equal to $25 ("Stated Value"). The Series H Convertible Preferred Stock was immediately convertible into shares of Common Stock, at an initial conversion price equal to $2.50 per share of Common Stock (the "Conversion Price"), subject to adjustment as provided in the Series H Preferred Stock Convertible Certificate of Designation, at any time at the option of the holder prior to the fifth anniversary of the closing date, at which time all shares of outstanding Series H Convertible Preferred Stock shall automatically and without any further action by the holders be converted into shares of Common Stock at the then effective conversion price. Certain holders of Series H Convertible Preferred Stock elected to convert to common stock and, as a result of such conversions, 428,291 shares of Series H Preferred remain outstanding.

The following description is a summary of the material provisions of the Series H Convertible Preferred Stock and the certificate of designation and rights and does not purport to be complete. This summary is subject to and is qualified by reference to all the provisions of the Series H Convertible Preferred Stock and certificate of designation and rights of Series H Convertible Preferred Stock, including the definitions of certain terms used in the certificate of designation and rights. We urge you to read this document because it, and not this description, defines the rights of a holder of the Series H Convertible Preferred Stock. A copy of the form of certificate of designation and rights that we filed with the Secretary of State of the State of Florida on June 30, 2025. A copy of the filed certificate of designation was filed with the Current Report on Form 8-K filed with the SEC on July 2, 2025.

Mandatory Conversion Date

The shares of Series H Convertible Preferred Stock hall automatically be converted into shares of Common Stock on July 2, 2030, as described below under "Conversion Rights."

Dividends

Holders of Series H Convertible Preferred Stock are entitled to receive annual non-compounding dividends at the rate per share (as a percentage of the Stated Value per share of Series H Convertible Preferred Stock) of 9% per annum. Dividends on shares of Series H Convertible Preferred Stock shall accrue and be cumulative from the Issuance Date and shall accrue from day to day thereafter for so long as Series H Convertible Preferred Stock is outstanding; *provided, however*, that dividends on shares of Series H Convertible Preferred Stock issued pursuant to the exercise of Warrants shall accrue and be cumulative from the date of the exercise of such Warrant.

Liquidation Preference

Upon any liquidation, dissolution or winding-up of the Company, whether voluntary or involuntary, each Holder shall be entitled to receive the amount of cash, securities or other property to which such Holder would be entitled to receive with respect to such shares of Series H Convertible Preferred Stock if such shares had been converted to Common Stock immediately prior to such Liquidation.

Ranking

The Series H Convertible Preferred Stock ranks on par with the Common Stock and Series F Convertible Preferred Stock.

Conversion Rights

The holders of shares of Series H Convertible Preferred Stock will, at any time, prior to July 2, 2030, be entitled to convert some or all of their Series H Convertible Preferred Stock into the number of shares of our common stock obtained by dividing the Stated Price of the shares to be converted by the Conversion Price. The Certificate of Designation for our Series H Preferred Stock contains anti-dilution provisions, which provisions require the lowering of the current $2.50 Conversion Price on any unconverted Series H Preferred Stock to the price of future issuances by us (subject to certain exclusions). If in the future we issue securities for less than the Conversion Price of our Series H Preferred Stock, we will be required to reduce the relevant Conversion Price of any unconverted Series H Preferred Stock, which will result in a greater number of shares of Common Stock being issuable upon conversion, which in turn will have a greater dilutive effect on our shareholders. In addition, as there is no floor price on the Conversion Price, we cannot determine the total number of shares issuable upon conversion. Effective as of March 14, 2025, as a result of the Company's issuance of shares of Common Stock to Dawson James in payment of advisory fees pursuant to an Engagement Agreement dated as of March 14, 2025, at a price of $1.00 per share, the Conversion Price of the Series H Preferred Stock was reduced to $1.00.

Voting Rights

Except as otherwise required by law, the Series H Convertible Preferred Stock shall have no voting rights.

Trading Market. There is no established trading market for any of the Series H Convertible Preferred Stock, and the Company does not expect a market to develop. The Company does not intend to apply for a listing for any of the Series H Convertible Preferred Stock on any securities exchange or other nationally recognized trading system.

The following descriptions are summaries of the material terms that are included in our amended and restated articles of incorporation (as amended) and our bylaws (as amended) as well as the specific agreements such descriptions relate to. This summary is qualified in its entirety by the specific terms and provisions contained in our restated articles of incorporation, bylaws and the specific agreements described herein, copies of which we have filed as exhibits to our Form 10-K.

Certain Anti-Takeover Provisions

Florida Law

We are not subject to the statutory anti-takeover provisions under Florida law because in our articles of incorporation we have specifically elected to opt out of both the "control-share acquisitions" (F.S. 607.0902) and the "affiliated transactions" (F.S. 607.0901) statutes. Since these anti-takeover statutes do not apply to a corporation that has specifically elected to opt out of such provisions, we would not be able to invoke the protection of such statutes in the event of a hostile takeover attempt.

Articles of Incorporation and Bylaw Provisions

Our articles of incorporation and bylaws contain provisions that could have an anti-takeover effect. 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 acquiror;
- the ability of the 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; and
- requirements that only our Board, our President or holders of more than 10% of our shares can call a special meeting of shareholders.

These provisions in our articles of incorporation and bylaws could delay or discourage transactions involving an actual or potential change in control of us, including transactions in which shareholders might otherwise receive a premium for their shares over their current prices. Such provisions could also limit the ability of shareholders to approve transactions that shareholders may deem to be in their best interests and could adversely affect the price of our common stock.

Transfer Agent and Registrar

The transfer agent and registrar of our common stock is Continental Stock Transfer & Trust Company, 1 State Street 30th Floor, New York, New York 10004, telephone: (212) 509-4000.

Exhibit 19.1

December 2019

ORAGENICS, INC.
POLICY REGARDING INSIDER TRADING

Overview. The Board of Directors of Oragenics, Inc. has adopted this Policy Regarding Insider Trading (the "Policy") to assist compliance with federal securities laws that prohibit insider trading. Oragenics requires all directors, officers and employees to read this Policy and acknowledge receipt of a copy of this Policy.

Under existing law, if you buy or sell securities (e.g. stock, stock options, debentures, etc.) of a public company with knowledge of material, non-public ("inside") information or communicate such information to another person who trades on the basis of the information, you subject yourself to potential severe civil and criminal penalties. Such activity is referred to as "insider trading." The violation is not limited to information obtained in the performance of your duties with Oragenics. Trading in public securities with knowledge of any material, non-public information, whether or not related to Oragenics, also may subject you to penalties.

Information is deemed to be material if a reasonable investor would consider it important in making a decision to buy, sell or hold a security of a company. Any information that could affect the price of a security may be considered material. If you are uncertain whether information that you have is material, you may consult with our Policy Administrator (see discussion below). If you have material, non-public information, you must not trade until the information has been made public and the trading market has had an opportunity to react to the information.

Inside information should not be communicated to anyone, except in the proper performance of your duties. This includes not communicating inside information to members of your family, friends, and strangers. Disclosing inside information to others ("tipping"), even casually in a social setting, is unlawful if that person trades with that information.

The phrase "buy or sell securities" includes selling the securities short (e.g. selling securities you do not own), trading in options to buy or sell securities, and any other transaction by which you seek to profit from inside information. You may be subject to penalties even if you do not profit from your possession of material inside information.

Policy Administrator. Our Chief Financial Officer, or in his absence, our Chief Executive Officer will act as our Policy Administrator and shall be responsible for administrative implementation of this Policy. They are authorized to take appropriate action for any known or suspected violations or non-compliance. Signed copies of this Policy will be maintained in our personnel files.

Prohibition Against Insider Trading. All Oragenics' personnel are prohibited from trading in any security (whether or not it is a security of Oragenics) on the basis of inside information and/or communicating that information to others. Common examples of information that is inside information until publicly disclosed are the following:

- an extremely favorable or unfavorable research discovery or FDA ruling
- a favorable acquisition
- an increase or a decline in earnings
- an extraordinary gain or loss not previously disclosed
- the failure to pay obligations when due
- an announcement of a significant previously undisclosed liability
- a probable sale of a company at a premium over the market price for its securities
- a proposed tender offer for a company's stock.

Guidelines for Trading Securities of Oragenics. As explained above, it is unlawful to trade public securities at any time on the basis of inside information. If you are aware of inside information regarding Oragenics, you are absolutely prohibited from trading in our securities. The following are guidelines for the trading of our securities to assist you in avoiding inadvertent trading when Oragenics may possess inside information but you may not.

(1) Pre-Clearance Policy for Trading. You may not trade at any time without prior clearance from the Policy Administrator. All directors, officers and employees are required to clear at least one (1) day in advance with the Policy Administrator any and all transactions involving our securities. The Policy Administrator will inform you whether or not a black-out period is currently in effect. Trading is prohibited during a black-out period. The Policy Administrator will maintain a written record of clearances given or withheld. The granting of clearance by the Policy Administrator will not constitute approval that any information known to you, but not disclosed by you to the Policy Administrator, is not inside information.

(2) Black-Out Period. Black-out periods are periods designated by Oragenics as times you may not trade regardless of your knowledge or lack of knowledge of material non-public information. These black-out periods are instituted for a variety of reasons. There will always be a black-out period in place relating to earnings announcements which period begins on the last day of Oragenics' fiscal quarter and year-end and last until after the second business day following the issuance of our financial results. Directors, officers and employees should limit their trades to the four-week period beginning two business days after quarterly or annual financial information has been released to the public. We may designate additional black-out periods that we believe are warranted under the circumstances.

(3) Rule 10b5-1 Plans. Rule 10b5-1 trading plans are required to be cleared in advance by the Policy Administrator prior to entering into the trading plan. You may only enter into a Rule 10b5-1 trading plan when you are not in possession of material, non-public information. Once a 10b5-1 trading plan is pre-cleared, trades made pursuant to the plan will not require the pre-clearance set forth in paragraph (1) above.

Although these guidelines may seem restrictive, it is the policy of Oragenics that directors, officers and employees who purchase our securities should do so with the intention of owning the securities for a period of years and not with the intention of realizing a short-term profit based on temporary circumstances.

Safeguarding Inside Information. During the ordinary course of performing your duties, you may become aware of inside information about Oragenics as well as inside information about other companies. If you acquire such inside information, you are prohibited from communicating that information to others, including family members, friends or other employees, except as required in the proper performance of your duties. In addition, you should follow these procedures in your communications with fellow employees:

(1) Emphasize to personnel involved in the matter the need for absolute confidentiality;

(2) Use a code name in the documents involving the matter and in referring to the matter, to the extent deemed necessary by your supervisor;

(3) Take all reasonable steps to protect the confidentiality of such information. For example, keep files and documents in a secure place, away from places where they might come into the view of personnel generally or persons coming into our offices; and

(4) Destroy documents referring to the matter that are discarded.

Inquiries by Outsiders. In the event that inquiries about Oragenics are made by the financial press, investment analysts or others in the financial community, it is important that all such communications on behalf of Oragenics be made by an appropriately designated officer under carefully controlled circumstances. Unless you are expressly authorized to the contrary, if you receive any inquiries of this nature, you should decline comment and refer the inquirer to our Chief Executive Officer or Chief Financial Officer.

Penalties. If you fail to comply with this insider trading policy, you may be subject to dismissal. If you engage in insider trading, you could also be subject to

(1) disgorging any profit realized, or loss avoided;

(2) a civil penalty up to three times that amount in an action by the Securities and Exchange Commission ("SEC"); and

(3) criminal penalties (up to $1,000,000 plus 10 years in prison, or both).

Questions. Any questions concerning this Policy or its application to any particular circumstances should be directed to the Policy Administrator.

Exhibit 21.1

Subsidiaries of Oragenics, Inc.

Name	State or Jurisdiction of Incorporation or Organization
Oragenics Australia Pty Ltd	Australia

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, 333-226150 and 333-288225), Form S-3 (333-213321, 333230422, 333-238789, 333-269225 and 333-292880), and Form S-8 (333-184588, 333-223088, 333-225894, 333-23230, 333-263821, 333-276460, 333-283841 and 333-289854) of the report dated March 16, 2026 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, 2025 (collectively referred to as, "Audit Report on the 2025 Form 10-K") and inclusion therein of the Audit Report on the 2024 Form 10-K filed March 14, 2025 with the Securities Exchange Commission.

/s/ Cherry Bekaert, LLP.

Tampa, Florida

March 16, 2026

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 16, 2026

By: */s/ Janet Huffman*
Janet Huffman
Chief Executive Officer, Chief Financial 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 16, 2026

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, 2025 (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
Chief Executive Officer

Date: March 16, 2026

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, 2025 (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
Chief Financial Officer

Date: March 16, 2026