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 fiscal year ended December 31, 2024

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

For the transition period from _____ to _____

Commission file number: 000-55347

Relmada Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Nevada	**45-5401931**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

2222 Ponce de Leon Blvd., Floor 3
Coral Gables, FL 33134
(Address of principal executive offices) (Zip Code)

(786) 629 1376
(Registrant's telephone number, including area code)

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

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock ($.001 par value)	RLMD	The NASDAQ Global Select Market

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 Act. Yes ☐ No ☒

Indicate by checkmark 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 Rule 12b-2 of the Act). Yes ☐ No ☒

As of June 30, 2024 (the last business day of the registrant's most recently completed second fiscal quarter), the aggregate market value of the registrant's common stock held by non-affiliates of the registrant was $89,007,030, based on the closing price on that date as reported on the NASDAQ.

As of March 25, 2025, there were 33,191,622 shares of common stock, $0.001 par value per share, outstanding.

Documents Incorporated by Reference

Portions of the registrant's definitive proxy statement for its 2025 Annual Meeting of Stockholders (the "Proxy Statement"), to be filed within 120 days of the

registrant's fiscal year ended December 31, 2024, are incorporated by reference in Part III of this Annual Report on Form 10-K. Except with respect to information specifically incorporated by reference in this Annual Report on Form 10-K, the Proxy Statement is not deemed to be filed as part of this Annual Report on Form 10-K.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (this "Annual Report") contains forward looking statements that involve risks and uncertainties, principally in the sections entitled "Description of Business," "Risk Factors," and "Management's Discussion and Analysis of Financial Condition and Results of Operations." All statements other than statements of historical fact contained in this Report, including statements regarding future events, our future financial performance, business strategy and plans and objectives of management for future operations, are forward-looking statements. We have attempted to identify forward-looking statements by terminology including "anticipates," "believes," "can," "continue," "could," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "should," or "will" or the negative of these terms or other comparable terminology. Although we do not make forward-looking statements unless we believe we have a reasonable basis for doing so, we cannot guarantee their accuracy. These statements are only predictions and involve known and unknown risks, uncertainties and other factors, including the risks outlined under "Risk Factors" or elsewhere in this Report, which may cause our or our industry's actual results, levels of activity, performance or achievements to differ materially from those expressed or implied by these forward-looking statements. Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time and it is not possible for us to predict all risk factors, nor can we address the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause our actual results to differ materially from those contained in any forward-looking statements. All forward-looking statements included in this document are based on information available to us on the date hereof, and we assume no obligation to update any such forward-looking statements.

You should not place undue reliance on any forward-looking statement, each of which applies only as of the date of this Annual Report. Before you invest in our securities, you should be aware that the occurrence of the events described in the section entitled "Risk Factors" and elsewhere in this Annual Report could negatively affect our business, operating results, financial condition and stock price. Except as required by law, we undertake no obligation to update or revise publicly any of the forward-looking statements after the date of this Annual Report on Form-10-K to conform our statements to actual results or changed expectations.

PART I

All brand names or trademarks appearing in this report are the property of their respective holders. Unless the context requires otherwise, references in this report to "Relmada," the "Company," "we," "us," and "our" refer to Relmada Therapeutics, Inc., a Nevada corporation.

ITEM 1. BUSINESS

Business Overview

Relmada Therapeutics, Inc. (Relmada, the Company, we or us) (a Nevada corporation), is a publicly traded, clinical-stage biotechnology company. We substantially redesigned our development programs following a comprehensive strategic review occasioned by disappointing interim analysis results in December 2024 indicating that our then lead development candidate, esmethadone (d-methadone, dextromethadone, or REL-1017) for the adjunctive treatment of Major Depressive Disorder (MDD), was unlikely to succeed in its pivotal trial. We concluded in our review that the most promising path to create shareholder value was to lever our extensive drug development expertise and clinical operations capabilities by acquiring new development candidates, while pausing further work on REL-1017. Hence we accelerated ongoing efforts to augment our development pipeline while diversifying its risk, which culminated in the recently announced licensing of NDV-01, a novel delivery formulation of a widely used chemotheraphy regimen used to treat non muscle-invasive bladder cancer (NMIBC) that is currently in Phase 2, and the acquisition of Sepranolone, a Phase 2b-ready neurosteroid with potential applications in Prader-Willi syndrome (PWS), Tourette Syndrome (TS), essential tremor and other diseases related to excessive GABAergic activity.

We also had been developing REL-P11, a modified-release formulation of psilocybin, as an investigational agent for the treatment of metabolic disease. The REL-P11 program has successfully completed a Phase 1 safety study. However, in light of an ongoing strategic review of this business opportunity, the changing regulatory landscape for psychedelics, its early stage of development and the acquisition of new, more advanced product candidates, this program has also been paused.

REL-1017 Program Updates

Since 2013, we had been developing esmethadone as our lead product candidate as an oral agent for the treatment of depression and other potential indications. In December 2024, we reported that the pre-planned interim analysis, conducted by the Independent Data Monitoring Committee (DMC), of Reliance II, our Phase 3 study of esmethadone as a potential adjunctive treatment for MDD, indicated that the study was futile and unlikely to meet the primary efficacy endpoint with statistical significance, and that we would pause the Reliance II and Relight Phase 3 studies of esmethadone.

Following this 2024 REL-1017 setback, which we believe mostly likely resulted from an overwhelming placebo response—a trend that has become more common than exceptional in central nervous system (CNS) clinical trials—the program has been paused pending a comprehensive data review, after which we will make a decision regarding the future of this program.

Strategic Business Review and New Approach

Following a comprehensive evaluation of the Company's business strategy and growth opportunities, management and the Board of Directors have implemented a revised approach aimed at maximizing shareholder value. This refined strategy remains focused on:

- Innovation – Advancing novel and differentiated therapeutic solutions
- Addressing Unmet Medical Needs – Targeting areas with significant gaps in treatment
- Large Market Opportunities – Prioritizing programs with substantial commercial potential
- Intellectual Property Protection – Strengthen and extending patent coverage to safeguard long-term value

Key Strategic Priorities

Under this updated approach, we will continue to emphasize:

- Leveraging Development Expertise – Focusing on high-value therapeutic areas while rigorously assessing development risks, market viability, and success probabilities
- Pipeline Diversification – Expanding and balancing our portfolio to mitigate risk and enhance growth potential
- Prioritizing Mid- to Late-Stage Programs – Concentrating resources on assets with clear path to commercialization
- Accelerating Market Entry – Streamline development timelines to bring therapies to patients faster
- Pursuing Cost-Effective Development Paths – Optimizing resource allocation and strategic partnerships
- Targeted Commercialization Strategy – Focusing on opportunities that require minimal sales and marketing infrastructure

This strategic framework positions the Company for long-term growth while maintaining execution and financial prudence.

Progress in Strategic Execution

We commenced a strategic review in December 2024 of our then existing development pipeline and the opportunities open to us given our core strengths in every aspect of drug development, with particular expertise in CNS. That process recently resulted in a series of transactions that have considerably expanded and strengthened Relmada's potential to create shareholder value. Over the past three months, we have successfully closed two important transactions, NDV-01 in-licensing and Sepranolone acquisition, which align with our new strategy.

On February 6, 2025, Relmada announced the acquisition from Asarina Pharma AB (Asarina) of Sepranolone, a Phase 2b ready neurosteroid being developed for the potential treatment of PWS, TS, essential tremor and other diseases related to the excessive GABAergic activity.

On March 25, 2025, Relmada announced the in-license agreement from Trigone Pharma Ltd. (Trigone) of NDV-01, a novel delivery formulation of a widely used chemotherapeutic regimen used to treat NMIBC.

Key Upcoming Anticipated Milestones

We expect multiple key milestones over the next 12 months. These include:

- NDV-01 Phase 2a data presentation at the 2025 American Urological Association Meeting – 1st Half 2025
- NDV-01 United States Investigative New Drug clearance – 2nd Half 2025
- Sepranolone – Initiation of clinical trial in PWS – Year-end 2025

Our Development Programs

Sepranolone Program

The GABAergic system is the primary inhibitory neurotransmitter pathway. It consists of two types of receptors, $GABA_A$ and GABAB. $GABA_A$ receptors are a major target for neuropsychiatric drugs, including benzodiazepines, barbituates and anesthetic agents. The GABAergic system regulates a host of physiological and neurological functions and their related moods and behaviors. The principal positive physiologic modulators of the GABAergic system are the neurotransmitter GABA (γ-aminobutyric acid) and the positive allosteric modulator Allopregnaolone. GABA generally inhibits nervous system excitability and thereby produces a calming effect that reduces anxiety and compulsive behavior, among other manifestations. While Allopregnanolone typically enhances GABA's calming effects, in some individuals it paradoxically exacerbates anxiety and compulsive behavior.

Sepranolone is a synthetic version of Isoallopregnanolone, a naturally occurring neurosteroid that counteracts the effects of Allopregnanolone. Sepranolone is designed to normalize $GABA_A$ receptor activity by targeting two specific receptor subtypes (alpha-2 and alpha-4) without directly interfering with GABA signaling, making it a novel and selective treatment approach for diseases such as PWS and TS and other disorders that feature compulsive behavior.

Data from an open-label Phase 2a randomized study demonstrated that Sepranolone has the potential to improve TS symptoms versus standard of care alone, as measured by changes in the YGTSS scoring system (the world-standard Yale Global Tic Severity Scale) compared to baseline. In the 12-week, dual-center, parallel-group study, 26 subjects were treated with Sepranolone (10 mg), administered by subcutaneous injection twice weekly in addition to standard of care (SOC) versus standard of care alone.

The Phase 2a results showed competitive tic reduction and improved quality of life while displaying no CNS off-target effects. Sepranolone not only reduced tic severity in its primary clinical endpoint as measured by YGTSS by 28% (p=0.051) – but also achieved positive results in four key secondary endpoints compared with standard of care:

- 69% greater increase of Quality of Life (using the Gilles de la Tourette Syndrome Quality of Life) total score (GTS-QOL)
- 50% greater reduction in impairment (YGTSS)
- 44% greater reduction of the premonitory urge to tic (PUTS – the Premonitory Urge to Tic scale)

Importantly, no off-target CNS effects or systemic side effects were observed in this study. Further, Sepranolone has been evaluated in multiple clinical neuro/hormonal studies involving over 335 participants and has demonstrated a favorable safety profile.

Relmada is currently evaluating the nonclinical and clinical strategy for the development of Sepranolone.

NDV-01 Program

The second program we recently in-licensed, NDV-01, is a novel intravesicular delivery technology designed for the long-acting, controlled release of gemcitabine and docetaxel. This combination therapy has gained significant interest as an alternative to Bacillus Calmette-Guérin (BCG) for treating NMIBC, especially given the global BCG shortage since 2019. Clinical studies have shown that gemcitabine and docetaxel achieve response rates and Recurrence-Free Survival comparable to or better than BCG. However, conventional administration is cumbersome, requiring sequential drug delivery over three hours, with limited tumor exposure time.

NDV-01 potentially addresses these limitations by enabling a single administration in approximately 10 minutes, delivering sustained, localized chemotherapy for up to 10 days. This extended exposure enhances the therapeutic effect while improving patient convenience. NDV-01 is currently in a Phase 2 clinical trial evaluating its safety and efficacy in patients with aggressive NMIBC.

NDV-01 is formulated as a controlled-release intravesical therapy containing gemcitabine and docetaxel. By maintaining continuous drug exposure within the bladder, NDV-01 may optimize local efficacy while minimizing systemic absorption and associated side effects. Unlike conventional intravesical instillations, which result in fluctuating drug levels, NDV-01 provides a continuous release of both agents over 10 days. This sustained delivery may improve cancer cell eradication and reduce recurrence risk while lowering the frequency of administration.

Esmethadone (d-Methadone, dextromethadone, REL-1017) as a treatment for MDD

Esmethadone's mechanism of action, as a low affinity, non-competitive NMDA channel blocker or antagonist, is fundamentally differentiated from most currently FDA-approved antidepressants, as well as all atypical antipsychotics used adjunctively with standard, FDA-approved antidepressants. Working through the same brain mechanisms as ketamine and esketamine but potentially lacking their adverse side effects, esmethadone is being developed as a rapidly acting, oral agent for the treatment of depression and potentially other CNS conditions.

Relmada has paused this program pending a comprehensive data review, after which a decision regarding the future of this program will be made.

Esmethadone (d-methadone, dextromethadone, REL-1017) in other indications

While our strategy was to focus on the development of esmethadone as an adjunctive treatment for MDD, we are also evaluating other indications that Relmada may explore in the future, including restless leg syndrome and other glutamatergic system activation related diseases.

Psilocybin Program

Relmada acquired the development and commercial rights to a novel psilocybin and derivative program from Arbormentis LLC in July of 2021. The original focus of the program was limited to neurodegenerative diseases. Psilocybin has neuroplastogen™ effects that have the potential to ameliorate the consequences of multiple neurodegenerative conditions. The pleiotropic metabolic effects of low-dose psilocybin were discovered while studying its neuroplastogen™ potential in a rodent model deficient in neurogenesis – obese rodents maintained on a high fructose, high fat diet (HFHFD). Specifically, in a rodent model of metabolic dysfunction-associated steatotic liver disease (MASLD), beneficial effects of psilocybin were observed on multiple metabolic parameters, including reduced hepatic steatosis, reduced body weight gain, and fasting blood glucose levels.

Relmada has paused this program in light of an ongoing strategic review of this business opportunity, the changing regulatory landscape for psychedelics, its early stage of development and the acquisition of new, more advanced product candidates.

Our Corporate History and Background

We are a clinical-stage, publicly traded biotechnology company developing NCEs and novel versions of drug products that potentially address areas of high unmet medical need in the treatment of cancer, neurological disorders, depression and other diseases.

Currently, none of our product candidates has been approved for sale in the United States or elsewhere. We have no commercial products, nor do we have a sales or marketing infrastructure. In order to market and sell our products we must conduct clinical trials on patients and obtain regulatory approvals from appropriate regulatory agencies, like the FDA in the United States, and similar organizations elsewhere in the world.

We have not generated revenues and do not anticipate generating revenues for the foreseeable future. We had net loss of approximately $79,979,400 and $98,791,700 for the years ended December 31, 2024 and 2023, respectively. As of December 31, 2024, we had an accumulated deficit of approximately $640,882,000.

Business Strategy

Our strategy is to leverage our considerable industry experience, understanding of pharmaceutical markets and development expertise to identify, develop and commercialize product candidates with significant market potential that can fulfill unmet medical needs. We have assembled a management team along with both scientific advisors and business advisors with significant industry and regulatory experience to lead and execute the development and commercialization of our product candidates.

Intellectual Property Portfolio and Market Exclusivity

We have more than 40 issued patents and pending patent applications related to Sepranolone for multiple uses, including diseases and disorders exhibiting compulsive behaviors such as PWS, TS, obsessive-compulsive disorder, and gambling disorder, potentially providing coverage beyond 2030.

We have more than 10 issued patents and pending patent applications related to NDV-01 for multiple uses, including formulations and methods for controlled release of therapeutics for treatment of diseases such as bladder cancer, potentially providing coverage beyond 2038.

We have more than 50 issued patents and pending patent applications related to REL-1017 for multiple uses, including psychological and neurological conditions, potentially providing coverage beyond 2033. We have also secured an Orphan Drug Designation from the FDA for d-methadone for “the treatment of postherpetic neuralgia” (postherpetic neuralgia is lasting pain in areas of skin affected by previous outbreaks of shingles, caused by the varicella-zoster, or herpes zoster, virus) which, upon potential NDA approval, carries 7-year FDA Orphan Drug marketing exclusivity. In the European Union, some of our prospective products may be eligible up to 10 years of market exclusivity, which includes 8 years data exclusivity and 2 years market exclusivity. In addition to any granted patents, REL-1017 will be eligible for market exclusivity to run concurrently with the term of the patent for 5 years in the U.S. (Hatch Waxman Act) and may be eligible for an additional 6 months of pediatric exclusivity and up to 10 years of exclusivity in the European Union.

We believe an extensive intellectual property estate of US and foreign patents and applications, once approved, will protect our technology and products.

Esmethadone License Agreement

As a result of a prior acquisition, the Company assumed an obligation to pay third parties (Dr. Charles E. Inturrisi and Dr. Paolo Manfredi – see below): (A) royalty payments up to 2% on net sales of licensed products that are not sold by sublicensee and (B) on each and every sublicense earned royalty payment received by licensee from its sublicensee on sales of license product by sublicensee, the higher of (i) 20% of the royalties received by licensee; or (ii) up to 2% of net sales of sublicensee. The Company will also make milestone payments of up to $4 or $2 million, for the first commercial sale of product in the field that has a single active pharmaceutical ingredient, and for the first commercial sale of product in the field of product that has more than one active pharmaceutical ingredient, respectively. As of December 31, 2024, the Company has not generated any revenue related to this license agreement.

Sepranolone Acquisition

On February 3, 2025, we entered into an Asset Purchase Agreement with Asarina, a Swedish corporation, pursuant to which we purchased, subject to the terms and conditions set forth therein, from Asarina all right, title, and interest in Sepranolone. The total purchase price was €3,000,000. The Company paid Asarina $2,756,000 on February 5, 2025, which includes a credit of $250,000 for a previous payment made by the Company to Asarina pursuant to an exclusivity agreement in October 2024.

We will only assume liabilities arising after the effective date of the Purchase Agreement. All other liabilities, including those arising before the effective date of the Purchase Agreement, taxes, employment-related liabilities, and those related to the negotiation and consummation of the Purchase Agreement, will remain with Asarina.

NDV-01 In-License Agreement

On March 24, 2025, we entered into an Exclusive License Agreement with Trigone, an Israeli company. The license agreement is for Trigone's NDV-01 product, which is a novel, sustained-release, intravesical gemcitabine/docetaxel, ready-for-use product candidate for the treatment of NMIBC. Under the terms of the agreement, the Company made a $3,500,000 upfront payment on March 25, 2025, and issued 3,017,420 shares of common stock, which represent 10% of the Company's outstanding shares, for exclusive worldwide rights to NDV-01, excluding Israel, India and South Africa.

In addition, the Company will pay up to $200 million in development, regulatory and sales milestones pending successful commercialization. The Company will also pay a royalty of 3% on any net sales. Following the completion of the ongoing Phase 2 study, the Company will assume responsibility for NDV-01's development, manufacturing and commercialization.

Inturrisi / Manfredi

In January 2018, the Company entered into an Intellectual Property Assignment Agreement (the Assignment Agreement) and License Agreement (the License Agreement and together with the Assignment Agreement, the Agreements) with Dr. Charles E. Inturrisi and Dr. Paolo Manfredi (collectively, the Licensor). Pursuant to the Agreements, Relmada assigned its existing rights, including patents and patent applications, to esmethadone in the context of psychiatric use (the Existing Invention) to Licensor. Licensor then granted Relmada under the License Agreement a perpetual, worldwide, and exclusive license to commercialize the Existing Invention and certain further inventions regarding esmethadone, in the context of other indications such as those contemplated above. In consideration of the rights granted to Relmada under the License Agreement, Relmada paid the Licensor an upfront, non-refundable license fee of $180,000. Additionally, Relmada will pay Licensor $45,000 every three months until the earliest to occur of the following events: (i) the first commercial sale of a licensed product anywhere in the world, (ii) the expiration or invalidation of the last to expire or be invalidated of the patent rights anywhere in the world, or (iii) the termination of the License Agreement. Relmada will also pay Licensor tiered royalties with a maximum rate of 2%, decreasing to 1.75%, and 1.5% in certain circumstances, on net sales of licensed products covered under the License Agreement. Relmada will also pay Licensor tiered payments up to a maximum of 20%, and decreasing to 17.5%, and 15% in certain circumstances, of all consideration received by Relmada for sublicenses granted under the License Agreement. As of December 31, 2024, no events have occurred, and the Company continues to pay Licensor $45,000 every three months.

The License Agreement includes standard termination rights for Licensor in the event of our insolvency, challenge of the licensed patents and uncured material breach of our obligations under the License Agreement. In addition, the License Agreement contains certain "Key Man" provisions such that Licensor may terminate the License Agreement if we terminate the employment of our Chief Executive Officer, Dr Sergio Traversa, for any reason other than for specified causes determined by a majority of our Board of Directors (including fraud, gross negligence, unauthorized use of our confidential information, conduct including harassment or discrimination, breach of fiduciary duty or uncured material breach), or if we (a) substantially modify Dr. Traversa's job responsibilities or decision-making rights in connection with the development and commercialization of esmethadone, (b) remove him from the role of Chief Executive Officer other than in connection with a permitted change-of-control transaction, (c) materially reduce his compensation, or (d) assign or transfer our rights under the License Agreement or the esmethadone intellectual property without Dr. Traversa's consent, in each case (termination or the events in (a) through (d)) during the period commencing on the effective date and ending on the later of five years from the original effective date of the License Agreement or December 31, 2022. The December 2019 amendment to the License Agreement made certain clarifications to the nature of a termination for Cause, including to clarify that termination due to Dr. Traversa's death or disability does not give Licensor the right to terminate the License Agreement. On December 27, 2022, the Licensor and the Company entered into a new amendment extending the "Key Man" provision period until December 31, 2027. The License Agreement was not otherwise modified.

Psilocybin License Agreement

On July 16, 2021, the Company entered into a License Agreement with Arbormentis, LLC, a privately held Delaware limited liability company, by which the Company acquired development and commercial rights to a novel psilocybin and derivate program from Arbormentis, LLC, worldwide excluding the countries of Asia. The Company will collaborate with Arbormentis, LLC on the development of new therapies targeting neurological and psychiatric disorders, leveraging Arbormentis' understanding of neuroplasticity, and focusing on this emerging new class of drugs targeting the neuroplastogen mechanism of action. Under the terms of the License Agreement, the Company paid Arbormentis, LLC an up-front fee of $12.7 million, consisting of a mix of cash and warrants to purchase the Company's common stock, in addition to potential milestone payments totaling up to approximately $160 million related to pre-specified development and commercialization milestones. Arbormentis, LLC is also eligible to receive a low single digit percentage royalty on net sales of any commercialized therapy resulting from this agreement. The license agreement is terminable by the Company but is perpetual and not terminable by the licensor absent material breach of its terms by us.

Key Strengths

We believe that the key elements for our market success include:

- Compelling lead product opportunities in NDV-01 and Sepranolone
- Experienced management team with considerable drug development expertise
- Multiple potential bladder cancer related indications for NDV-01
- Extensive safety database for Sepranolone as well as promising signal of efficacy in Tourette Syndrome
- Substantial and growing IP portfolio for both Sepranolone and NDV-01
- Scientific support of leading experts: Our scientific advisors include clinicians and scientists who are affiliated with a number of highly regarded medical institutions.

Competition

The pharmaceutical and biotechnology industry is characterized by intense competition, rapid product development and technological change. Competition is intense among manufacturers of prescription pharmaceuticals and other product areas where we may develop and market products in the future. Most of our competitors are large, well-established pharmaceutical or healthcare companies with considerably more financial, marketing, sales and technical resources than are available to us. Additionally, many of our competitors have research and development capabilities that may allow such competitors to develop new or improved products that may compete with our products. Our products could be rendered obsolete or made uneconomical by the development of new products.

Regarding our competitive position in the industry, we currently have no products approved for sale.

Government Regulation

Government authorities in the United States, at the federal, state and local level, and in other countries and jurisdictions extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting, and import and export of pharmaceutical products. The processes for obtaining regulatory approvals in the United States and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources.

FDA Approval Process

In the United States, pharmaceutical products are subject to extensive regulation by the FDA. The Federal Food, Drug, and Cosmetic Act (FD&C 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, 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 nonclinical laboratory and animal tests, the submission to FDA of an investigational new drug application (IND) which must become effective before clinical testing may commence, and adequate and well-controlled clinical trials to establish the safety and effectiveness of the drug for each indication for which FDA approval is sought. 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.

Nonclinical 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 nonclinical tests must comply with federal regulations and requirements, including good laboratory practices. The results of nonclinical testing are submitted to 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 nonclinical 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. During this period, if FDA concludes that a deficiency exists in a clinical investigation that may be grounds for the imposition of clinical hold, FDA will usually attempt to discuss and satisfactorily resolve the matter with the IND applicant. If such resolution is not possible, FDA may issue a clinical hold order by telephone or other means of rapid communication or in writing. No more than 30 days after imposition of the clinical hold, a written explanation of the basis for the hold will be issued by FDA and sent to the applicant. The applicant must respond in writing to each deficiency before the clinical hold can be lifted. If 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 investigational new drug 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 FDA as part of the IND.

FDA may not permit a clinical trial to begin, or 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 either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. The study protocol and informed consent information for patients in clinical trials must also be submitted to an institutional review board (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 for marketing approval are typically conducted in three sequential phases, but the phases may overlap. In Phase 1, 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 of 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 drug 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 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, FDA requires two adequate and well-controlled Phase 3 clinical trials, each convincing on its own, to demonstrate the efficacy of the drug. A single Phase 3 trial with other confirmatory evidence may be sufficient in rare instances, such as (i) where the study 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 or (ii) when in conjunction with other confirmatory evidence.

After completion of the required clinical testing, an NDA is prepared and submitted to FDA. FDA approval of the NDA is required before marketing of the product may begin in the U.S. The NDA must include the results of all nonclinical, 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 submission of most NDAs is additionally subject to a substantial application user fee, and the applicant under an approved NDA is also subject to an annual program fee for each prescription product. These fees are typically increased annually. Sponsors of applications for drugs granted Orphan Drug Designation are exempt from these user fees.

FDA has 60 days from its receipt of an NDA to determine whether the application will be filed based on the agency's threshold determination that it is sufficiently complete to permit substantive review. Once the submission is filed, FDA begins an in-depth review. FDA has agreed to certain performance goals in the review of NDAs to encourage timeliness. Applications for most standard review drug products are reviewed within twelve months from submission of NDAs for new molecular entities (NMEs) and ten months from submission of NDAs for non-NMEs. Priority review can be applied to drugs that FDA determines offer major advances in treatment or provide a treatment where no adequate therapy exists. The review process for both standard and priority review may be extended by FDA for three

additional months to consider certain late-submitted information or information intended to clarify information already provided in the submission.

FDA may also refer applications for novel drug products, or drug products that present difficult questions of safety or efficacy, to an outside 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. FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations.

Before approving an NDA, FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, FDA will inspect the facility or the facilities at which the drug is manufactured. FDA will not approve the product unless compliance with current good manufacturing practices (cGMPs) is satisfactory and the NDA contains data that provide substantial evidence that the drug is safe and effective in the indication studied.

After FDA evaluates the NDA 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 FDA to reconsider the application. If, or when, those deficiencies have been addressed to FDA's satisfaction in a resubmission of the NDA, FDA will issue an approval letter. 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 approval, FDA may require a risk evaluation and mitigation strategy (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 (ETASU). ETASU can include, but are 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 NDA supplement before the change can be implemented. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and FDA uses the same procedures and actions in reviewing NDA supplements as it does in reviewing NDAs.

Fast Track Designation

FDA is required to facilitate the development, and expedite the review, of drugs that are intended for the treatment of a serious or life-threatening disease or condition for which there is no effective treatment and which demonstrate the potential to address unmet medical needs for the condition. Under the Fast Track program, the sponsor of a new drug candidate may request that FDA designate the drug candidate for a specific indication as a Fast Track drug concurrent with, or after, the submission of the IND for the drug candidate. FDA must determine if the drug candidate qualifies for Fast Track Designation within 60 days of receipt of the sponsor's request.

If a submission is granted Fast Track Designation, the sponsor may engage in more frequent interactions with FDA, and FDA may review sections of the NDA before the application is complete. This rolling review is available if the applicant provides, and FDA approves, a schedule for the submission of the remaining information and the applicant pays applicable user fees. However, FDA's time period goal for reviewing an application does not begin until the last section of the NDA is submitted. Additionally, Fast Track Designation may be withdrawn by FDA if FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

Orphan Drugs

Under the Orphan Drug Act, FDA may grant Orphan Drug Designation to drugs intended to treat a rare disease or condition – generally a disease or condition that affects fewer than 200,000 individuals in the U.S. Orphan Drug designation must be requested before submitting an NDA. After FDA grants Orphan Drug Designation, the generic identity of the drug and its potential orphan use are disclosed publicly by FDA. Orphan Drug Designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. The first NDA applicant to receive FDA approval for a particular active ingredient to treat a particular disease with FDA Orphan Drug Designation is entitled to a seven-year exclusive marketing period in the U.S. for the active ingredient in that product, for that indication. During the seven-year exclusivity period, FDA may not approve any other applications to market the same drug for the same disease, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. Orphan drug exclusivity does not prevent FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition. Among the other benefits of Orphan Drug Designation are tax credits for certain research and an exemption from the NDA application user fee.

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.

Pediatric Information

Under the Pediatric Research Equity Act (PREA), NDAs or supplements to NDAs 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. FDA may grant full or partial waivers, or deferrals, for submission of data. With certain exceptions, PREA does not apply to any drug for an indication for which orphan designation has been granted.

The Best Pharmaceuticals for Children Act (BPCA) provides NDA holders a six-month extension of any exclusivity – patent or nonpatent – for a drug if certain conditions are met. Conditions for exclusivity include FDA's determination that information relating to the use of a new drug in the pediatric population may produce health benefits in that population, 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.

Post-Approval Requirements

Once an NDA is approved, a product will be subject to certain post-approval requirements. For instance, 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. FDA also may require post-marketing testing, known as Phase 4 testing, REMS and surveillance to monitor the effects of an approved product, or 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 FDA and certain state agencies. Registration with FDA subjects entities to periodic unannounced inspections by 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.

FDA strictly regulates marketing, labeling, advertising and promotion of drugs that are placed on the market. Advertising and promotion of drugs must be in compliance with the Federal Food, Drug, and Cosmetic Act (FDCA) and its implementing regulations and only for the approved indications and in a manner consistent with the approved labeling. FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including investigation by federal and state authorities.

Generic Competition

In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent whose claims cover the applicant's 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 (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 through bioequivalence testing to be therapeutically equivalent to the listed drug. Other than the requirement for bioequivalence testing, ANDA applicants are not required to conduct, or submit results of, nonclinical 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 (a Paragraph IV certification). The ANDA applicant may also elect to submit a section viii statement certifying that its proposed ANDA label does not contain (or carve 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 or certifies that the listed patents will not be infringed by the new product, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired. If the ANDA applicant has provided a Paragraph IV certification, the NDA and patent holders may then initiate a patent infringement lawsuit in response. The filing of a patent infringement lawsuit within 45 days of the receipt of a such 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.

Exclusivity

Upon NDA approval of an NCE, which is a drug that contains no active moiety that has been approved by FDA in any other NDA, that drug receives five years of marketing exclusivity during which FDA cannot receive any ANDA seeking approval of a generic version of that drug. An ANDA may be submitted one year before NCE exclusivity expires if a Paragraph IV certification is filed. If there is no listed patent in the Orange Book, there may not be a Paragraph IV certification, and, thus, no ANDA may be filed before the expiration of the exclusivity period. Certain changes to a drug, such as the addition of a new indication to the package insert, can be the subject of a three-year period of exclusivity if the application contains reports of new clinical investigations (other than bioavailability studies) conducted or sponsored by the sponsor that were essential to approval of the application. FDA cannot approve an ANDA for a generic drug that includes the change during the period of exclusivity.

In the case of a non-racemic drug containing as an active ingredient a single enantiomer that is contained in a racemic drug approved in another NDA, such as esmethadone, the applicant for the non-racemic drug may elect, in the NDA, to have the single enantiomer not be considered the same active ingredient as that contained in the approved racemic drug and therefore eligible for NCE exclusivity, if certain conditions are met. These conditions include: (1) the single enantiomer has not been previously approved except in the approved racemic drug, (2) the NDA for the non-racemic drug includes full reports of new clinical investigations necessary for the approval of the product conducted or sponsored by the applicant and not submitted for approval of the racemic drug, and (3) the NDA for the non-racemic drug is not submitted for approval of a condition of use in a therapeutic category in which the approved racemic drug has been approved or for which any other enantiomer of the racemic drug has been approved. In addition, FDA will not approve the non-racemic drug for any condition of use in the therapeutic category in which the racemic drug has been approved for a period of 10 years after approval of the racemic drug, and the labeling of the non-racemic drug will include a statement in the indication that the non-racemic drug is not approved, and has not been shown to be safe and effective, for any condition of use of the racemic drug. The applicant for the non-racemic drug may make this election only in an application submitted before October 1, 2027.

Patent Term Extension

After NDA approval, owners of relevant drug patents may apply for up to a five-year patent extension. The allowable patent term extension is calculated as half of the drug's testing phase (the time between IND application 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 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 can 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 United States 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.

Controlled Substances

The active ingredients in esmethadone and psilocybin are regulated as controlled substances pursuant to the Comprehensive Drug Abuse Prevention and Control Act of 1970 (CSA) and regulations promulgated by the United States Drug Enforcement Administration (DEA). The CSA and its implementing regulations establish a closed chain of distribution for entities handling controlled substances. The DEA is responsible for enforcing the law and regulations that impose registration, security, inventory, recordkeeping, reporting and storage requirements on entities that manufacture, distribute, import and export, prescribe, dispense or otherwise physically handle controlled substances. The law and regulations require those individuals or entities that handle controlled substances to comply with these requirements in order to ensure legitimate use and prevent the diversion of controlled substances to illicit channels of commerce.

The CSA classifies controlled substances into one of five schedules – Schedule I, II, III, IV, or V – depending on the potential for abuse and physical or psychological dependence. Schedule I substances by definition have a high potential for abuse, have no currently accepted medical use in treatment in the U.S. and lack accepted safety for use under medical supervision. . Drugs classified as schedule I drugs may not be marketed, sold or prescribed for dispensing to patients in the U.S. Controlled substances that have a currently accepted medical use and that are otherwise approved for marketing may be listed as Schedule II, III, IV, or V substances depending on the comparative abuse potential of the drug or substance, Schedule II substances by definition are classified as having the highest potential for abuse and physical or psychological dependence, whereas Schedule V substances are classified as having the lowest relative potential for abuse and dependence. Schedule II substances are subject to the strictest regulatory requirements involving registration, storage, recordkeeping, reporting and security. Schedule II drugs are subject to manufacturing quotas and the distribution and dispensing of Schedule II drugs are more limited and tightly controlled. For example, Schedule II drug prescriptions cannot be refilled and must contain a written or electronic signature of a practitioner when presented to a pharmacy. Schedules III, IV and V controlled substances are subject to registration, recordkeeping, reporting and security requirements, but these requirements are less restrictive than Schedule II drugs.

Esmethadone is the single isomer of methadone, is currently classified as a Schedule II substance, and psilocybin is currently classified as a Schedule I substance. Any Schedule I substance, such as psilocybin, that obtains FDA-approval for marketing in the United States will need to be rescheduled from Schedule I to Schedule II-V by the DEA before it can be commercially marketed, distributed, sold, prescribed or dispensed. Rescheduling requires the FDA to provide the DEA with a scientific and medical evaluation related to the FDA approval and the FDA also must make a recommendation to the DEA on the appropriate schedule. The DEA must conduct notice and comment rulemaking to reschedule any controlled substance. Such action is subject to public comment and potential requests for an administrative hearing objecting to, or supporting, any such action. In addition, because each state has its own statutory and regulatory requirements related to controlled substances (which often mirror the federal scheduling), each state or jurisdiction must also take appropriate administrative or legislative action to reschedule a controlled substance within that state based on federal rescheduling.

Facilities that manufacture, distribute, import or export any controlled substance must register annually with the DEA. The DEA registration is specific to a particular location, activity, and controlled substance schedule. For example, separate registrations are required for importation and manufacturing activities, and the authority granted under each registration determines which schedules of controlled substances the registrant may handle. However, certain DEA registrations permit coincident activities without obtaining a separate DEA registration, such as authorizing a manufacturer to also distribute controlled substances produced by that registrant.

The CSA and DEA regulations impose certain security, recordkeeping and reporting requirements on DEA registrants. The DEA will conduct a preregistration inspection to evaluate compliance with these requirements before issuing a new registration. The DEA also conducts cyclic inspections of current manufacturers, distributors, importers, and exporters to review compliance with these requirements. The specific security requirements vary by the type of business activity and the schedule and quantity of controlled substances handled by the registrant. The most stringent requirements apply to manufacturers of Schedule I and Schedule II substances. For example, manufacturers and distributors must store Schedule I and II drugs in a secure vault with specific structural requirements. Other physical security requirements that apply to all controlled substances include safes and cages, and the use of alarm systems and surveillance cameras. DEA regulations also require that registrants restrict employee access to controlled substances. Once registered, manufacturing, distribution, exporting or importing facilities must maintain records documenting the receipt, manufacture, storage, distribution, import, or export of all controlled substances. Manufacturers and distributors must also submit regular reports to the DEA of the acquisition and distribution of Schedule I and II controlled substances, Schedule III narcotic substances, and certain other designated substances. All DEA registrants must report any controlled substance thefts or significant losses and must obtain authorization to destroy or dispose of controlled substances. In addition to maintaining an importer and/or exporter registration, importers and exporters of controlled substances must obtain a permit for every import or export of a Schedule I or II substance and a narcotic substance in Schedule III, IV and V. For all other drugs in Schedule III, IV and V, importers and exporters must submit an import or export declaration to be authorized to import or export these substances. The DEA conducts cyclic inspections to determine whether registrants are complying with these requirements.

Practitioners such as pharmacies and physicians, as well as other types of entities that handle controlled substances, such as researchers and analytical laboratories, are also subject to DEA registration, recordkeeping, reporting, and security requirements on the receipt, storage, and dispensing of controlled substances.

The CSA also requires that the DEA establish annual aggregate quotas for manufacturing of each Schedule II and some Schedule III drugs for the entire industry. In addition, DEA registered manufacturers must obtain annual individual manufacturing and procurement quotas. The DEA establishes annually an aggregate production quota for the amount of substances within Schedules I and II and certain Schedule III substances, that may be produced in the U.S. based on the DEA's estimate of the quantity needed to meet legitimate medical, scientific, research and industrial needs. The aggregate quota for each controlled substance is allocated among the various individual bulk manufacturers through an application process. Manufacturers of dosage forms are also subject to procurement quotas to obtain the bulk active pharmaceutical ingredients to make finished drugs. Manufacturers may not exceed the manufacturing or procurement quota granted in a given year. The quotas apply equally to the manufacturing of the active pharmaceutical ingredient and production of dosage forms. The DEA may adjust aggregate production quotas and individual manufacturing or procurement quotas from time to time during the year, although the DEA has substantial discretion concerning whether or not to make such adjustments.

Failure to comply with applicable DEA requirements, particularly as manifested in the loss or diversion of controlled substances, can result in an enforcement action. The DEA may seek civil penalties for recordkeeping and reporting violations, refuse to renew necessary registrations, or initiate administrative proceedings to revoke the DEA registrations. In certain circumstances, violations of the CSA and DEA regulations could lead to criminal prosecution.

The various states, commonwealths, and the District of Columbia, also have established laws to regulate controlled substances and impose similar licensing, recordkeeping, and reporting requirements on entities that manufacture, distribute, sell, dispense or prescribe controlled substances in their jurisdiction. Entities must independently comply with the various state requirements in addition to the federal controlled substance requirements.

The United States and the majority of countries are signatories to the United Nations (UN) international drug control treaties which dictate certain scheduling, licensing, restrictions and other requirements involving controlled substances. Because psilocybin is classified as a Schedule I controlled substance under the UN Convention on Psychotropic Substances, 1971 most countries maintain laws and regulations comparable to those in the United Stated related to methadone, psilocybin and other controlled substances.

Other Healthcare Laws

In the United States, biotechnology company activities are subject to regulation by various federal, state and local authorities in addition to the FDA, including but not limited to, the Centers for Medicare& Medicaid Services (CMS), other divisions of the U.S. Department of Health and Human Services (HHS) (e.g., the Office of Inspector General and the Office for Civil Rights), the U.S. Department of Justice (DOJ) and individual U.S. Attorney offices within the DOJ, and state and local governments.

The federal Anti-Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully offering, soliciting or receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid, or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers, among others, on the other. Although there are a number of statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, the exceptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. In addition, a person or entity does not need to have actual knowledge of the Anti-Kickback Statute or specific intent to violate it in order to commit a violation.

Federal civil and criminal false claims laws, including the federal civil False Claims Act, prohibit any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to have a false claim paid. This includes claims made to programs where the federal government reimburses, such as Medicare and Medicaid, as well as programs where the federal government is a direct purchaser, such as when it purchases off the Federal Supply Schedule. Recently, several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly inflating drug prices they report to pricing services, which in turn were used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws. Additionally, 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. Most states also have statutes or regulations similar to the federal Anti-Kickback Statute and civil False Claims Act, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

Other federal statutes pertaining to healthcare fraud and abuse include the civil monetary penalties statute, which prohibits, among other things, the offer or payment of remuneration to a Medicaid or Medicare beneficiary that the offeror or payor knows or should know is likely to influence the beneficiary to order a receive a reimbursable item or service from a particular supplier.

Further, pursuant to the federal Physician Payment Sunshine Act, CMS, has issued a final rule that requires manufacturers of prescription drugs to collect and report information on certain payments or transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), physician assistants, certain types of advance practice nurses and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. The reported data is made available in searchable form on a public website on an annual basis. Failure to submit required information may result in civil monetary penalties.

In addition, several states now require prescription drug companies to report certain expenses relating to the marketing and promotion of drug products and to report gifts and payments to individual healthcare practitioners in these states. Other states prohibit various marketing-related activities, such as the provision of certain kinds of gifts or meals. Still other states require the posting of information relating to clinical studies and their outcomes. Some states require the reporting of certain drug pricing information, including information pertaining to and justifying price increases and new high-cost drug introductions. In addition, certain states require pharmaceutical companies to implement compliance programs and/or marketing codes. Certain states and local jurisdictions also require the registration of pharmaceutical sales and medical representatives. Compliance with these laws is difficult and time consuming, and companies that do not comply with these state laws may face civil penalties.

Data privacy and security regulations by both the federal government and the states in which business is conducted may also be applicable. Health Insurance Portability and Accountability Act of 1996 (HIPAA), as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH), and its implementing regulations, imposes requirements relating to the privacy, security and transmission of individually identifiable health information. HIPAA prohibits, among other things, 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 of any money or property owned by or under the control of any healthcare benefit program in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to commit a violation. HIPAA requires covered entities to limit the use and disclosure of protected health information to specifically authorized situations and requires covered entities to implement security measures to protect health information that they maintain in electronic form. Among other things, HITECH made HIPAA's security standards directly applicable to business associates, independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways, may not have the same effect, and often are not preempted by HIPAA, thus complicating compliance efforts. For example, the California Consumer Privacy Act (CCPA), which went into effect on January 1, 2020, creates new data privacy obligations for covered companies and provides new privacy rights to California residents. On January 1, 2023, the California Privacy Rights Act (CPRA), which substantially amends the CCPA, went into effect. The CCPA and CPRA provide for unlimited civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. Virginia's Consumer Data Protection Act, which took effect on January 1, 2023, requires businesses subject to the legislation to conduct data protection assessments in certain circumstances and requires opt-in consent from consumers to acquire and process their sensitive personal information, which includes information revealing a consumer's physical and mental health diagnosis and genetic and biometric information that can identify a consumer. Colorado enacted the Colorado Privacy Act, and Connecticut enacted the Connecticut Data Privacy Act, each of which took effect on July 1, 2023, and Utah enacted the Consumer Privacy Act, which became effective on December 31, 2023, and each of these laws may increase the complexity, variation in requirements, restrictions, and potential legal risks.

Healthcare Reform

Healthcare reforms that have been adopted, and that may be adopted in the future, could result in further reductions in coverage and levels of reimbursement for pharmaceutical products, increases in rebates payable under U.S. government rebate programs and additional downward pressure on pharmaceutical product prices.

Healthcare reform proposals recently culminated in the enactment of the Inflation Reduction Act (IRA) in August 2022, which, among other things, allows the HHS to directly negotiate the selling price of statutorily specified number of drugs and biologics each year that CMS reimburses under Medicare Part B and Part D. The negotiated price may not exceed a statutory ceiling price. Only high-expenditure single-source drugs that have been approved for at least 7 years (11 years for biologics) can be selected by CMS for negotiation, with the negotiated price taking effect two years after the selection year. For 2026, the first year in which negotiated prices become effective, CMS selected 10 high-cost Medicare Part D products in 2023, negotiations began in 2024, and the negotiated maximum fair price for each product has been announced. CMS has selected 15 additional Medicare Part D drugs for negotiated maximum fair pricing in 2027. For 2028, an additional 15 drugs, which may be covered under either Medicare Part B or Part D, will be selected, and for 2029 and subsequent years, 20 Part B or Part D drugs will be selected. A drug or biological product that has an orphan drug designation for only one rare disease or condition will be excluded from the IRA's price negotiation requirements, but will lose that exclusion if it receives designations for more than one rare disease or condition, or if it is approved for an indication that is not within that single designated rare disease or condition, unless such additional designation or such disqualifying approvals are withdrawn by the time CMS evaluates the drug for selection for negotiation. The IRA also imposes rebates on Medicare Part D and Part B drugs whose prices have increased at a rate greater than the rate of inflation, and in November 2024, CMS finalized regulations for these inflation rebates. In addition, the IRA extends enhanced subsidies for individuals purchasing health insurance coverage in Patient Protection and Affordable Care Act (ACA) marketplaces through plan year 2025. The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. Manufacturers that fail to comply with the IRA may be subject to various penalties, including civil monetary penalties. It is unclear to what extent other statutory, regulatory, and administrative initiatives will be enacted and implemented.

Insurance Coverage and Reimbursement

Significant uncertainty exists as to the insurance coverage and reimbursement status of any products for which we may obtain regulatory approval. In the United States, sales of any product candidates for which regulatory approval for commercial sale is obtained will depend in part on the availability of coverage and adequate reimbursement from third-party payors. Third-party payors include government authorities and health programs in the United States such as Medicare and Medicaid, managed care providers, private health insurers and other organizations. These third-party payors are increasingly reducing reimbursements for medical products and services. The process for determining whether a payor will provide coverage for a drug product may be separate from the process for setting the reimbursement rate that the payor will pay for the drug product. Third-party payors may limit coverage to specific drug products on an approved list, or formulary, which might not include all of FDA-approved drugs for a particular indication. A payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Further, 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 products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

Human Capital

As of December 31, 2024, we had a total of 17 employees. We understand people are our greatest asset and that our innovation and operational excellence are ultimately noted in our human capital. Our success depends in large part on our ability to recruit, develop and retain a qualified, productive, and engaged workforce.

Total Rewards and Employee Engagement

We maintain competitive compensation and benefits package including incentive compensation tied to both company and individual performance, and retirement benefits. Our performance-based compensation strategy is designed to recognize and reward employees for their contribution to our success, and we strive to provide strong, equitable incentives for performance. Compensation is comprised of two elements: base compensation, which is determined based upon a number of factors, including size, scope and impact of the employee's role, the market value associated with the employee's role, leadership skills, length of service and individual performance; and an annual bonus, which is a cash award determined based on a combination of individual and company performance during the period to which the bonus relates. We seek to determine compensation on the basis of merit and without regard to demographic characteristics. During 2023, we employed a third-party consultant to assist us in evaluating our pay practices. In conducting this exercise, we found no meaningful difference in compensation based upon gender, race or any other defining characteristic examined.

Corporate Information

Our principal executive offices are located at 2222 Ponce de Leon Blvd., Floor 3, Coral Gables, Florida 33134 and our telephone number is (786) 629-1376. Our website address is *www.relmada.com*. The information contained in, or that can be accessed through, our website is not part of, and is not incorporated in, this Annual Report.

Available Information

Reports we file with the Securities and Exchange Commission (SEC) pursuant to the Exchange Act of 1934, as amended (the Exchange Act), including annual and quarterly reports, and other reports we file, can be inspected and copied at the public reference facilities maintained by the SEC at 100 F Street NE, Washington, D.C. 20549.

ITEM 1A. RISK FACTORS

Our business faces significant risks. You should carefully consider the risks described below, together with all of the other information included in our filings with the United States Securities and Exchange Commission (SEC) when evaluating our business. If any of the following risks actually occurs, our business, financial condition or results of operations could be materially adversely affected and the trading price of shares of our common stock could decline. The occurrence of any of the following risks could cause our actual results to differ materially from those contained in forward-looking statements we have made in this report and those we may make from time to time.

Summary of Risks

This section provides a summary of the risks that may impact our performance in the future. For details of our various risk factors and their impacts, see "Risk Factors Discussion."

Our risk factors are organized into the following categories: 1) Risks related to our business, 2) Risks related to clinical and regulatory matters, 3) Risks related to our

intellectual property, 4) Risks related to government regulations, 5) Risks related to our reliance on third parties, and 6) Risks related to ownership of our common stock.

Risks related to our business

Business risks include risks associated with our products (including as a result of pausing the development of our prior drug candidates and refocusing on new drug candidates) and regulatory approval, licensing agreements, historical losses, managing growth, and acquisitions. In general, the risks related to our business can cause variability in the future profits of the Company.

Risks related to clinical and regulatory matters

Clinical and regulatory matters include risks associated with clinical trials and the future ability to commercially market the product. In order for any of our products to be commercialized and produce future profits, successful trials need to be completed with supporting data to receive regulatory approval. Failing to complete the trial will significantly increase our cost of doing business. In addition, the active ingredient in some of our products is a controlled substance which can affect the supply available for clinical trials, as well as commercial sales. A limited supply could increase the time needed to complete clinical trials and overall costs including product liability claims. We could also face potential fines or reputational risk if we do not comply. Developments from competitors and the ability to obtain market exclusivity could also negatively impact future profits.

Risks related to our intellectual property

Our products depend upon securing and protecting critical intellectual property. Patent positions are highly uncertain and involve complex legal and factual questions. Infringing upon patents or trade secrets could force us to cease or alter our product development efforts or obtain a license to continue to develop or sale our products. These risks could not only impact the future profits of the company but also create adverse publicity for us.

Risks related to government regulations

We are required to comply with various federal and state pharmaceutical and healthcare laws and regulations, and to maintain secure systems to protect sensitive confidential information. Complying with the various regulations can increase our cost of doing business. We could also face potential fines or reputational risk if we do not comply. Litigation or investigations can increase costs, negatively affect our operating results and create adverse publicity for us.

Risks related to our reliance on third parties

The Company relies on third parties to conduct nonclinical and clinical studies, as well as to manufacture our product candidates. Third parties' failure to perform the trials as contractually required could impact our ability to obtain regulatory approval. If our third-party manufacturers fail to meet our requirements and strict regulatory requirements, our product development and commercialization efforts may be materially harmed.

Risks related to ownership of our common stock

Common stocks risks include risks associated with the limited market for our common stock, a potential issuance of a substantial number of additional shares, stock price volatility, and reporting requirements of federal securities laws. The net effect of these risks can include reductions in future profits, additional operating expenses, inability to meet liquidity needs, inability to access capital and increased cost of capital.

Risk Factors Discussion

Risks Related to Our Business

Pausing of Our Former Primary Drug Candidate May Adversely Affect Our Business and Financial Condition

We recently paused the development of our former primary drug candidate, esmethadone (d-methadone, dextromethadone, or REL-1017) as a potential treatment for major depressive disorder (MDD), which had been the cornerstone of our research and development efforts. This decision was made due to an interim analysis indicating that our Phase 3 study of esmethadone, Reliance II, was futile and unlikely to meet the primary efficacy endpoint with statistical significance. We also recently paused development of REL-P11, a modified-release formulation of psilocybin, as an investigational agent for the treatment of metabolic disease. These determinations have resulted in the loss of significant time, resources and capital invested in the development of esmethadone and REL-P11. There can be no assurance that our refocusing on new drug candidates will successfully offset these setbacks.

Our Refocusing on New Drug Candidates Involves Significant Uncertainty and Risk

We are now focusing our efforts on the development of two new drug candidates, NDV-01 and Sepranolone. These drug candidates are in early stages of development, and we have limited data regarding their safety, efficacy or commercial viability. The transition to these new candidates requires us to redirect resources, establish new research protocols and secure additional regulatory approvals, all of which may increase our operational costs and extend our development timeline. The mechanisms of action and therapeutic potential of our new drug candidates are different from those of our prior drug candidates. There is no guarantee that our experience with the prior drug candidates will translate to success with the new ones. Investors should be aware that our refocused strategy is largely untested, and we may encounter unforeseen scientific, regulatory, or market challenges that could materially impact our business prospects. If either or both new drug candidates fail to demonstrate sufficient promise in clinical trials, we may face further delays and/or an inability to sustain our operations.

Our business depends on the success of our drug candidates. If we are unable to obtain regulatory approval for and successfully commercialize our drug candidates or other future product candidates, or we experience significant delays in doing so, our business will be materially harmed.

The primary focus of our product development is NDV-01 and Sepranolone.

This may make an investment in our Company riskier than similar companies that have multiple product candidates in advanced stages of active development and that therefore may be able to better sustain a setback of a product candidate. Our operating history with our new drug candidates, NDV-01 and Sepranolone, is limited. This lack of historical data and experience makes it difficult to predict the likelihood of success in development, regulatory approval, or commercialization. Successful continued development and ultimate regulatory approval of our drug candidates is critical to the future success of our business. We have invested, and will continue to invest, a significant portion of our time and financial resources in the clinical development of our drug candidates. If we cannot successfully develop,

obtain regulatory approval for and commercialize our drug candidates, we may not be able to continue our operations. The future regulatory and commercial success of our drug candidates is subject to a number of risks, including the following:

- we may not be able to obtain adequate evidence from clinical trials to support the efficacy and safety products' respective indications;
- we may not be able to demonstrate the clinical benefits of our drug candidates for their respective indications;
- in our clinical trials for our drug candidates, enrollment may be slower than anticipated and we may need additional clinical trial sites than originally planned, which could delay our clinical trial progress;
- the results of our clinical trials may not meet the level of statistical or clinical significance required by the FDA or comparable foreign regulatory authorities for marketing approval;
- patients in our clinical trials may suffer serious adverse effects for reasons that may or may not be related to our drug candidates, which could delay or prevent further clinical development;
- the standards implemented by clinical or regulatory agencies may change at any time and we cannot be certain what efficacy endpoints the FDA or foreign clinical or regulatory agencies may require in pivotal clinical trials;
- the results of later stage clinical trials may not be as favorable as the results we have observed to date in our nonclinical studies and Phase 1 and 2 clinical trials;
- we cannot be certain of the number and type of clinical trials and nonclinical or toxicology studies that the FDA or other regulatory agencies will require in order to approve our drug candidates for their respective indications;
- we may not have sufficient financial and other resources to complete the necessary clinical trials for our drug candidates, including, but not limited to, the clinical trials needed to obtain drug approval;
- if approved, our drug candidates will likely compete with products that may reach approval prior to these products, products that are currently approved and the off-label use of currently marketed products; and
- we may not be able to obtain, maintain or enforce our patents and other intellectual property rights.

Our drug candidates and any future product candidates will be subject to rigorous and extensive clinical trials and extensive regulatory approval processes implemented by the FDA and comparable foreign regulatory authorities before obtaining marketing approval, if at all, from these regulatory authorities. The drug development and approval process is lengthy and expensive, and approval is never certain. Investigational new drugs, such as our drug candidates may not prove to be safe and effective in clinical trials. We have limited experience as a company in conducting later stage clinical trials required to obtain regulatory approval. We may be unable, if at all, to conduct future clinical trials at preferred sites, enlist clinical investigators, enroll sufficient numbers of participants or begin or successfully complete clinical trials in a timely fashion. In addition, the design of a clinical trial can determine whether its results will support approval of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. Because we have limited experience as a company designing clinical trials, we may be unable to design and execute clinical trials to support regulatory approval.

There is a high failure rate for drugs and biological products proceeding through clinical trials. Failure can occur at any time during the clinical trial process. The results of nonclinical studies and early clinical trials of our drug candidates or any future product candidate may not be predictive of the results of later-stage clinical studies or trials and the results of studies or trials in one set of patients or line of treatment may not be predictive of those obtained in another. In fact, many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late stage clinical trials even after achieving promising results in nonclinical studies and earlier stage clinical trials. In addition, data obtained from nonclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval. Owing in part to the complexity of biological pathways, our drug candidates or any future product candidate may not demonstrate in patients the biochemical and pharmacological properties we anticipate based on laboratory studies or earlier stage clinical trials, and they may interact with human biological systems or other drugs in unforeseen, ineffective or harmful ways. The number of patients exposed to product candidates and the average exposure time in the clinical development programs may be inadequate to detect rare adverse events or findings that may only be detected once a product candidate is administered to more patients and for greater periods of time. If we are unable to successfully demonstrate the safety and efficacy of our drug candidates or other future product candidates and receive the necessary regulatory approvals, our business will be materially harmed.

Even if we do receive regulatory approval to market our drug candidates or other future product candidates, any such approval may be subject to limitations on the indicated uses or patient populations for which we may market the products. Accordingly, even if we are able to obtain the requisite financing to continue to fund our development programs, we may be unable to successfully develop or commercialize our drug candidates or other future product candidates. If we or any of our future development collaborators are unable to develop, or obtain regulatory approval for, or, if approved, successfully commercialize our drug candidates or other future product candidates, we may not be able to generate sufficient revenue to continue our business.

Preliminary or top-line results may not accurately reflect the complete results of the clinical study.

Preliminary or top-line data remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary or top-line data. As a result, preliminary or top-line data should be viewed with caution until the final data are available.

Our license agreement for NDV-01 or esmethadone could terminate under certain circumstances, including if we terminate our Chief Executive Officer except for cause, and we would be unable to conduct our business as planned.

In January 2018, we entered into an Intellectual Property Assignment Agreement (the Assignment Agreement) and License Agreement (the License Agreement and together with the Assignment Agreement, the Agreements), with Dr. Charles E. Inturrisi and Dr. Paolo Manfredi (collectively, the Licensor). Pursuant to the Assignment Agreement, we assigned our existing rights, including patents and patent applications, to esmethadone in the context of psychiatric use to Licensor, and pursuant to the License Agreement, Licensor then granted us an exclusive perpetual, worldwide license under the assigned intellectual property rights as well as patents and know-how covering certain new inventions developed by Licensor and relating to esmethadone in neurological and other uses, to develop and commercialize esmethadone in all fields of use. The License Agreement also grants to us rights in all future inventions developed by Licensor, whether or not in collaboration with us that relate in any way to esmethadone or the use thereof. The License Agreement was amended in December 2019 to modify certain termination rights relating to the Chief Executive Officer, which are described further below.

If we develop any new inventions relating to esmethadone, we are required to do so in collaboration with Licensor, and to file patents covering such inventions jointly in the name of the Company and Licensor. All such future inventions or patents shall be jointly owned by us and Licensor and, will be included in and subject to the financial and other terms of the License Agreement.

The License Agreement includes standard termination rights for Licensor in the event of our insolvency, challenge of the licensed patents and uncured material breach of our obligations under the License Agreement. In addition, the License Agreement contains certain "Key Man" provisions such that the Licensor may terminate the License Agreement if we terminate the employment of our Chief Executive Officer, Mr. Sergio Traversa, for any reason other than for specified causes determined by a majority of our Board of Directors (including fraud, gross negligence, unauthorized use of our confidential information, conduct including harassment or discrimination, breach of fiduciary duty or uncured material breach), or if we (a) substantially modify Mr. Traversa's job responsibilities or decision-making rights in connection with the development and commercialization of esmethadone, (b) remove him from the role of Chief Executive Officer other than in connection with a permitted change-of-control transaction, (c) materially reduce his compensation, or (d) assign or transfer our rights under the License Agreement or the esmethadone intellectual property without Mr. Traversa's consent, in each case (termination or the events in (a) through (d) during the period commencing on the effective date and ending on the later of five years from the original effective date of the License Agreement on December 31, 2022. The December 2019 amendment to the License Agreement made certain clarifications to the nature of a termination for Cause, including to clarify that termination due to Mr. Traversa's death or disability does not give Licensor the right to terminate the License Agreement. On December 27, 2022, the Licensor and the Company entered into a new amendment extending the "Key Man" provision period until December 31, 2027. The License Agreement was not otherwise modified.

As a result of the provisions described above, we are limited in our ability to terminate, as well as to decrease the salary or authority of, our Chief Executive Officer until December 31, 2027. In addition, the agreement provides that any assignor that we assign the agreement to must agree in writing to all terms of the license, including the key man provisions, and as noted above, our Chief Executive Officer has the right to consent to any such assignment of the agreement unless previously terminated for cause or due to death. As the license agreement relates to our only product candidate currently under clinical development, these provisions may be deemed to have an anti-takeover effect and may delay, deter or prevent a tender offer or takeover attempt that a stockholder might consider to be in its best interests, including attempts that might result in a premium being paid over the market price for the shares held by stockholders. If we fail to comply with the terms of the License Agreement, our rights to those patents may be terminated, and we will be unable to conduct our business.

We May Require Substantial Additional Funding, Which May Not Be Available on Favorable Terms, or at All

The pause of our former drug candidates and the pivot to new candidates may increase our need for additional capital to fund ongoing research, clinical trials and operational expenses. There is no guarantee that we will be able to secure additional funding on acceptable terms, or at all, particularly given the perceived risk associated with our recent strategic shift. Failure to obtain sufficient capital could force us to curtail operations, delay development or seek alternative strategies, such as liquidation or bankruptcy.

We have generated no revenue from commercial sales to date and our future profitability is uncertain.

We have a limited operating history, and our business is subject to all of the risks inherent in the establishment of a new business enterprise. Our likelihood of success must be considered in light of the problems, expenses, difficulties, complications and delays frequently encountered in connection with this. Since we began our business, we have focused on research, development and clinical trials of product candidates, and have incurred significant losses since inception and generated no product revenues. If we continue to incur operating losses and fail to become a profitable company, we may be unable to continue our operations. We expect to continue to operate at a net loss for at least the next several years as we continue our research and development efforts, continue to conduct clinical trials and develop manufacturing, sales, marketing and distribution capabilities. There can be no assurance that the products under development by us will be approved for sales in the US or elsewhere. Furthermore, there can be no assurance that if such products are approved they will be successfully commercialized, and the extent of our future losses and the timing of our profitability are highly uncertain.

International commercialization of our product candidates faces significant obstacles.

We may plan to commercialize some of our products internationally through collaborative relationships with foreign partners. We have limited foreign regulatory, clinical and commercial resources. Future partners are critical to our international success. We may not be able to enter into collaboration agreements with appropriate partners for important foreign markets on acceptable terms, or at all. Future collaborations with foreign partners may not be effective or profitable for us. We will need to obtain approval from the appropriate regulatory, pricing and reimbursement authorities to market any of our proposed products internationally, and we may be unable to obtain foreign regulatory approvals. Pursuing foreign regulatory approvals will be time-consuming and expensive. The regulations can vary among countries and foreign regulatory authorities may require different or additional clinical trials than we conducted to obtain FDA approval for our product candidates. In addition, adverse clinical trial results, such as death or injury due to side effects, could jeopardize not only regulatory approval, but if approval is granted, may also lead to marketing restrictions. Our product candidates may also face foreign regulatory requirements applicable to controlled substances.

We have a history of losses and we may never achieve or sustain profitability.

We have incurred substantial losses since our inception, and we may not achieve profitability for the foreseeable future, if at all. Since inception, we have an accumulated deficit of approximately $640.8 million at December 31, 2024. The Company had cash, cash equivalents and short-term investments of approximately $44.9 million at December 31, 2024. Even if we succeed in developing and commercializing one or more of our product candidates, we expect to incur substantial net losses and negative cash flows for the foreseeable future due in part to increasing research and development expenses, including clinical trials, and increasing expenses from leasing additional facilities and hiring additional personnel. As a result, we will need to generate significant revenues in order to achieve and maintain profitability. We may not be able to generate these revenues or achieve profitability in the future. Even if we do achieve profitability, we may not be able to sustain or increase profitability.

We have a limited operating history upon which to base an investment decision.

Our limited operating history may limit your ability to evaluate our prospects due to our limited historical financial data and our unproven potential to generate profits. You should evaluate the likelihood of financial and operational success in light of the risks, uncertainties, expenses and difficulties associated with an early-stage business, many of which may be beyond our control, including:

- our potential inability to continue to undertake nonclinical studies, pharmaceutical development and clinical trials,
- our potential inability to obtain regulatory approvals, and
- our potential inability to manufacture, sell and market our products.

Our operations have been limited to organizing and staffing, on a limited basis, our company, acquiring, developing and securing our proprietary technology and undertaking nonclinical studies and clinical trials of our principal product candidates. These operations provide a limited basis for you to assess our ability to commercialize our product candidates and the advisability of investing in our common stock.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

As of December 31, 2024, we had Federal, New York State and New York City net operating loss (NOL) carryforwards of approximately $127,041,000, $1,068,000 and $1,068,000, respectively, which begin expiring in 2027, 2032 and 2032, respectively. Under U.S. federal tax legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act, or Tax Act, federal NOLs incurred in 2018 and in future years may be carried forward indefinitely, but the deductibility of such federal NOLs is limited to 80% of taxable income in the year. It is uncertain if and to what extent various states will conform to the Tax Act. Under Sections 382 and 383 of the U.S. Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change" (generally defined as a greater than 50 percentage-point cumulative change (by value) in the equity ownership of certain stockholders over a rolling three-year period), the corporation's ability to use its pre-change NOLs and other pre-change tax attributes to offset its post-change taxable income or taxes may be limited. We may also experience ownership changes as a result of stock offerings or as a result of subsequent shifts in our stock ownership, some of which are outside our control. We have not completed an analysis to determine whether any such limitations have been triggered. If any were determined to be triggered, our ability to use our current NOLs and other pre-change tax attributes to offset post-change taxable income or taxes would be subject to limitation. We will be unable to use our NOLs if we do not attain profitability sufficient to offset our available NOLs prior to their expiration.

We may not be successful in hiring and retaining key employees.

Our future operations and successes depend in large part upon the continued service of key members of our senior management team whom we are highly dependent upon to manage our business, specifically Dr. Sergio Traversa, our Chief Executive Officer and our executive team. If any terminates employment with us, such a departure would have a material adverse effect on our business.

Our future success also depends on our ability to identify, attract, hire or engage, retain and motivate other well-qualified managerial, technical, clinical and regulatory personnel. Our success depends heavily on the expertise of our management team and scientific personnel. The pivot to new drug candidates may require specialized knowledge or skills that our current team lacks. If we lose key personnel or fail to attract and retain qualified replacements, our ability to execute our revised strategy could be compromised, leading to delays or failure in our development program. We currently only have 17 full time employees and are likely to hire additional qualified personnel with expertise in nonclinical pharmacology and toxicology, pharmaceutical development, clinical research, regulatory affairs, manufacturing, sales and marketing. We compete for qualified individuals with numerous biopharmaceutical companies, universities and other research institutions. Competition for such individuals, particularly in the United States, is intense, and we may not be able to hire sufficient personnel to support our efforts. There can be no assurance that these professionals will be available in the market, or that we will be able to retain existing professionals or to meet or to continue to meet their compensation requirements. Furthermore, the cost base in relation to such compensation, which may include equity compensation, may increase significantly, which could have a material adverse effect on us. Failure to establish and maintain an effective management team and work force could adversely affect our ability to operate, grow and manage our business.

Managing our growth as we expand operations may strain our resources.

We expect to need to grow rapidly in order to support ongoing and additional, larger, and potentially international, pivotal clinical trials of our drug candidates, which will place a significant strain on our financial, managerial and operational resources. In order to achieve and manage growth effectively, we must continue to improve and expand our operational and financial management capabilities. Moreover, we will need to increase staffing and to train, motivate and manage our employees.

We may expand our business through the acquisition of rights to new drug candidates that could disrupt our business, harm our financial condition and may also dilute current stockholders' ownership interests in our company.

Our business strategy includes expanding our products and capabilities, and we may seek acquisitions of drug candidates or technologies to do so. Acquisitions involve numerous risks, including substantial cash expenditures; potentially dilutive issuance of equity securities; incurrence of debt and contingent liabilities, some of which may be difficult or impossible to identify at the time of acquisition; difficulties in assimilating the acquired technologies or the operations of the acquired companies; diverting our management's attention away from other business concerns; risks of entering markets in which we have limited or no direct experience; and the potential loss of our key employees or key employees of the acquired companies.

We cannot assure you that any acquisition will result in short-term or long-term benefits to us. We may incorrectly judge the value or worth of an acquired product, company or business. In addition, our future success would depend in part on our ability to manage the rapid growth associated with some of these acquisitions. We cannot assure you that we will be able to make the combination of our business with that of acquired products, businesses or companies work or be successful. Furthermore, the development or expansion of our business or any acquired products, business or companies may require a substantial capital investment by us. We may not have these necessary funds or they might not be available to us on acceptable terms or at all. We may also seek to raise funds by selling shares of our preferred or common stock, which could dilute each current stockholder's ownership interest in us.

Business interruptions could limit our ability to operate our business.

Our operations as well as those of our collaborators on which we depend are vulnerable to damage or interruption from computer viruses, human error, natural disasters, electrical and telecommunication failures, international acts of terror and similar events. We have not established a formal disaster recovery plan and our back-up operations and our business interruption insurance may not be adequate to compensate us for losses we may suffer. A significant business interruption could result in losses or damages incurred by us and require us to cease or curtail our operations.

There is doubt about our ability to continue as a going concern.

As of December 31, 2024, the Company had an accumulated deficit of $640,882,035. Losses have principally occurred as a result of the substantial resources required

for research and development of the Company's product candidates which included the general and administrative expenses associated with its organization and product development as well as the lack of sources of revenues until such time as the Company's products are commercialized. These factors raise substantial doubt about the Company's ability to continue as a going concern for the 12 months from the issuance date of these audited consolidated financial statements for the year ended December 31, 2024. These financial statements do not include any adjustments to reflect the possible future effect on the recoverability and classification of assets or the amounts and classifications of liabilities that may result from the outcome of these uncertainties. Management intends to pursue additional funding and implement its strategic plan to allow the opportunity for the Company to continue as a going concern. However, there cannot be any assurance that we will be successful in doing so.

Risks Related to Clinical and Regulatory Matters

If we or our potential collaborators fail to obtain the necessary regulatory approvals, or if such approvals are limited, we and our potential collaborators will not be allowed to commercialize our drug candidates, and we will not generate product revenues.

Satisfaction of all regulatory requirements for commercialization of a drug candidate typically takes many years, is dependent upon the type, complexity and novelty of the drug candidate, and requires the expenditure of substantial resources for research and development. Our research and clinical approaches may not lead to drugs that the FDA considers safe for humans and effective for indicated uses we are studying. The FDA may require studies in addition to those we are conducting, in which case we or our collaborators would have to expend additional time and resources and would likely delay the date of potentially receiving regulatory approval. The approval process may also be delayed by changes in government regulation, future legislation or administrative action or changes in FDA policy that occur prior to or during our regulatory review. Delays in obtaining regulatory approvals would:

- delay commercialization of, and product revenues from, our drug candidates; and
- diminish the competitive advantages that we may have otherwise enjoyed, which would have an adverse effect on our operating results and financial condition.

Even if we or our collaborators comply with all FDA regulatory requirements, our drug candidates may never obtain regulatory approval. If we or our collaborators fail to obtain regulatory approval for any of our drug candidates we will have fewer commercial products, if any, and corresponding lower product revenues, if any. Even if our drug candidates receive regulatory approval, such approval may involve limitations on the indications and conditions of use or marketing claims for our products. Further, later discovery of previously unknown problems or adverse events could result in additional regulatory restrictions, including withdrawal of products. The FDA may also require us or our collaborators to commit to perform lengthy Phase 4 post-approval clinical efficacy or safety studies. Our expending additional resources on such trials would have an adverse effect on our operating results and financial condition.

In jurisdictions outside the United States, we or our collaborators must receive marketing authorizations from the appropriate regulatory authorities before commercializing our drugs. Regulatory approval processes outside the United States generally include all of the aforementioned requirements and risks associated with FDA approval.

If we or our collaborators are unable to design, conduct and complete successful clinical trials, our drug candidates will not be able to receive regulatory approval.

Before obtaining regulatory approvals for the commercial sale of any of our product candidates, we must demonstrate through lengthy, complex and expensive nonclinical testing and clinical trials that the product is both safe and effective for use in each target indication.

Results from early clinical trials may not support moving a drug candidate to later-stage clinical trials. Phase 3 clinical trials may not demonstrate the safety or efficacy of our drug candidates. Success in nonclinical studies and early clinical trials does not ensure that later clinical trials will be successful. Results of later clinical trials may not replicate the results of prior clinical trials and nonclinical studies.

We or our collaborators may have to commit substantial time and additional resources to conducting further nonclinical studies and clinical trials before obtaining FDA approval for any of our drug candidates.

Clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous requirements. The clinical trial process also consumes a significant amount of time. Furthermore, if participating patients in clinical trials suffer drug-related adverse reactions during the course of such clinical trials, or if we, our collaborators or the FDA believe that participating patients are being exposed to unacceptable health risks, such clinical trials will have to be suspended or terminated. Failure can occur at any stage of the clinical trials, and we or our collaborators could encounter problems that cause abandonment or repetition of clinical trials.

We have a limited history of developing drug candidates. We do not know whether any of our ongoing or planned clinical trials will result in marketable drugs.

In addition, completion of clinical trials can be delayed by numerous factors, including:

- delays in identifying and agreeing on acceptable terms with prospective clinical trial sites;
- slower than expected rates of patient recruitment and enrollment;
- unanticipated patient dropout rates; and
- increases in time required to complete monitoring of patients during or after participation in a clinical trial.

Any of these delays could significantly impact the timing, approval and commercialization of our drug candidates and could significantly increase our overall costs of drug development.

We cannot predict whether regulatory agencies will determine that the data from our clinical trials support marketing approval.

The FDA's and other regulatory agencies' decisions to approve our product candidates will depend on our ability to demonstrate, through adequate well-controlled clinical trials, that the product candidate is effective. However, there is a possibility that our data may fail to show a statistically significant difference from the placebo control or the active control. Alternatively, there is a possibility that our data may be statistically significant, but that the actual clinical benefit of the product candidates may not be considered to be clinically significant, clinically relevant or clinically meaningful. Even if we believe that the data from our trials will support marketing approval in the United States or in Europe, we cannot predict whether the agencies will agree with our analysis and approve our applications.

Developments by competitors may establish standards of care that affect our ability to conduct our clinical trials as planned.

Changes in standards related to clinical trial design could affect our ability to design and conduct clinical trials as planned. In that case, both the cost and the amount of time required to conduct a clinical trial could increase.

Conducting clinical trials of our drug candidates or commercial sales of a drug candidate may expose us to expensive product liability claims and we may not be able to maintain product liability insurance on reasonable terms or at all.

The risk of product liability is inherent in the testing of pharmaceutical products. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit or terminate testing of one or more of our drug candidates. Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against product liability claims could prevent or inhibit the commercialization of our drug candidates. We currently carry clinical trial insurance but do not carry product liability insurance. If we successfully commercialize our drug candidates, we may face product liability claims, regardless of FDA approval for commercial manufacturing and sale. We may not be able to obtain such insurance at a reasonable cost, if at all. Even if our agreements with any current or future corporate collaborators entitle us to indemnification against product liability losses, such indemnification may not be available or adequate should any claim arise.

If our drug candidates receive regulatory approval, we and our collaborators will also be subject to ongoing FDA obligations and continued regulatory review, such as continued safety reporting requirements, and we and our collaborators may also be subject to additional FDA post-marketing obligations or new regulations, all of which may result in significant expense and limit our and our collaborators' ability to commercialize our drugs.

Any regulatory approvals that our drug candidates receive may also be subject to limitations on the indicated uses for which the drug may be marketed or contain requirements for costly post-marketing follow-up studies. In addition, if the FDA approves any of our drug candidates, the manufacturing processes, labeling, packaging, distribution, post-approval monitoring and adverse event reporting, storage, import, export, advertising, promotion and record keeping for the drug will be subject to extensive and ongoing regulatory requirements. The FDA has significant post-market authority, including the authority to require labeling changes based on new safety information and to require post-market studies or clinical trials to evaluate safety risks related to the use of a product or to require withdrawal of the product from the market. The manufacturing facilities used to manufacture our product candidates will also be subject to periodic review and inspection by the FDA and other regulatory agencies, including for continued compliance with cGMPs requirements. The discovery of any new or previously unknown problems with our third-party manufacturers, manufacturing processes or facilities may result in restrictions on the product, manufacturer or facility, including withdrawal of the product from the market. Any product promotion and advertising will also be subject to regulatory requirements and continuing regulatory review. The FDA imposes stringent restrictions on manufacturers' communications regarding use of their products. If we promote our product candidates in a manner inconsistent with FDA-approved labeling or otherwise not in compliance with FDA regulations, we may be subject to enforcement action. If we or our collaborators, manufacturers or service providers fail to comply with applicable continuing regulatory requirements in the United States or foreign jurisdictions in which we seek to market our products, we or they may be subject to, among other things, fines, warning or untitled letters, holds on clinical trials, suspension or withdrawal of regulatory approval, product recalls and seizures, administrative detention of products, refusal to permit the import or export of products, operating restrictions, injunction, civil penalties and criminal prosecution.

The FDA's policies may change and additional government regulations may be enacted that could prevent or delay regulatory approval of our drug candidates. 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.

Fast Track Designation may not lead to a faster development or regulatory review or approval process.

We have obtained Fast Track Designation for esmethadone for the adjunctive treatment of MDD. Fast Track Designation is granted if a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition. Fast Track Designation does not guarantee a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw Fast Track Designation if it believes that the designation is no longer supported by data from our clinical development program. Our esmethadone development program is currently paused and under evaluation.

Even though we have obtained orphan drug designation in the United States for esmethadone for the treatment of postherpetic neuralgia, we may not obtain or maintain orphan drug exclusivity for that product candidate, and we may not obtain orphan drug designation or exclusivity for any of our other product candidates or indications.

The FDA may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States.

Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the active ingredient is entitled to a period of marketing exclusivity, which precludes the FDA from approving another marketing application for the same active ingredient for the same disease for seven years. Orphan drug exclusivity may be lost if the FDA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

We have obtained orphan drug designation for esmethadone for the treatment of postherpetic neuralgia. If the product candidate were to obtain orphan drug exclusivity upon approval, such exclusivity would prevent the FDA from approving another application to market a drug containing the same active moiety for the same orphan indication, except in very limited circumstances, including when the FDA concludes that the later drug is safer, more effective or makes a major contribution to patient care. In addition, a designated orphan drug may not receive orphan drug exclusivity if it is approved for a use, such as MDD, that is broader than the indication for which it received orphan designation.

Even though we have received orphan drug designation for esmethadone for the treatment of postherpetic neuralgia, we may not be the first to obtain marketing approval for this active moiety for the orphan-designated indication due to the uncertainties associated with developing pharmaceutical product candidates. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties can be approved for the same condition or a drug with the same active moiety can be approved for a different indication. Orphan drug designation by the FDA neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process. In addition, even if we intend to seek orphan drug designation for other product candidates or indications, we may never receive such designations or obtain orphan drug exclusivity.

Our esmethadone development program is currently paused and under evaluation.

We may not be able to obtain marketing exclusivity under the Hatch-Waxman Amendments or equivalent regulatory data exclusivity protection in other jurisdictions for our products.

We intend to rely, in part, on Hatch-Waxman exclusivity for the commercialization of our products in the United States, if approved. The Hatch-Waxman Amendments provide marketing exclusivity to the first applicant to gain approval of an NDA under specific provisions of the FDCA. For esmethadone, which we intend to elect to have not be considered the same active ingredient as methadone and therefore an NCE, we anticipate obtaining 5-year exclusivity. If FDA were to determine that we do not meet the requirements to make the election, we may not be able to obtain 5-year exclusivity for the product. In addition, under the statute, this election currently may only be made in an NDA submitted before October 1, 2027.

There can be no assurance that European authorities will grant data exclusivity for esmethadone, because it does not contain a new active molecule. Even if European data exclusivity is granted for esmethadone, this may not protect us from direct competition. A competitor(s) with a generic version of our product may be able to obtain approval of its product during our product's period of data exclusivity, by submitting a marketing authorization application (MAA) with a less than full package of nonclinical and clinical data.

We may need to focus our future efforts in new therapeutic areas where we have little or no experience.

If our drug development efforts fail, or if the competitive landscape or investment climate for antidepressant drug development is less attractive, we may need to change the company's strategic focus to include development of our product candidates, or of newly acquired product candidates. We have very limited drug development experience in therapeutic areas other than depression and we may be unsuccessful in making this change from a depression focused company to a company with a focus in areas other areas, or a company with a focus in multiple therapeutic areas.

Some of our product candidates contain controlled substances, the supply of which may be limited by U.S. statutes and regulations, and the use of which may generate public controversy.

The active ingredients in esmethadone and psilocybin are stated in the CSA and regulations promulgated by the DEA as controlled substances. The CSA and regulations promulgated by the DEA regulate certain drug substances in Schedule I, II, III, IV or V, with Schedule I substances considered to present the highest risk of substance abuse and Schedule V substances the lowest risk. These product candidates are also subject to the CSA and DEA regulations relating to manufacturing, storage, distribution, prescribing and dispensing. Furthermore, the amount of controlled substances that can be obtained for clinical trials and commercial distribution is limited by the DEA through its quota system. Quotas may not be sufficient to complete clinical trials or meet commercial demand. There is a risk that federal statutes and DEA regulations concerning applicable quotas may interfere with the supply of the drugs used in clinical trials for our product candidates and the ability to manufacture and distribute our product candidates, if approved, in the volume needed to meet commercial demand.

Products containing controlled substances may generate public controversy. Opponents of these products may seek restrictions on marketing and withdrawal of any regulatory approvals. In addition, these opponents may seek to generate negative publicity in an effort to persuade the medical community to reject these products. Political pressures and adverse publicity could lead to delays in, and increased expenses for, and limit or restrict the introduction and marketing of our product candidates.

Failure to comply with the CSA or DEA regulations, or the cost of compliance with these regulations, may adversely affect our business.

Esmethadone and psilocybin are subject to extensive regulation by the DEA. Although esmethadone is substantially devoid of opioid activity, and psychotomimetic effects, it is currently classified as a Schedule II drug. Upon approval, the DEA may continue to designate it as a controlled substance falling under a DEA controlled substance schedule. Esmethadone is produced by separation from racemic methadone, a scheduled drug subject to extensive regulation by the DEA. Any psilocybin-containing product candidate we develop is also subject to extensive regulation by the DEA as a Schedule I substance.

The manufacture, shipment, storage, sale and use of controlled substances are highly regulated, including security, recordkeeping and reporting obligations enforced by the DEA and state authorities. Schedule I substances by definition have a high potential for abuse, have no currently "accepted medical use" in the United States, lack accepted safety for use under medical supervision, and may not be prescribed, marketed or sold in the United States. Schedule I and II substances (as well as substances defined as narcotics in any Schedule) are subject to the strictest regulatory requirements and restrictions involving registration, storage, security, recordkeeping and reporting. In particular, distribution and dispensing of Schedule II drugs are strictly controlled. For example, all Schedule II drug prescriptions cannot be refilled and must contain a written or electronic signature of a practitioner when presented to a pharmacy. This high degree of regulation can result in significant costs in order to comply with the required regulations, which may have an adverse effect on the development and commercialization of our product candidates.

The DEA limits the availability and production of all Schedule I and II and some Schedule III controlled substances, including esmethadone and psilocybin, through a quota system. The DEA requires substantial evidence and documentation of expected legitimate medical and scientific needs before granting quotas to manufacturers. In future years, we may need greater amounts of controlled substances to sustain our development program, and we will need significantly greater amounts to implement our commercialization plans if the FDA approves our proposed formulations. Any delay or refusal by the DEA in establishing the procurement quota or a reduction in our quota for scheduled controlled substances or a failure to increase it over time as we anticipate could delay or stop the clinical development or commercial sale of some of our products or product candidates. This could have a material adverse effect on our business, results of operations, financial condition and prospects.

Psilocybin is currently classified as a Schedule I drug in the United States, and any product containing this substance must be rescheduled to be marketed. There can be no assurance that the DEA will make a favorable rescheduling decision. Even assuming categorization as a Schedule II or lower controlled substance (i.e., Schedule III, IV or V) at the federal level, such substances would also require scheduling determinations under state laws and regulations.

If we determine to restart our psilocybin development program and a future psilocybin-containing drug product is approved by FDA, and if the finished dosage form of that drug is listed by the DEA as a Schedule II, III, or IV controlled substance, its manufacture, importation, exportation, domestic distribution, storage, sale, prescribing, and dispensing will continue to be subject to a significant degree of regulation by the DEA. In addition, the final scheduling process may take significantly longer than the 90-day deadline set forth in the CSA, especially if there are objections to such scheduling, thereby delaying the launch of our psilocybin-containing product candidate in the United States. Furthermore, the FDA, DEA or any comparable foreign regulatory authority could require us to generate more clinical or other data than we currently anticipate to establish whether or to what extent the substance has an abuse or misuse potential, which could increase the cost and/or delay the launch of any future psilocybin-containing product candidates. In addition, product candidates containing controlled substances are subject to regulations relating to manufacturing, storage, distribution, prescribing, and dispensing, including:

- *State-controlled substances laws.* Individual U.S. states have also established controlled substance laws and regulations. Though state-controlled substances laws often mirror federal law, because the states are separate jurisdictions, they will need to separately reschedule any future psilocybin-containing drug products we develop, if approved by FDA. State scheduling may delay commercial sale of any product for which we obtain federal regulatory approval and adverse scheduling would have a material adverse effect on the commercial attractiveness of such product. We or our vendors must also obtain separate state registrations, permits or licenses in order to be able to obtain, handle, and distribute controlled substances for clinical trials or, if approved, commercial sale, and failure to meet applicable regulatory requirements could lead to enforcement and sanctions by the states in addition to those from the DEA or otherwise arising under federal law.

- *Clinical trials.* Because we plan to conduct clinical trials of a psilocybin-containing product candidate in the United States prior to approval, each of our research sites must submit a research protocol to the DEA and obtain and maintain a DEA Schedule I researcher registration that will allow those sites to handle and dispense this product candidate and to obtain the product from our importer. If the DEA delays or denies the grant of a researcher registration or approval of the research protocol to one or more research sites, the clinical trial could be significantly delayed, and we could lose clinical trial sites. The importer for the clinical trials must also obtain a Schedule I importer registration and an import permit for each import. We do not currently conduct any manufacturing or repackaging/relabeling of either psilocybin or the psilocybin-containing product candidate in the United States.

If we determine to restart our psilocybin development program, the potential reclassification of psilocybin in the United States could create additional regulatory burdens on our operations and negatively affect our results of operations.

If we determine to restart our psilocybin development program, and if psilocybin, rather than just a specific FDA-approved formulation, is rescheduled under the CSA as a Schedule II or lower controlled substance (i.e., Schedule III, IV or V), the ability to conduct research on psilocybin would most likely be improved. However, rescheduling psilocybin may materially alter enforcement policies across many federal and state agencies, primarily FDA and DEA. FDA's responsibilities include regulating the ingredients as well as the marketing and labeling of drugs sold in interstate commerce. Because it is currently illegal under federal law to produce and sell psilocybin, and because there are no federally recognized medical uses, FDA has historically deferred enforcement related to psilocybin to the DEA. If psilocybin were to be rescheduled to a federally controlled, yet legal, substance, FDA would likely play a more active regulatory role. The DEA would continue to be active in regulating manufacturing, distribution and dispensing of such substances. The potential for multi-agency enforcement post-rescheduling, including state agencies, e.g., Boards of Pharmacy, could threaten or have a materially adverse effect on our business. In addition, if the psilocybin-containing product candidate is rescheduled as Schedule II, III, IV or V, we would also need to identify wholesale distributors with the appropriate DEA registrations and authority to distribute the psilocybin-containing product candidate. The failure to obtain, or delay in obtaining, or the loss of any of those registrations could result in increased costs to us. If the psilocybin-containing product candidate is classified as a Schedule II drug, participants in our supply chain may have to maintain enhanced security including specially constructed vaults at manufacturing and distribution facilities. The additional regulatory requirements related to ordering, storing (e.g., security) and dispensing may also discourage some pharmacies from carrying the product.

If a supplier of an active pharmaceutical ingredient (API) or a pharmaceutical excipient fails to provide us sufficient quantities, we may not be able to obtain an alternative supply on a timely or acceptable basis.

Our APIs and pharmaceutical excipients are multisource, although not all sources have an active Drug Master File (DMF) with the FDA. A DMF is a submission to the FDA used to provide confidential detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of drugs to support drug development and approval. In addition, some of the countries for our multisource APIs may not be same as our drug manufacturing locations. Thus, any disruption in supply from our preferred vendors could result in significant delays with our pharmaceutical development, clinical trials, NDA submission, NDA approval or commercial sale of the finished product due to contract delays, the need to manufacture a new batch of API, out of specification API, the need for import and export permits, and the failure of the newly sourced API to perform to the standards of the previously sourced API.

Modifications to our products, if approved, may require new NDA approvals.

After a product candidate receives FDA approval, expanded uses or uses in new indications of our products may require additional clinical trials and new regulatory approvals, including additional IND submissions before we can begin clinical development and supplemental NDA approval prior to marketing and sales. If we are required to conduct additional clinical studies, it would require additional expenditures and impact our operating results. Delays in obtaining required future approvals could adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth.

Delays in the commencement or completion of pharmaceutical development, manufacturing or clinical testing could result in increased costs to us and delay our ability to generate revenues.

We do not know whether our pharmaceutical development, manufacturing or clinical testing will be on time or be completed on schedule, if at all. For example, we may encounter delays during the manufacture of pilot scale batches including delays with our contract development or manufacturing organization, sourcing satisfactory quantities of APIs, narcotic import and export permits, sourcing of excipients, contract disputes with our third party vendors and manufacturers, or failure of the product to meet specification. Similar delays may occur a during our cGMP manufacture of the product.

The commencement and completion of clinical trials can be disrupted for a variety of reasons, including difficulties in:

- recruiting and enrolling patients to participate in a clinical trial;

- obtaining regulatory approval to commence a clinical trial;
- reaching agreement on acceptable terms with prospective clinical research organizations and trial sites;
- obtaining approval of the IRB at each site selected for participation in our clinical trials;
- manufacturing sufficient quantities of a product candidate;
- investigator fraud, including data fabrication by clinical trial personnel; and
- diversion of controlled substances by clinical trial personnel.

A clinical trial may also be suspended or terminated by us, the FDA or other regulatory authorities due to a number of factors, including:

- failure to conduct the clinical trial in accordance with regulatory requirements or in accordance with our clinical protocols;
- inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;
- unforeseen safety issues; or
- inadequate patient enrollment or lack of adequate funding to continue the clinical trial.

In addition, changes in regulatory requirements and guidance may occur and we may need to amend clinical trial protocols to reflect these changes, which could impact the cost, timing or successful completion of a clinical trial. If we experience delays in the commencement or completion of our clinical trials, the commercial prospects for our product candidates will be harmed, and our ability to generate product revenues will be delayed. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also lead to the denial of regulatory approval of a product candidate.

Conducting successful clinical studies may require the enrollment of large numbers of patients, and suitable patients may be difficult to identify and recruit.

Patient enrollment in clinical trials and completion of patient participation and follow-up depends on many factors, including the size of the patient population; the nature of the trial protocol; the attractiveness of, or the discomforts and risks associated with, the treatments received by enrolled subjects; the availability of appropriate clinical trial investigators; support staff; the number of ongoing clinical trials in the same indication that compete for the same patients; and proximity of patients to clinical sites and ability to comply with the eligibility and exclusion criteria for participation in the clinical trial and patient compliance. For example, patients may be discouraged from enrolling in our clinical trials if the trial protocol requires them to undergo extensive post-treatment procedures or follow-up to assess the safety and effectiveness of our products or if they determine that the treatments received under the trial protocols are not attractive or involve unacceptable risks or discomforts. Patients may also not participate in our clinical trials if they choose to participate in contemporaneous clinical trials of competitive products.

Adverse safety outcomes could affect our ability to conduct our clinical trials or obtain approval of our product candidates.

Serious injury or death resulting from a failure of one of our drug candidates during current or future clinical trials could result in the FDA halting or delaying our clinical trials or denying or delaying clearance or approval of a product. Even though an adverse event may not be the result of the failure of our drug candidate, FDA or an IRB could delay or halt a clinical trial for an indefinite period of time while an adverse event is reviewed, and likely would do so in the event of multiple such events. Any delay or termination of our current or future clinical trials as a result of the risks summarized above, including delays in obtaining or maintaining required approvals from IRBs, delays in patient enrollment, the failure of patients to continue to participate in a clinical trial, and delays or termination of clinical trials as a result of protocol modifications or adverse events during the trials, may cause an increase in costs and delays in the submission of any NDAs to the FDA, delay the approval and commercialization of our products or result in the failure of the clinical trial, which could adversely affect our business, operating results and prospects. Lengthy delays in the completion of clinical trials of our products would adversely affect our business and prospects and could cause us to cease operations.

On November 29, 2006, the FDA required a boxed warning to be added to the Prescribing Information related to cardiac death for racemic methadone, a parent compound to our esmethadone. Although the decision was based on case reports and not on a controlled clinical trial, as part of any future development of esmethadone, we would have to assess (and have previously assessed) the cardiac safety profile of esmethadone in any future Phase 3 clinical trials. There is no assurance that the results of any future clinical studies will demonstrate an absence of cardiac adverse events with esmethadone. An adverse safety outcome could result in a similar bolded warning on the label of esmethadone or in a decision not to approve esmethadone, either one of which could have serious consequences for our continued operation.

If approved, our drug candidates and any psilocybin-containing drug product we successfully develop may require Risk Evaluation and Mitigation Strategies (REMS).

Our drug candidates and any psilocybin-containing drug product we successfully develop, may require REMS. The REMS may include requirements for special labeling or medication guides for patients, special communication plans to health care professionals and restrictions on distribution and use. Methadone indicated as an analgesic is currently subject to a REMS that strongly encourages healthcare providers to complete a REMS-compliant education program, counsel patients and/or their caregivers on safe use, serious risks, and proper storage and disposal using the drug's Medication Guide, and consider other tools to improve patient, household, and community safety. We cannot predict the specific REMS to be required as part of the FDA's approval of any of our products. Depending on the extent of the REMS requirements, our costs to commercialize our products may increase significantly. Furthermore, controlled substances risks that are not adequately addressed through proposed REMS for our product candidates may also prevent or delay their approval for commercialization.

Our products will face significant competition in the markets for such products, and if they are unable to compete successfully, our business will suffer.

Our products candidates face, and will continue to face, intense competition from large pharmaceutical companies, specialty pharmaceutical and biotechnology companies as well as academic and research institutions. We compete in an industry that is characterized by: (i) rapid technological change, (ii) evolving industry standards, (iii) emerging competition and (iv) new product introductions. Our competitors have existing products and technologies that will compete with our products and technologies and may develop and commercialize additional products and technologies that will compete with our products and technologies. Because several competing companies and institutions have greater financial resources than us, they may be able to: (i) provide broader services and product lines, (ii) make greater investments in research and development, (R&D), and (iii) carry on larger R&D initiatives. Our competitors also have greater development capabilities than we

do and have substantially greater experience in undertaking nonclinical and clinical testing of products, obtaining regulatory approvals, and manufacturing and marketing pharmaceutical products. They also have greater name recognition and better access to customers than us. Our chief competitors include companies such as Johnson and Johnson, CG Oncology, UroGen, Soleno Therapeutics, Aardvark Therapeutics, and Protara Therapeutics, among others.

We may be exposed to liability claims associated with the use of hazardous materials and chemicals.

Our research and development activities involve the controlled use of hazardous materials and chemicals. Although we believe that our safety procedures for using, storing, handling and disposing of these materials comply with federal, state and local laws and regulations, we cannot completely eliminate the risk of accidental injury or contamination from these materials. In the event of such an accident, we could be held liable for any resulting damages and any liability could materially adversely affect our business, financial condition and results of operations. In addition, the federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous or radioactive materials and waste products may require us to incur substantial compliance costs that could materially adversely affect our business and financial condition.

We may incur substantial liabilities and may be required to limit commercialization of our products in response to product liability lawsuits.

The testing and marketing of medical products entail an inherent risk of product liability. We may be held liable if serious adverse reactions from the use of our product candidates occur. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of pharmaceutical products we develop, alone or with corporate collaborators. We currently do not carry product liability insurance. We, or any corporate collaborators, may not be able to obtain insurance at a reasonable cost, if at all. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate if any claim arises.

Risks Related to Our Intellectual Property

Our business depends upon securing and protecting critical intellectual property.

Our commercial success will depend in part on our obtaining and maintaining patent, trade secret, copyright and trademark protection of our technologies in the United States and other jurisdictions as well as successfully enforcing this intellectual property and defending this intellectual property against third-party challenges. We will only be able to protect our technologies from unauthorized use by third parties to the extent that valid and enforceable intellectual property protection, such as patents or trade secrets, cover them. In particular, we place considerable emphasis on obtaining patent and trade secret protection for significant new technologies, products and processes. Furthermore, the degree of future protection of our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. Moreover, the degree of future protection of our proprietary rights is uncertain for products that are currently in the early stages of development because we cannot predict which of these products will ultimately reach the commercial market or whether the commercial versions of these products will incorporate proprietary technologies.

Our patent position is highly uncertain and involves complex legal and factual questions.

Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents. For example, we or our licensors might not have been the first to make the inventions covered by each of our pending patent applications and issued patents; we or our licensors might not have been the first to file patent applications for these inventions; others may independently develop similar or alternative technologies or duplicate any of our technologies; it is possible that none of our pending patent applications or the pending patent applications of our licensors will result in issued patents; our issued patents and issued patents of our licensors may not provide a basis for commercially viable technologies, or may not provide us with any competitive advantages, or may be challenged and invalidated by third parties; and, we may not develop additional proprietary technologies that are patentable.

As a result, our owned and licensed patents may not be valid and we may not be able to obtain and enforce patents and to maintain trade secret protection for the full commercial extent of our technology. The extent to which we are unable to do so could materially harm our business.

Unpatented trade secrets, improvements, confidential know-how and continuing technological innovation are important to our scientific and commercial success. Although we attempt to and will continue to attempt to protect our proprietary information through reliance on trade secret laws and the use of confidentiality agreements with our corporate partners, collaborators, employees and consultants and other appropriate means, these measures may not effectively prevent disclosure of our proprietary information, and, in any event, others may develop independently, or obtain access to, the same or similar information.

Certain of our patent rights are licensed to us by third parties. If we fail to comply with the terms of these license agreements, our rights to those patents may be terminated, and we will be unable to conduct our business.

If we are found to be infringing on patents or trade secrets owned by others, we may be forced to cease or alter our product development efforts, obtain a license to continue the development or sale of our products, and/or pay damages.

Our manufacturing processes and potential products may violate proprietary rights of patents that have been or may be granted to competitors, universities or others, or the trade secrets of those persons and entities. As the pharmaceutical industry expands and more patents are issued, the risk increases that our processes and potential products may give rise to claims that they infringe the patents or trade secrets of others. These other persons could bring legal actions against us claiming damages and seeking to enjoin clinical testing, manufacturing and marketing of the affected product or process. If any of these actions are successful, in addition to any potential liability for damages, we could be required to obtain a license in order to continue to conduct clinical tests, manufacture or market the affected product or use the affected process. Required licenses may not be available on acceptable terms, if at all, and the results of litigation are uncertain. If we become involved in litigation or other proceedings, it could consume a substantial portion of our financial resources and the efforts of our personnel.

Our ability to protect and enforce our patents does not guarantee that we will secure the right to commercialize our patents.

A patent is a limited monopoly right conferred upon an inventor, and his successors in title, in return for the making and disclosing of a new and non-obvious invention. This monopoly is of limited duration but, while in force, allows the patent holder to prevent others from making and/or using his invention. While a patent gives the holder this right to exclude others, it is not a license to commercialize the invention, where other permissions may be required for permissible commercialization to occur. For example, a drug cannot be marketed without the appropriate authorization from the FDA, regardless of the existence of a patent covering the product. Further, the invention, even if patented itself, cannot be commercialized if it infringes the valid patent rights of another party.

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

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative:

- others may be able to make a product that is similar to our current and future product candidates we intend to commercialize that is not covered by the patents that we own or license and have the right to enforce;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our current and future patent applications will not lead to issued patents;
- issued patents that we own or license may not provide us with any competitive advantages, or may be held invalid or unenforceable as a result of legal challenges; and
- our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights, and then use the information learned from such activities to develop competitive products for sale in our major commercial markets; and we may not develop additional proprietary technologies that are patentable.

Risks Related to Government Regulation

We may undertake international operations, which will subject us to risks inherent with operations outside of the United States.

Although we do not have any foreign operations at this time, we intend to seek to obtain market clearances in foreign markets that we deem to generate significant opportunities. However, even with the cooperation of a commercialization partner, conducting drug development in foreign countries involves inherent risks, including, but not limited to: difficulties in staffing, funding and managing foreign operations; unexpected changes in regulatory requirements; export restrictions; tariffs and other trade barriers; difficulties in protecting, acquiring, enforcing and litigating intellectual property rights; fluctuations in currency exchange rates; and potentially adverse tax consequences.

If we were to experience any of the difficulties listed above, or any other difficulties, any international development activities and our overall financial condition may suffer and cause us to reduce or discontinue our international development and registration efforts.

We depend on our information technology systems and those of our third-party collaborators, service providers, contractors or consultants. Our internal computer systems, or those of our third-party collaborators, service providers, contractors or consultants, may fail or suffer security breaches, disruptions, or incidents, which could result in a material disruption of our development programs or loss of data or compromise the privacy, security, integrity or confidentiality of sensitive information related to our business and have a material adverse effect on our reputation, business, financial condition or results of operations.

In the ordinary course of our business, we collect, store and transmit large amounts of confidential information, including intellectual property, proprietary business information and personal information. Our internal technology systems and infrastructure, and those of our current or future third-party collaborators, service providers, contractors and consultants are vulnerable to damage from computer viruses, unauthorized access or use resulting from malware, natural disasters, terrorism, war and telecommunication and electrical failures, denial-of-service attacks, cyber-attacks or cyber-intrusions over the internet, hacking, phishing and other social engineering attacks, persons inside our organizations (including employees or contractors), loss or theft, or persons with access to systems inside our organization. Attacks on information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and they are being conducted by increasingly sophisticated and organized foreign governments, groups and individuals with a wide range of motives and expertise. In addition to extracting or accessing sensitive information, such attacks could include the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the security, confidentiality, integrity and availability of information. The prevalent use of mobile devices that access sensitive information also increases the risk of data security incidents which could lead to the loss of confidential information or other intellectual property. While to our knowledge we have not experienced any material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations or the operations of third-party collaborators, service providers, contractors and consultants, it could result in a material disruption of our development programs and significant reputational, financial, legal, regulatory, business or operational harm. The costs to us to mitigate, investigate and respond to potential security incidents, breaches, disruptions, network security problems, bugs, viruses, worms, malicious software programs and security vulnerabilities could be significant, and while we have implemented security measures to protect our data security and information technology systems, our efforts to address these problems may not be successful, and these problems could result in unexpected interruptions, delays, cessation of service and other harm to our business and our competitive position.

Failure to comply with existing or future laws and regulations related to privacy or data security could lead to government enforcement actions (which could include civil or criminal fines or penalties), private litigation, other liabilities, and/or adverse publicity. Compliance or the failure to comply with such laws could increase the costs of our products and services, could limit their use or adoption, and could otherwise negatively affect our operating results and business.

Regulation of data processing is evolving, as federal, state, and foreign governments continue to adopt new, or modify existing, laws and regulations addressing data privacy and security, and the collection, processing, storage, transfer, and use of data. We and our partners may be subject to current, new, or modified federal, state, and foreign data privacy and protection laws and regulations (e.g., laws and regulations that address data privacy and data security including, without limitation, health data). These new or proposed laws and regulations are subject to differing interpretations and may be inconsistent among jurisdictions, and guidance on implementation and compliance practices are often updated or otherwise revised, which adds to the complexity of processing personal data. These and other requirements could require us or our partners to incur additional costs to achieve compliance, limit our competitiveness, necessitate the acceptance of more onerous obligations in our contracts, restrict our ability to use, store, transfer, and process data, impact our or our partners' ability to process or use data in order to support the provision of our products or services, affect our or our partners' ability to offer our products and services in certain locations, or cause regulators to reject, limit or disrupt our clinical trial activities.

Failure to comply with U.S. and international data privacy and protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties, fines or sanctions), private litigation, and/or adverse publicity and could negatively affect our operating results and business. Moreover, patients about whom we or our partners obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations related to security or privacy, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business. Compliance with data protection laws may be time-consuming, require additional resources and could result in increased expenses, reduce overall demand for our products and services and make it more difficult to meet expectations of or commitments to customers or partners.

Our operations and relationships with future customers, providers and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to penalties including criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers and third-party payors will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our future arrangements with providers, third-party payors and customers will subject us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute any product candidates for which we obtain marketing approval.

Restrictions under applicable U.S. federal and state healthcare laws and regulations include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation;

- federal false claims laws, including the federal False Claims Act, imposes criminal and civil penalties, including through 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. In addition, the government may assert that a claim including items or services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;

- HIPAA, as amended by HITECH, imposes criminal and civil liability for, among other things, knowingly and willfully executing or attempting to execute a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- the federal Physician Payment Sunshine Act requires applicable manufacturers of covered drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to report payments and other transfers of value provided during the previous year to physicians, as defined by such law, physician assistants, certain types of advance practice nurses, and teaching hospitals, as well as certain ownership and investment interests held by such physicians and their immediate family, which includes annual data collection and reporting obligations; 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; and some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures or drug pricing.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion of product candidates from government-funded healthcare programs, such as Medicare and Medicaid, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government-funded healthcare programs.

Enacted and future legislation may affect the prices we may set. The full effect of recent United States healthcare reform and other changes in the healthcare industry, laws, and regulations and in healthcare spending is currently unknown, and the reform and other changes may adversely affect our business model.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, affect our ability to profitably sell any products for which we obtain marketing approval.

The commercial potential for our products, if any, could also be affected by changes in healthcare spending and policy in the United States and abroad. New laws, regulations, or judicial decisions or new interpretations of existing laws, regulations, or decisions, related to healthcare availability, the method of delivery, or payment for healthcare products and services could adversely affect our business, operations, and financial condition, if and when we are able to obtain marketing approval and commercialize our products. For example, the ACA was enacted in 2010 with a goal, among others, of reducing the cost of healthcare and substantially changing the way healthcare is financed by both government and private insurers. The ACA, among other things, expanded manufacturers' rebate liability under the Medicaid Drug Rebate Program, imposed a significant annual, nondeductible fee on companies that manufacture or import certain branded prescription drug products, and enacted substantial provisions affecting compliance, which may affect our business practices with healthcare practitioners.

There have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs in general and the cost of pharmaceuticals in particular. These initiatives recently culminated in the enactment of the IRA in August 2022, which, among other things, allows HHS to directly negotiate the selling price of a statutorily specified number of drugs and biologics each year that CMS reimburses under Medicare Part B and Part D. The negotiated price may not exceed a statutory ceiling price. Only high-expenditure single-source drug that have been approved for at least 7 years (11 years for single-source biologics) can be selected by CMS for negotiation, with the negotiated price taking effect two years after the selection year. For 2026, the first year in which negotiated prices become effective, CMS selected 10 high-cost Medicare Part D products in 2023, negotiations began in 2024, and the negotiated maximum fair price

for each product has been announced. CMS has selected 15 additional Medicare Part D drugs for negotiated maximum fair pricing in 2027. For 2028, an additional 15 drugs, which may be covered under either Medicare Part B or Part D, will be selected, and for 2029 and subsequent years, 20 Part B or Part D drugs will be selected. A drug or biological product that has an orphan drug designation for only one rare disease or condition will be excluded from the IRA's price negotiation requirements, but will lose that exclusion if it has designations for more than one rare disease or condition, or if is approved for an indication that is not within that single designated rare disease or condition, unless such additional designation or such disqualifying approvals are withdrawn by the time CMS evaluates the drug for selection for negotiation. The IRA also imposes rebates on Medicare Part D and Part B drugs whose prices have increased at a rate greater than the rate of inflation and in November 2024, CMS finalized regulations for these inflation rebates. In addition, the law eliminates, beginning in 2025, the coverage gap under Medicare Part D by significantly lowering the beneficiary maximum out-of-pocket cost and requiring manufacturers to subsidize, through a newly established manufacturer discount program, 10% of Part D enrollees' prescriptions costs for brand drugs below the out-of-pocket limit, and 20% once the out-of-pocket limit has been reached. The IRA also extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. Manufacturers that fail to comply with the IRA may be subject to various penalties, including civil monetary penalties. These provisions will take effect progressively starting in 2023, although they may be subject to legal challenges. For example, the provisions related to the negotiation of selling prices of high-expenditure single-source drugs and biologics have been challenged in multiple lawsuits brought by pharmaceutical manufacturers. Thus, while it is unclear how the IRA will be implemented, it will likely have a significant impact on the pharmaceutical industry.

Further, at the U.S. state level, legislatures are increasingly enacting laws and implementing regulations designed to control pharmaceutical and biological product pricing, including price or reimbursement constraints, discount requirements, marketing cost disclosure, price gouging prohibitions, and price transparency reporting. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services or otherwise negatively impact our business model.

Disruptions at the FDA, the SEC and other government agencies or comparable regulatory authorities caused by funding shortages or global health concerns, in addition to substantial uncertainty regarding the new Administration's initiatives and how these might impact the FDA, its implementation of laws, regulations, policies and guidance, and its personnel, could hinder government agencies' ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner, or otherwise prevent those agencies from performing normal business functions on which our business operations rely, including timely reviews, which could negatively impact our business.

The ability of the FDA or comparable foreign regulatory authorities to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes that may otherwise affect the FDA's or comparable foreign regulatory authorities' ability to perform routine functions. In addition, government funding of the SEC and other government agencies or comparable foreign regulatory authorities on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies, including substantial leadership, personnel, and policy changes, may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would harm our business. Changes in FDA staffing could result in delays in the FDA's responsiveness or in its ability to review submissions or applications, issue regulations or guidance, or implement or enforce regulatory requirements in a timely fashion or at all. Similar consequences would also result in the event of another significant shutdown of the federal government. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. If a prolonged government shutdown occurs, or if geopolitical or global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could materially adversely affect our business, financial condition, results of operations and prospects. Such changes could significantly impact the ability of the FDA to timely review and take action on our regulatory submissions, which could have a material adverse effect on our business. Further, in our operations as a public company, future government shutdowns or substantial leadership, personnel, and policy changes could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations. If the FDA is constrained in its ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

With the change in the U.S. Presidential Administration in 2025, there is substantial uncertainty as to whether and how the new administration will seek to modify or revise the requirements and policies of the FDA and other regulatory agencies with jurisdiction over our product candidates. This uncertainty could present new challenges and/or opportunities as we navigate development of our product candidates. Some of these efforts have manifested to date in the form of personnel measures that could impact the FDA's ability to hire and retain key personnel, which could result in delays or limitations on our ability to obtain guidance from the FDA on our product candidates in development and obtain the requisite regulatory approvals in the future. Moreover, the new Administration has proposed action to freeze or reduce the budget of the National Institutes of Health, or NIH, as related to its funding for medical research, which could decrease the ability of facilities that rely on NIH funding to enroll and conduct clinical trials or increase the costs to us of conducting clinical trials. There remains general uncertainty regarding future activities. The new Administration could issue or promulgate executive orders, regulations, policies or guidance that adversely affect us or create a more challenging or costly environment to pursue the development of new therapeutic products. Alternatively, state governments may attempt to address or react to changes at the federal level with changes to their own regulatory frameworks in a manner that is adverse to our operations. If we become negatively impacted by future governmental orders, regulations, policies or guidance as a result of the new Administration, there could be a material adverse effect on us and our business.

Risks Related to Our Reliance on Third Parties

We have no manufacturing capabilities and depend on other parties for our manufacturing operations. If these manufacturers fail to meet our requirements and strict regulatory requirements, our product development and commercialization efforts may be materially harmed.

We do not own or operate facilities for drug manufacturing, storage, distribution or quality testing. We currently rely, and may continue to rely, on third-party contract manufacturers to manufacture APIs, drug products and other components of our product candidates. Reliance on third-party manufacturers may expose us to different risks than if we were to manufacture product candidates ourselves.

The manufacturing process for a product candidate is subject to FDA and foreign regulatory authority review. We, and our suppliers and manufacturers, must meet applicable manufacturing requirements and undergo rigorous facility and process validation tests required by regulatory authorities in order to comply with regulatory standards, such as cGMPs. Securing marketing approval also requires the submission of information about the product manufacturing process to, and

inspection of manufacturing facilities by, the FDA and foreign regulatory authorities. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or comparable foreign regulatory authorities, we may not be able to rely on their manufacturing facilities for the manufacture of our product candidates. Moreover, we do not control the manufacturing process at our contract manufacturers and are completely dependent on them for compliance with current regulatory requirements. In the event that any of our manufacturers fail to comply with such requirements or to perform their obligations in relation to quality, timing or otherwise, or if our supply of components or other materials becomes limited or interrupted for other reasons, we may be forced to enter into an agreement with other third parties, which we may not be able to do on reasonable terms, if at all. In some cases, the technical skills or technology required to manufacture our product candidates may be unique or proprietary to original manufacturers and we may have difficulty transferring such to other third parties. These factors would increase our reliance on such manufacturers or require us to obtain a license from such manufacturers in order to enable us, or to have other third parties, manufacture our product candidates.

We expect to continue to rely on third-party manufacturers if we receive regulatory approval for any product candidate. To the extent that we have existing, or enter into future, manufacturing arrangements with third parties, we will depend on these third parties to perform their obligations in a timely manner consistent with contractual and regulatory requirements, including those related to quality control and assurance. Any manufacturing facilities used to produce our products will be subject to periodic review and inspection by the FDA and foreign regulatory authorities, including for continued compliance with cGMP requirements, quality control, quality assurance and corresponding maintenance of records and documents. If we are unable to obtain or maintain third-party manufacturing for product candidates, or to do so on commercially reasonable terms, we may not be able to develop and commercialize our product candidates successfully. Or a third parties' failure to execute on our manufacturing requirements, comply with cGMPs or maintain a compliance status acceptable to the FDA or foreign regulatory authorities could adversely affect our business in a number of ways, including:

- an inability to initiate or continue clinical trials of product candidates under development;
- delay in submitting regulatory applications, or receiving regulatory approvals, for product candidates;
- loss of the cooperation of existing or future collaborators;
- subjecting third-party manufacturing facilities to additional inspections by regulatory authorities;
- requirements to cease distribution or to recall batches of our product candidates; and
- in the event of approval to market and commercialize a product candidate, an inability to meet commercial demands for our products.

Our contract manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If our contract manufacturers were to encounter difficulties, our ability to provide our product candidates to patients in nonclinical and clinical trials, or to provide product for treatment of patients once approved, would be jeopardized.

We intend to rely on third parties to conduct our nonclinical studies and clinical trials. If these third parties do not perform as contractually required or otherwise expected, we may not be able to obtain regulatory approval for our product candidates.

We do not currently conduct nonclinical studies or clinical trials on our own, and instead will rely on third parties, such as contract research organizations (CROs), medical institutions, clinical investigators and contract laboratories, to assist us with our nonclinical studies and clinical trials. Accordingly, we have less control over the timing, quality and other aspects of nonclinical studies and clinical trials than if we conducted them on our own. These investigators, CROs and consultants are not our employees and we will have limited control over the amount of time and resources that they dedicate to our programs. These third parties may have contractual relationships with other entities, some of which may be our competitors, which may draw time and resources from our programs. The third parties with which we may contract might not be diligent, careful or timely in conducting our nonclinical studies or clinical trials, resulting in the nonclinical studies or clinical trials being delayed or unsuccessful.

If we cannot contract with acceptable third parties on commercially reasonable terms, or at all, or if these third parties do not carry out their contractual duties, satisfy legal and regulatory requirements for the conduct of nonclinical studies or clinical trials or meet expected deadlines, our clinical development programs could be delayed and otherwise adversely affected. In all events, we will be responsible for ensuring that each of our nonclinical studies and clinical trials are conducted in accordance with the general investigational plan and protocols for the trial as well as applicable legal and regulatory requirements. The FDA generally requires nonclinical studies to be conducted in accordance with good laboratory practices and clinical trials to be conducted in accordance with good clinical practices, including for designing, conducting, recording and reporting the results of nonclinical studies and clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of clinical trial participants are protected. Our reliance on third parties that we do not control will not relieve us of these responsibilities and requirements. Any adverse development or delay in our nonclinical studies or clinical trials as a result of our reliance on third parties could have a material and adverse effect on our business, financial condition, results of operations and prospects.

Risks Related to Ownership of Our Common Stock

There is a limited market for our common stock that may make it more difficult to dispose of your stock.

Our common stock is currently listed on the Nasdaq Global Select Market under the symbol "RLMD". There is a limited trading market for our common stock. Accordingly, there can be no assurance as to the liquidity of any markets that may develop for our common stock, the ability of holders of our common stock to sell shares of our common stock, or the prices at which holders may be able to sell their common stock.

We are not in compliance with The Nasdaq Stock Market $1.00 minimum bid price requirement and failure to maintain compliance with this standard could result in delisting and adversely affect the market price and liquidity of our common stock.

Our common stock is currently traded on The Nasdaq Global Select Market under the symbol "RLMD". If we fail to meet any of the continued listing standards of The Nasdaq Stock Market, our common stock will be delisted from The Nasdaq Global Select Market. These continued listing standards include specifically enumerated criteria, such as a $1.00 minimum closing bid price. On January 21, 2025, we received a deficiency letter from the Listing Qualifications Department (the "Staff") of The Nasdaq Stock Market advising that, for 30 consecutive business days preceding the notification letter, the Company did not meet the minimum $1.00 per share bid price requirement for continued inclusion on The Nasdaq Global Select Market. The deficiency letter does not result in the immediate delisting of our common stock from the Nasdaq Global Select Market. In accordance with Nasdaq Listing Rule 5810(c)(3)(A) (the "Compliance Period Rule"), we have been provided an initial period of 180 calendar days, or until July 21, 2025 (the "Compliance Date"), to regain compliance with the minimum bid price requirement. If, at any time before the Compliance Date, the bid price for our common stock closes at $1.00 per share or more for a minimum of 10 consecutive business days, as required by the

Compliance Period Rule, the Staff will provide written notification to us that we comply with the minimum bid price requirement, unless the Staff exercises its discretion to extend this 10-day period pursuant to Nasdaq Listing Rule 5810(c)(3)(H).

While we intend to regain compliance with the minimum bid price requirement, there can be no assurance that we will be able to maintain continued compliance with this rule or the other listing requirements of The Nasdaq Stock Market. If we were unable to meet these requirements, we would receive another delisting notice from the Nasdaq Stock Market for failure to comply with one or more of the continued listing requirements. If our common stock were to be delisted from The Nasdaq Global Select Market, trading of our common stock most likely will be conducted in the over-the-counter market on an electronic bulletin board established for unlisted securities such as the OTC Markets or in the "pink sheets." Such a downgrading in our listing market may limit our ability to make a market in our common stock and which may impact purchases or sales of our securities.

A sale of a substantial number of shares of our common stock may cause the price of the common stock to decline.

If our stockholders sell substantial amounts of our common stock in the public market, the market price of our common stock could fall. These sales also may make it more difficult for us to sell equity or equity-related securities in the future at a time and price that we deem reasonable or appropriate. Stockholders who have held their shares for at least six months are able to sell their shares pursuant to Rule 144 under the Securities Act of 1933, as amended (the Securities Act). We have registered under separate registration statements in aggregate up to 21,041,717 shares of our common stock for sale into the public market by certain selling stockholders named therein. These shares represent a large number of shares of our common stock, and if sold in the market all at once or at about the same time, could depress the market price of our common stock during the period the registration statement remains effective and could also affect our ability to raise equity capital.

We are subject to the reporting requirements of federal securities laws, which can be expensive and may divert resources from other projects, thus impairing our ability grow.

We are a public reporting company and, accordingly, subject to the information and reporting requirements of the Exchange Act and other federal securities laws, including compliance with the Sarbanes-Oxley Act of 2002 (the Sarbanes-Oxley Act). The costs of preparing and filing annual and quarterly reports, proxy statements and other information with the SEC and furnishing audited reports to stockholders cause our expenses to be higher than they would be if we remained privately held.

It may be time-consuming, difficult and costly for us to develop and implement the internal controls and reporting procedures required by the Sarbanes-Oxley Act. We may need to hire additional financial reporting, internal controls and other finance personnel in order to develop and implement appropriate internal controls and reporting procedures. If we are unable to comply with the internal controls requirements of the Sarbanes-Oxley Act, then we may not be able to obtain the independent accountant certifications required by such act, which may preclude us from keeping our filings with the SEC current.

If we fail to establish and maintain an effective system of internal control, we may not be able to report our financial results accurately or to prevent fraud. Any inability to report and file our financial results accurately and timely could harm our reputation and adversely impact the trading price of our common stock.

Effective internal control is necessary for us to provide reliable financial reports and prevent fraud. If we cannot provide reliable financial reports or prevent fraud, we may not be able to manage our business as effectively as we would if an effective control environment existed, and our business and reputation with investors may be harmed. As a result, our small size and any undiscovered current internal control deficiencies may adversely affect our financial condition, results of operation and access to capital. We have not performed an in-depth analysis to determine if historical un-discovered failures of internal controls exist and may in the future discover areas of our internal control that need improvement. In addition, as a smaller reporting company, our independent registered public accounting firm is not required to formally attest to the effectiveness of our internal control over financial reporting so long as we remain a smaller reporting company, which could increase the likelihood of undiscovered errors in our internal controls or reported financial statements as compared to issuers whose independent registered public accounting firms have provided such attestations.

Our stock price may be volatile.

The market price of our common stock is likely to be highly volatile and could fluctuate widely in price in response to various factors, many of which are beyond our control, including the following:

- changes in our industry;
- competitive pricing pressures;
- our ability to obtain working capital financing;
- additions or departures of key personnel;
- limited "public float" in the hands of a small number of persons whose sales or lack of sales could result in positive or negative pricing pressure on the market price for our common stock;
- sales of our common stock;
- our ability to execute our business plan;
- operating results that fall below expectations;
- negative or poor clinical results;
- regulatory developments;
- economic and other external factors;
- period-to-period fluctuations in our financial results; and
- inability to develop or acquire new or needed technology or products.

In addition, the securities markets have from time-to-time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. These market fluctuations may also materially and adversely affect the market price of our common stock.

Our Stock Price May Be Volatile Due to Recent Developments

The pause of our primary drug candidate and our shift to new development programs may contribute to significant volatility in the price of our common stock. Negative perceptions of our strategic pivot, combined with uncertainties surrounding the new drug candidates' potential, could lead to sharp declines in our stock price.

The Nevada Revised Statutes and our articles of incorporation and bylaws contain provisions that could discourage, delay or prevent a change in control of our Company, prevent attempts to replace or remove current management and reduce the market price of our stock.

Provisions in our articles of incorporation and bylaws may discourage, delay or prevent a merger or acquisition involving us that our stockholders may consider favorable. For example, our articles of incorporation authorize our board of directors to issue up to 200,000,000 shares of "blank check" preferred stock. As a result, without further stockholder approval, the board of directors has the authority to attach special rights, including voting and dividend rights, to this preferred stock. With these rights, preferred stockholders could make it more difficult for a third party to acquire us.

We are also subject to the anti-takeover provisions of the Nevada Revised Statutes (NRS). Depending on the number of residents in the state of Nevada who own our shares, we could be subject to the provisions of Sections 78.378 et seq. of the Nevada Revised Statutes, which, unless otherwise provided in the Company's articles of incorporation or by-laws, restricts the ability of an acquiring person to obtain a controlling interest of 20% or more of our voting shares. Our articles of incorporation and by-laws do not contain any provision which would currently keep the change of control restrictions of Section 78.378 from applying to us.

In addition, our articles of incorporation and amended and restated bylaws provide that our board of directors is classified into three classes of directors with staggered three-year terms. Only one class of directors will be elected at each annual meeting of stockholders, with the other classes continuing for the remainder of their respective three-year terms. A third party may be discouraged from making a tender offer or otherwise attempting to obtain control of us as it is more difficult and time-consuming for stockholders to replace a majority of the directors on a classified board of directors.

Our bylaws provides that a Nevada court and the federal district courts of the United States will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Pursuant to our bylaws, to the fullest extent permitted by law, and unless we consent in writing to the selection of an alternative forum, the Eighth Judicial District Court of Clark County, Nevada, is the sole and exclusive forum for any stockholder (including a beneficial owner of stock) to bring (a) any derivative action or proceeding brought in the name or right of the Company or on our behalf, (b) any action asserting a claim of, or a claim based on, breach of any fiduciary duty owed by any current or former director, officer, employee, agent or stockholder of the Company to the Company or the Company's stockholders, (c) any action arising or asserting a claim arising pursuant to any provision of NRS Chapters 78 or 92A or any provision of the articles of incorporation or our bylaws or (d) any action asserting a claim against us or any current or former director, officer, employee or stockholder (including a beneficial owner of stock) governed by the internal affairs doctrine, including, without limitation, any action to interpret, apply, enforce or determine the validity of our articles of incorporation or bylaws. By its terms, to the fullest extent permitted by law, our forum selection provision applies to actions arising under the Securities Act or Exchange Act. (However, Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder, and the Company does not intend for its exclusive forum jurisdiction provision to apply to Exchange Act claims.) These choice of forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees. If a court were to find the choice of forum provision contained in our bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 1C. CYBERSECURITY

To respond to the threat of security breaches and cyberattacks, we have developed a cybersecurity risk management program designed to identify, assess, manage, mitigate, and respond to cybersecurity threats to all information and systems owned by us. We maintain certain risk management processes intended to identify cybersecurity threats, determine their likelihood of occurring, and assess potential material impacts to our business. Based on our assessment, we implement and maintain risk management processes designed to protect the confidentiality, integrity, and availability of our information systems and the information residing therein.

Cybersecurity is reviewed as part of our overall enterprise risk management program, led by our Chief Compliance Officer (CCO), which assesses our significant enterprise risks, provides a summary of those risks and primary mitigations, identifies control improvement projects for our significant risks, and regularly reports on the progress of control improvement projects for those risks to the Audit Committee of our Board of Directors. Cybersecurity risks are reviewed by the Board of Directors, at least annually, as part of the Company's corporate risk mapping exercise.

The Company's processes are designed to identify such threats by, among other things, monitoring the threat environment using manual and automated tools, subscribing to services that identify cybersecurity threats, analyzing reports of threats, conducting scans of the threat environment, evaluating threats reported to us and conducting vulnerability assessments to identify vulnerabilities.

We rely on a multidisciplinary team (including from management and third-party service providers) to assess how identified cybersecurity threats could impact our business. These assessments may leverage, among other processes, industry tools and metrics designed to assist in the assessment of risks from such cybersecurity threats. Management also conducts periodic and on-demand assessments of our cybersecurity risks.

Our CCO, is responsible for developing and implementing the cybersecurity risk management program and reporting on cybersecurity matters to the Board.

Additionally, members of the third-party service providers have cybersecurity experience and/or certifications. We view cybersecurity as a shared responsibility across our management team and periodically perform simulations and incorporate external resources and advisors as needed. All employees are required to complete cybersecurity training at least annually and have access to more frequent cybersecurity training through online events.

The CCO is responsible for continuously monitoring and assessing the Company's cybersecurity risk management program, informing senior management regarding the prevention, detection and mitigation and remediation of cybersecurity incidents and supervising such efforts.

To operate our business, we utilize certain third-party service providers to perform a variety of functions, such as outsourced business critical functions, clinical research, professional services, SaaS platforms, cloud-based infrastructure, encryption and other functions. We have certain vendor management processes designed to help to manage cybersecurity risks associated with our use of these providers. Depending on the nature of the services provided, and the sensitivity and quantity of information processed, our vendor management process may include reviewing the cybersecurity practices of such provider, contractually imposing obligations on the provider related to the services they provide and/or the information they process, conducting security assessments, conducting on-site inspections, requiring their completion of written questionnaires regarding their services and data handling practices, and conducting periodic re-assessments during their engagement.

We have not experienced any material cybersecurity incidents in the past, and we believe no cybersecurity events have occurred that have materially affected the Company or its business strategy, results of operations or financial condition. We continue to invest in the cybersecurity of our infrastructure and the enhancement of our internal controls and processes, which are designed to help protect our systems and data, and the information they contain. We carry insurance in amounts that we believe are reasonable for our business that provides protection against potential losses arising from a cybersecurity incident. However, there is no assurance that our insurance coverage will cover or be sufficient to cover all losses or claims that may arise from a cybersecurity incident.

ITEM 2. PROPERTIES

We do not own any property.

The Company's corporate headquarters are located at 2222 Ponce de Leon Blvd., Floor 3, Coral Gables, Florida 33134.

Pursuant to a lease agreement, dated August 1, 2021, and renewed for each subsequent year after, the Company leased office space at 2222 Ponce de Leon Blvd, Floor 3, Coral Gables, FL 33134. Under the 2021 lease agreement the average monthly rent expense was approximately $11,000. For 2023, 2024 and 2025, the renewed lease agreement was for an average monthly rent expense of approximately $7,000, $7,000 and $4,100, respectively.

Beginning on January 1, 2023, the Company also leased office space at 880 Third Avenue, 12th Floor, New York, NY 10022 for approximately $15,000 per month, this lease was terminated on November 30, 2023.

Beginning on December 1, 2023, the Company leased office space at 12 E 49th Street, New York, NY 10022 for approximately $12,000 per month, that lease was terminated on May 31, 2024.

Beginning on May 29, 2024, we leased office space at 12 E 49th Street, New York, NY 10022 with monthly rent of approximately $10,500; that lease expires on May 30, 2025.

ITEM 3. LEGAL PROCEEDINGS

From time to time, the Company may become involved in lawsuits and other legal proceedings that arise in the course of business. Litigation is subject to inherent uncertainties, and it is not possible to predict the outcome of litigation with total confidence. The Company is currently not aware of any legal proceedings or potential claims against it whose outcome would be likely, individually or in the aggregate, to have a material adverse effect on the Company's business, financial condition, operating results, or cash flows.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

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

Market Information

Our common stock is listed on Nasdaq Global Select Market, under the symbol "RLMD." On January 21, 2025, we received a written notification from the Listing Qualifications Department of the Nasdaq Stock Market ("Nasdaq") notifying us that, for the 30 consecutive business days ended January 17, 2025, the Company's common stock did not maintain a minimum bid price of $1.00 per share. Nasdaq stated in its letter that in accordance with Nasdaq Listing Rule 5810(c)(3)(A), the Company has a compliance period of 180 calendar days from the date of the notice ("Compliance Period"), and that it may regain compliance if the closing bid of the Company's security is at least $1 for a minimum of ten consecutive business days during the Compliance Period, which will end on July 21, 2025. We intend to actively monitor the bid price of our common stock during the Compliance Period and to take all reasonable measures available to regain compliance with the requirements for continued listing on the Nasdaq Global Market. If we do not regain compliance with the continued listing requirements for the minimum bid price by the end of the Compliance Period, the Nasdaq Staff will provide us with written notification that the common stock is subject to delisting from the Nasdaq Global Market. Alternatively, Nasdaq Marketplace Rules may permit the Company to transfer the our common stock to the Nasdaq Capital Market prior to the Compliance Date, if the common stock satisfies the criteria for continued listing on such market. While we plan to make diligent efforts to maintain the listing of our common stock on Nasdaq, there can be no assurance that we will be able to regain or maintain compliance with the applicable continued listing standards set forth in the Nasdaq Listing Rules.

Holders

As of March 25, 2025, 33,191,202 shares of common stock were issued and outstanding, which were held by 123 holders of record. These stockholders held their stock either individually or in nominee or "street" names through various brokerage firms. There are no shares of our Class A convertible preferred stock outstanding. Our transfer agent is:

Empire Stock Transfer
1859 Whitney Mesa Drive
Henderson, NV 89014
Telephone (702) 818-5898
www.empirestock.com

Inquiries regarding stock transfers, lost certificates or address changes should be directed to the above address.

Dividends

We plan to retain any earnings for the foreseeable future for our operations. We have never paid any cash dividends on our stock and do not anticipate paying any cash dividends in the foreseeable future. Any future determination to pay cash dividends will be at the discretion of our Board of Directors and will depend on our financial condition, operating results, capital requirements and such other factors as our Board of Directors deems relevant.

Unregistered Sales of Securities

There were no unregistered sales of securities during the year ended December 31, 2024 that have not been previously reported in a Quarterly Report on Form 10-Q or in a Current Report on Form 8-K.

ITEM 6. [RESERVED]

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

The information and financial data discussed below is derived from the consolidated financial statements of Relmada for the years ended December 31, 2024 and 2023. The consolidated financial statements of Relmada were prepared and presented in accordance with generally accepted accounting principles in the United States. The information and financial data discussed below is only a summary and should be read in conjunction with the historical financial statements and related notes of Relmada contained elsewhere in this Annual Report. The consolidated financial statements contained elsewhere in this Report fully represent Relmada's financial condition and operations; however, they are not indicative of the Company's future performance. See "Cautionary Note Regarding Forward Looking Statements" above for a discussion of forward-looking statements and the significance of such statements in the context of this Annual Report.

This discussion contains forward-looking statements reflecting our current expectations that involve risks and uncertainties. Actual results may differ materially from those discussed in these forward-looking statements due to a number of factors, including those set forth in the section entitled "**Risk Factors**" and elsewhere herein. The information and financial data discussed below is only a summary and should be read in conjunction with the historical financial statements and related notes of Relmada Therapeutics, Inc. contained elsewhere in this document. Relmada's current consolidated financial position and consolidated results of operations; are not necessarily indicative of the Company's future performance. See "Cautionary Note Regarding Forward Looking Statements" above for a discussion of forward-looking statements and the significance of such statements in the context of this document.

Our Corporate History and Background

Relmada Therapeutics, Inc. (Relmada, the Company, we or us) (a Nevada corporation), is a publicly traded, clinical-stage biotechnology company. We substantially redesigned our development programs following a comprehensive strategic review occasioned by disappointing interim analysis results in December 2024 indicating that our then lead development candidate, esmethadone (d-methadone, dextromethadone, or REL-1017) for the adjunctive treatment of Major Depressive Disorder (MDD), was unlikely to succeed in its pivotal trial. We concluded in our review that the most promising path to create shareholder value was to lever our extensive drug development expertise and clinical operations capabilities by acquiring new development candidates, while pausing further work on REL-1017. Hence we accelerated ongoing efforts to augment our development pipeline while diversifying its risk, which culminated in the recently announced licensing of NDV-01, a novel delivery formulation of a widely used chemotheraphy regimen used to treat non muscle-invasive bladder cancer (NMIBC) that is currently in Phase 2, and the acquisition of Sepranolone, a Phase 2b-ready neurosteroid with potential applications in Prader-Willi syndrome (PWS), Tourette Syndrome (TS), essential tremor and other diseases related to excessive GABAergic activity.

We also had been developing REL-P11, a modified-release formulation of psilocybin, as an investigational agent for the treatment of metabolic disease. The REL-P11 program has successfully completed a Phase 1 safety study. However, in light of an ongoing strategic review of this business opportunity, the changing regulatory landscape for psychedelics, its early stage of development and the acquisition of new, more advanced product candidates, this program has also been paused.

REL-1017 Program Update

Since 2013, we had been developing esmethadone as our lead product candidate as an oral agent for the treatment of depression and other potential indications. In December 2024, we reported that the pre-planned interim analysis, conducted by the Independent Data Monitoring Committee (DMC), of Reliance II, our Phase 3 study of esmethadone as a potential adjunctive treatment for MDD, indicated that the study was futile and unlikely to meet the primary efficacy endpoint with statistical significance, and that we would pause the Reliance II and Relight Phase 3 studies of esmethadone.

Following this 2024 REL-1017 setback, which we believe most likely resulted from an overwhelming placebo response—a trend that has become more common than exceptional in central nervous system (CNS) clinical trials—the program has been paused pending a comprehensive data review, after which we will make a decision regarding the future of this program.

Strategic Business Review and New Approach

Following a comprehensive evaluation of the Company's business strategy and growth opportunities, management and the Board of Directors have implemented a revised approach aimed at maximizing shareholder value. This refined strategy remains focused on:

- Innovation – Advancing novel and differentiated therapeutic solutions
- Addressing Unmet Medical Needs – Targeting areas with significant gaps in treatment
- Large Market Opportunities – Prioritizing programs with substantial commercial potential
- Intellectual Property Protection – Strengthen and extending patent coverage to safeguard long-term value

Key Strategic Priorities

Under this updated approach, we will continue to emphasize:

- Leveraging Development Expertise – Focusing on high-value therapeutic areas while rigorously assessing development risks, market viability, and success probabilities
- Pipeline Diversification – Expanding and balancing our portfolio to mitigate risk and enhance growth potential
- Prioritizing Mid- to Late-Stage Programs – Concentrating resources on assets with clear path to commercialization
- Accelerating Market Entry – Streamline development timelines to bring therapies to patients faster
- Pursuing Cost-Effective Development Paths – Optimizing resource allocation and strategic partnerships
- Targeted Commercialization Strategy – Focusing on opportunities that require minimal sales and marketing infrastructure

This strategic framework positions the Company for long-term growth while maintaining execution and financial prudence.

Progress in Strategic Execution

We commenced a strategic review in December 2024 of our then existing development pipeline and the opportunities open to us given our core strengths in every aspect of drug development, with particular expertise in CNS. That process recently resulted in a series of transactions that have considerably expanded and strengthened Relmada's potential to create shareholder value. Over the past three months, we have successfully closed two important transactions, NDV-01 in-licensing and Sepranolone acquisition, which align with our new strategy.

On February 6, 2025, Relmada announced the acquisition from Asarina Pharma AB (Asarina) of Sepranolone, a Phase 2b ready neurosteroid being developed for the potential treatment of PWS, TS, essential tremor and other diseases related to the excessive GABAergic activity.

On March 25, 2025, Relmada announced the in-license agreement from Trigone Pharma Ltd. (Trigone) of NDV-01, a novel delivery formulation of a widely used chemotherapeutic regimen used to treat NMIBC.

We have not generated revenues and do not anticipate generating revenues for the foreseeable future. We had a net loss of approximately $79,979,400 and $98,791,700 for the years ended December 31, 2024 and 2023, respectively. At December 31, 2024, we have an accumulated deficit of approximately $640,882,000.

Results of Operations

For the Year Ended December 31, 2024 vs the Year Ended December 31, 2023

Research and Development Expense

Total research and development expense for the year ended December 31, 2024 was approximately $46,175,500, as compared to $54,807,400 for the same period of 2023, a decrease of $8,631,900. The decrease in research and development expense was primarily due to:

- Decrease in study costs of $8,667,500 associated with the completion of two Phase 3 trials and the long-term, open-label, safety study (Study 310) during 2023;
- Decrease in stock-based compensation expense of $1,286,400;
- Decrease in compensation expense of $280,700 due to lower employee-related costs;
- Increase in other research expenses of $1,248,700 primarily associated with additional consultants contracted to assist in the execution of our Phase 3 trials;
- Increase in pre-clinical and toxicology expenses of $328,900; and
- Increase in manufacturing and drug storage costs of $25,100 related to materials needed to complete the Phase 3 program.

General and Administrative Expense

Total general and administrative expense for the year ended December 31, 2024 was approximately $37,715,500, as compared to $48,894,900 for the same period of 2023, a decrease of $11,179,400. The decrease in general and administrative expenses was primarily due to:

- Decrease in stock-based compensation expense of $12,335,900 which can be attributed to two key factors. First, equity grants from four years ago have dropped off the amortization schedule, as they reached the end of their vesting period. Second, the Company granted significantly fewer options this past year due to the lack of shareholder approval to increase the 2021 Equity Incentive Plan. Without this approval, the company was unable to issue a substantial number of new stock options, further contributing to the reduction in stock-based compensation expenses for the current period. These two factors combined have led to the notable decrease in these expenses;

- Increase in other general and administrative expenses of $1,006,000 due to increases in professional fees and consulting expenses during 2024; and

- Increase in compensation expense of $150,500 due to higher employee-related costs.

Other Income, Net

Interest/investment income was approximately $3,530,000 for the year ended December 31, 2024 compared to approximately $5,151,700 for the same period of 2023, a decrease of $1,621,700. The decrease was primarily related to lower average investment balance during 2024 as compared to 2023.

Realized gain on short-term investments was approximately $374,900 compared to a realized loss of approximately $4,064,400 for the same period of 2023, an increase of $4,439,300. The increase was related to the timing of the sales of short-term investments along with market conditions.

Unrealized gain on short-term investments was approximately $6,700 compared to approximately $3,823,200 for the same period of 2023, a decrease of $3,816,500. The decrease was related to the market conditions.

Income Taxes

The Company did not provide for income taxes for the years ended December 31, 2024 and 2023, since there was a loss and a full valuation allowance against all deferred tax assets.

Net Loss

The Company recorded a net loss of approximately $79,979,400 and $98,791,700 or $2.65 and $3.28 per common share, basic and diluted, during the years ended December 31, 2024 and 2023, respectively, based on the factors described above.

Liquidity

As shown in the accompanying audited consolidated financial statements, the Company has incurred losses and negative cash flows from operations since inception and expects to incur additional losses until such time that it can generate significant revenue from the commercialization of its product candidates. During the twelve months ended December 31, 2024, the Company incurred a net loss of $79,979,354 and had negative operating cash flows of $51,755,798. Given the Company's projected operating requirements and its existing cash and cash equivalents and short-term investments, the Company is projecting insufficient liquidity to sustain its operations through one year following the date that the financial statements are issued. These conditions and events raise substantial doubt about the Company's ability to continue as a going concern.

In response to these conditions, management is currently evaluating the size and scope of any subsequent operations and clinical trials that will affect the timing to obtain the required funding of future operations. Financing strategies may include, but are not limited to, the public or private sale of equity or debt securities or from bank or other loans or through strategic collaboration and/or licensing agreements. There can be no assurances that the Company will be able to secure additional financing, or if available, that it will be sufficient to meet its needs or on favorable terms. Because management's plans have not yet been finalized and are not within the Company's control, the implementation of such plans cannot be considered probable. As a result, the Company has concluded that management's plans do not alleviate substantial doubt about the Company's ability to continue as a going concern.

Cash Flows from Operating, Investing and Financing Activities

The following table sets forth selected cash flow information for the periods indicated below:

	For the Year Ended December 31, 2024	For the Year Ended December 31, 2023
Cash used in operating activities	$ (51,755,798)	$ (51,659,206)
Cash provided by investing activities	51,561,597	50,453,332
Cash used in financing activities	(40,341)	(98,463)
Net decrease in cash and cash equivalents	$ (234,542)	$ (1,304,337)

For the year ended December 31, 2024, net cash used in operating activities was $51,755,798 primarily due to the net loss of $79,979,354. This was offset by non-cash expenses which primarily consisted of stock-based compensation of $30,184,414 and stock appreciation rights compensation of $4,467. There were realized and unrealized gains on short term investments of $374,926 and $6,735, respectively. In addition, there were decreases in operating assets and liabilities for the year ended December 31, 2024 of $1,583,664.

For the year ended December 31, 2023, net cash used in operating activities was $51,659,206 primarily due to the net loss of $98,791,746. This was offset by non-cash expenses which primarily consisted of stock-based compensation of $43,811,149. There were realized losses and unrealized gains on short term investments of $4,064,391 and $3,823,234, respectively. In addition, there were increases in operating assets and liabilities for the year ended December 31, 2023 of $3,080,234.

For the year ended December 31, 2024, net cash provided by investing activities was $51,561,597, due to $12,079,628 of purchases of short term investments offset by $63,641,225 of sales of short term investments.

For the year ended December 31, 2023, net cash provided by investing activities was $50,453,332, due to $90,463,532 of purchases of short term investments offset by $140,916,864 of sales of short term investments.

Net cash used in financing activities for the year ended December 31, 2024, was $40,341 due to proceeds from cash exercises of options of $246,747 offset by ATM reactivation fees of $287,088.

Net cash used in financing activities for the year ended December 31, 2023, was $98,463 due to ATM reactivation fees.

Effects of Inflation

Our assets are primarily monetary, consisting of cash and cash equivalents and short-term investments. Because of their liquidity, these assets are not directly affected by inflation. However, the rate of inflation affects our expenses, such as those for employee compensation and contract services, which could increase our level of expenses and the rate at which we use our resources.

Lease Obligations

The Company is obligated to pay approximately $105,000 under 2 leases for office space over the next year.

Seasonality

We do not have a seasonal business cycle.

Critical Accounting Policies and Use of Estimates

A critical accounting policy is one that is both important to the portrayal of a company's financial condition and results of operations and requires management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain.

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses for the reporting period. Management bases its estimates on historical experience and on various assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. On a continual basis, management reviews its estimates utilizing currently available information, changes in facts and circumstances, historical experience, and reasonable assumptions. After such reviews, and if deemed appropriate, managements estimates are adjusted accordingly. Actual results could differ from those estimates and assumptions under different and/or future circumstances. Management considers an accounting estimate to be critical if:

- it requires assumptions to be made that were uncertain at the time the estimate was made; and
- changes in the estimate, or the use of different estimating methods that could have been selected, could have a material impact on results of operations or financial condition.

We evaluate our estimates and assumptions on an ongoing basis and none of the Company's estimates and assumptions used within the consolidated financial statements involve a high level of estimation uncertainty. For additional discussion regarding the application of the significant accounting policies, see Note 3 to the Company's consolidated financial statements included in this report.

Recent Accounting Pronouncements

The Company lists material recent accounting pronouncements in Note 3 of the consolidated financial statements.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest rate risk

Our cash and cash equivalents include all highly liquid investments with an original maturity of three months or less. Our cash equivalents are in a money market account. Because of the short-term maturities of our cash and cash equivalents, we do not believe that an increase in market rates would have a significant impact on the realized value of our investments. We place our cash and cash equivalents on deposit with financial institutions in the United States. The Federal Deposit Insurance Corporation limits coverage for all depository accounts. Our cash and cash equivalents at times may exceed covered limits.

Foreign currency exchange risk

We currently have limited, but may in the future have increased, clinical and commercial manufacturing agreements which are denominated in Euros or other foreign currencies. As a result, our financial results could be affected by factors such as a change in the foreign currency exchange rate between the U.S. dollar and the Euro or other applicable currencies, or by weak economic conditions in Europe or elsewhere in the world. We are not currently engaged in any foreign currency hedging activities.

Market indexed security risk

We have issued warrants to various holders underlying shares of our common stock. These warrants are re-measured to their fair value at each reporting period with changes in their fair value recorded as derivative gain (loss) in the accompanying consolidated statement of operations. We use the Black-Scholes model for valuation of the warrants.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Our audited consolidated financial statements as of December 31, 2024 and 2023 for the years then ended are included beginning on Page F-1 immediately following the signature page to this report. See Item 15 for a list of the financial statements included herein.

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we carried out an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of December 31, 2024, such disclosure controls and procedures were effective.

Disclosure controls and procedures are controls and other procedures that are designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified by the SEC. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, or persons performing similar functions, as appropriate, to allow timely decisions regarding required disclosure.

This Annual Report does not include an attestation report from our registered public accounting firm regarding internal control over financial reporting. Our internal control over financial reporting was not subject to such attestation as we are a non-accelerated filer.

Limitations on the Effectiveness of Controls

Our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of our disclosure control system are met. Because of inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if any, within a company have been detected. Our Chief Executive Officer and Chief Financial Officer have concluded, based on their evaluation as of the end of the period covered by this Annual Report that our disclosure controls and procedures were effective to provide reasonable assurance that the objectives of our disclosure control system were met.

Changes in Internal Control Over Financial Reporting

There were no changes in the Company's internal controls over financial reporting that occurred during the fourth quarter of the fiscal year covered by this Annual Report that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

Management's Report on Internal Control Over Financial Reporting

As required by the SEC rules and regulations for the implementation of Section 404 of the Sarbanes-Oxley Act, our management is responsible for establishing and maintaining adequate internal control over financial reporting. Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our consolidated financial statements for external reporting purposes in accordance with United States Generally Accepted Accounting Principles (GAAP). Our internal control over financial reporting includes those policies and procedures that:

(1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of our company,

(2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of consolidated financial statements in accordance with accounting principles generally accepted in the United States of America, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors, and

(3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the consolidated financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect errors or misstatements in our consolidated financial statements. 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 or compliance with the policies or procedures may deteriorate. Management assessed the effectiveness of our internal control over financial reporting as of December 31, 2024. In making these assessments, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission COSO (2013 framework). Based on our assessments and those criteria, management determined that we did maintain effective internal control over financial reporting as of December 31, 2024.

ITEM 9B. OTHER INFORMATION

Insider Trading Arrangements

No officers, as defined in Rule 16a-1(f), or directors adopted and/or terminated a "Rule 10b5-1 trading arrangement" or a "non-Rule 10b5-1 trading arrangement," as defined in Item 408 of Regulation S-K, during the fourth fiscal quarter of 2024.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

The information required for the Items contained in Part III is incorporated herein by reference from our definitive proxy statement for our 2025 Annual Meeting of Stockholders (the "Proxy Statement"), which will be filed with the SEC no later than 120 days after December 31, 2024.

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS, AND CORPORATE GOVERNANCE

ITEM 11. EXECUTIVE COMPENSATION

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

Securities Authorized for Issuance under Equity Compensation Plans

Relmada has a 2014 Option and Equity Incentive Plan, as amended (the 2014 Plan) in which its directors, officers, employees and consultants shall be eligible to participate. The 2014 Plan allows for the granting of common stock awards, stock appreciation rights, and incentive and nonqualified stock options to purchase shares of the Company. On May 20, 2021, at the annual shareholders meeting, our shareholders approved our 2021 Equity Incentive Plan (the 2021 Plan) which allows for the granting of incentive and nonqualified stock options, stock appreciation rights, restricted stock awards, performance share awards and other equity-based awards for up to 1,500,000 options or stock awards. At the annual shareholders meeting on May 25, 2022, our shareholders approved an amendment to the 2021 Plan to increase the shares of the Company's common stock available for issuance thereunder by 3,900,000 shares. At the annual shareholders meeting on May 25, 2023, our shareholders approved an amendment to the 2021 Plan to increase the shares of the Company's common stock available for issuance thereunder by 2,500,000 shares. At the annual shareholders meeting (currently anticipated for May 23, 2025), our shareholders will vote on a management proposal to increase the shares authorized for awards under the 2021 Plan by an additional 2,000,000 shares, but there can be no assurance such amendment will be approved. With these grants and approvals, as of December 31, 2024, the Company had 789,925 shares available to be issued pursuant to awards under the 2014 or 2021 Plan.

The following table summarizes our equity compensation plan information as of December 31, 2024:

Equity Compensation Plan Information

Plan Category	Number of securities to be issued upon exercise of outstanding options and stock appreciation rights	Weighted-average exercise price of outstanding options and stock appreciation rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
	(a)	(b)	(c)
Equity compensation plans approved by security holders (1)	12,263,017	$ 16.61	789,925
Equity compensation plans not approved by security holders	-	-	-
Total	12,263,017	$ 16.61	789,925

(1) The 2014 and the 2021 Plan, as amended.

The additional information required by this item will be included in the Proxy Statement, which will be filed with the SEC no later than 120 days after the end of our fiscal year ended December 31, 2024 and is incorporated herein by reference.

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

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

Financial Statement Schedules

Our consolidated financial statements are listed on the Index to Financial Statements on this Annual Report on Form 10-K beginning on page F-1.

All financial statement schedules are omitted because they are not applicable or the required information is shown in the financial statements or notes thereto.

Our independent registered public accounting firm is Marcum LLP (PCAOB ID #688) of Houston, Texas.

RELMADA THERAPEUTICS, INC.
(INDEX TO FINANCIAL STATEMENTS)

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of Directors of
Relmada Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Relmada Therapeutics, Inc. (the "Company") as of December 31, 2024 and 2023, the related consolidated statements of operations, changes in stockholders' equity and cash flows for each of the two years in the period ended December 31, 2024, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024 and 2023, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2024, in conformity with accounting principles generally accepted in the United States of America.

Explanatory Paragraph – Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 2, the Company has incurred significant losses and negative cash flows from operations since inception, expects to incur additional losses until such time that it can generate revenue, and is projecting insufficient liquidity to sustain its operations through one year following the date that the financial statements are issued. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

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

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

Critical Audit Matter

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

/s/ Marcum LLP.

Marcum LLP

We have served as the Company's auditor since 2014.

Houston, Texas
March 27, 2025

Relmada Therapeutics, Inc.
Consolidated Balance Sheets

	As of December 31, 2024	As of December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 3,857,026	$ 4,091,568
Short-term investments	41,052,356	92,232,292
Prepaid expenses	886,461	1,185,057
Total current assets	45,795,843	97,508,917
Other assets	21,975	43,125
Total assets	$ 45,817,818	$ 97,552,042
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 4,130,563	$ 3,506,009
Accrued expenses	6,160,827	8,688,791
Total current liabilities	10,291,390	12,194,800
Stock appreciation rights	4,467	-
Total liabilities	10,295,857	12,194,800
Commitments and Contingencies (Note 10)		
Stockholders' Equity:		
Preferred stock, $0.001 par value, 200,000,000 shares authorized, none issued and outstanding	-	-
Class A convertible preferred stock, $0.001 par value, 3,500,000 shares authorized, none issued and outstanding	-	-
Common stock, $0.001 par value, 150,000,000 shares authorized, 30,174,202 and 30,099,203 shares issued and outstanding, respectively	30,174	30,099
Additional paid-in capital	676,373,822	646,229,824
Accumulated deficit	(640,882,035)	(560,902,681)
Total stockholders' equity	35,521,961	85,357,242
Total liabilities and stockholders' equity	$ 45,817,818	$ 97,552,042

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

Relmada Therapeutics, Inc.
Consolidated Statements of Operations
For the Years Ended December 31, 2024 and 2023

	2024	2023
Operating expenses:		
Research and development	$ 46,175,512	$ 54,807,348
General and administrative	37,715,524	48,894,945
Total operating expenses	83,891,036	103,702,293
Loss from operations	(83,891,036)	(103,702,293)
Other income (expenses):		
Interest/investment income, net	3,530,021	5,151,704
Realized gain (loss) on short-term investments	374,926	(4,064,391)
Unrealized gain on short-term investments	6,735	3,823,234
Total other income (expenses), net	3,911,682	4,910,547
Net loss	$ (79,979,354)	$ (98,791,746)
Net loss per common share – basic and diluted	$ (2.65)	$ (3.28)
Weighted average number of common shares outstanding – basic and diluted	30,163,751	30,099,203

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

Relmada Therapeutics, Inc.
Consolidated Statements of Changes in Stockholders' Equity
For the Years Ended December 31, 2024 and 2023

	Common Stock		Additional Paid-in	Accumulated	
	Shares	Par Value	Capital	Deficit	Total
Balance – December 31, 2022	30,099,203	$ 30,099	$ 602,517,138	$ (462,110,935)	$ 140,436,302
Stock-based compensation expense	-	-	43,811,149	-	43,811,149
ATM fees			(98,463)	-	(98,463)
Net loss	-	-	-	(98,791,746)	(98,791,746)
Balance – December 31, 2023	30,099,203	30,099	646,229,824	(560,902,681)	85,357,242
Stock-based compensation expense	-	-	30,184,414	-	30,184,414
Net proceeds from cash exercise options	74,999	75	246,672	-	246,747
ATM fees	-	-	(287,088)	-	(287,088)
Net loss	-	-	-	(79,979,354)	(79,979,354)
Balance – December 31, 2024	30,174,202	$ 30,174	$ 676,373,822	$ (640,882,035)	$ 35,521,961

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

Relmada Therapeutics, Inc.
Consolidated Statements of Cash Flows
For the Years Ended December 31, 2024 and 2023

	2024	2023
Cash flows from operating activities		
Net loss	$ (79,979,354)	$ (98,791,746)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	30,184,414	43,811,149
Stock appreciation rights compensation	4,467	-
Realized (gain) loss on short-term investments	(374,926)	4,064,391
Unrealized gain on short-term investments	(6,735)	(3,823,234)
Change in operating assets and liabilities:		
Other receivable	-	512,432
Prepaid expenses and other assets	319,746	2,841,879
Accounts payable	624,554	(1,755,927)
Accrued expenses	(2,527,964)	1,481,850
Net cash used in operating activities	(51,755,798)	(51,659,206)
Cash flows from investing activities		
Purchase of short-term investments	(12,079,628)	(90,463,532)
Sale of short-term investments	63,641,225	140,916,864
Net cash provided by investing activities	51,561,597	50,453,332
Cash flows from financing activities		
Payment of ATM fees	(287,088)	(98,463)
Proceeds from options exercised for common stock	246,747	-
Net cash used in financing activities	(40,341)	(98,463)
Net decrease in cash and cash equivalents	(234,542)	(1,304,337)
Cash and cash equivalents at beginning of the year	4,091,568	5,395,905
Cash and cash equivalents at end of the year	$ 3,857,026	$ 4,091,568

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

Relmada Therapeutics, Inc.
Notes to Consolidated Financial Statements

NOTE 1 - BUSINESS

Relmada Therapeutics Inc. ("Relmada" or the "Company") (a Nevada corporation), is a clinical-stage, publicly traded biotechnology company focused on the development of NDV-01 and Sepranolone.

NDV-01 is a novel, controlled-release intravesical formulation of gemcitabine and docetaxel. NDV-01 is currently in a Phase 2 clinical trial to assess its safety and efficacy in patients with aggressive forms of non-muscle invasive bladder cancer (NMIBC).

Sepranolone is a novel neurosteroid epimer of allopregnanolone. Sepranolone is being developed for the potential treatment of Prader-Willi Syndrome, Tourette Syndrome, excessive tremor and other diseases related to excessive GABAergic activity.

Esmethadone (d-methadone, dextromethadone, REL-1017), an N-methyl-D-aspartate (NMDA) receptor antagonist. Esmethadone is a new chemical entity (NCE) that potentially addresses areas of high unmet medical need in the treatment of central nervous system (CNS) diseases and other disorders. This program has been

paused pending a comprehensive data review.

Relmada was also developing a proprietary, modified-release formulation of psilocybin (REL-P11) for metabolic indications. This program has also been paused.

In addition to the normal risks associated with a new business venture, there can be no assurance that the Company's research and development will be successfully completed or that any product will be approved or commercially viable. The Company is subject to risks common to companies in the biotechnology industry including, but not limited to, dependence on collaborative arrangements, development by the Company or its competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, and compliance with the Food and Drug Administration (FDA) and other governmental regulations and approval requirements.

On January 21, 2025, we received a deficiency letter from the Listing Qualifications Department (the "Staff") of The Nasdaq Stock Market advising that, for 30 consecutive business days preceding the notification letter, the Company did not meet the minimum $1.00 per share bid price requirement for continued inclusion on The Nasdaq Global Select Market. The deficiency letter does not result in the immediate delisting of our common stock from the Nasdaq Global Select Market. In accordance with Nasdaq Listing Rule 5810(c)(3)(A) (the "Compliance Period Rule"), we have been provided an initial period of 180 calendar days, or until July 21, 2025 (the "Compliance Date"), to regain compliance with the minimum bid price requirement. If, at any time before the Compliance Date, the bid price for our common stock closes at $1.00 per share or more for a minimum of 10 consecutive business days, as required by the Compliance Period Rule, the Staff will provide written notification to us that we comply with the minimum bid price requirement, unless the Staff exercises its discretion to extend this 10-day period pursuant to Nasdaq Listing Rule 5810(c)(3)(H).

NOTE 2 - GOING CONCERN

These audited consolidated financial statements have been prepared in accordance with generally accepted accounting principles applicable to a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business.

As shown in the accompanying audited consolidated financial statements, the Company has incurred losses and negative cash flows from operations since inception and expects to incur additional losses until such time that it can generate significant revenue from the commercialization of its product candidates. During the twelve months ended December 31, 2024, the Company incurred a net loss of $79,979,354 and had negative operating cash flows of $51,755,798. Given the Company's projected operating requirements and its existing cash and cash equivalents and short-term investments, the Company is projecting insufficient liquidity to sustain its operations through one year following the date that the financial statements are issued. These conditions and events raise substantial doubt about the Company's ability to continue as a going concern.

In response to these conditions, management is currently evaluating the size and scope of any subsequent operations and clinical trials that will affect the timing to obtain the required funding of future operations. Financing strategies may include, but are not limited to, the public or private sale of equity or debt securities or from bank or other loans or through strategic collaboration and/or licensing agreements. There can be no assurances that the Company will be able to secure additional financing, or if available, that it will be sufficient to meet its needs or on favorable terms. Because management's plans have not yet been finalized and are not within the Company's control, the implementation of such plans cannot be considered probable. As a result, the Company has concluded that management's plans do not alleviate substantial doubt about the Company's ability to continue as a going concern.

The audited consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

NOTE 3 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation and Principles of Consolidation

The accompanying consolidated financial statements and related notes have been prepared in accordance with accounting principles generally accepted in the United States of America (U.S. GAAP). The consolidated financial statements include the Company's accounts and those of the Company's wholly-owned subsidiary. All significant intercompany accounts and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses for the reporting period. Actual results could differ from those estimates. The significant estimates are stock-based compensation expenses, and recorded amounts related to income taxes.

Cash and Cash Equivalents

The Company considers cash deposits and all highly liquid investments with a maturity of three months or less when purchased to be cash and cash equivalents. The Company's cash deposits are held at two high-credit-quality financial institutions. The Company's cash and cash equivalents are carried at cost, which approximates their fair value. The Company's cash and cash equivalents of $3,857,026 and $4,091,568 at December 31, 2024 and 2023, respectively, at these institutions exceed federally insured limits.

Short-term Investments

The Company's investments consist entirely of mutual funds. The securities are measured at fair value based on the net asset value "NAV". Substantially all equity investments in nonconsolidated entities are measured at fair value with recurring changes recognized in earnings, except for those accounted for using equity method accounting. Changes in fair value of the securities are recorded as part of other income on the consolidated statements of operations. Short term investment activity is presented in the investing activities section on the consolidated statements of cash flows.

Short-term investments at December 31, 2024 and 2023 consisted of mutual funds with a fair value of $41,052,356 and 92,232,292, respectively.

Patents

Costs related to filing and pursuing patent applications are recorded as general and administrative expense and expensed as incurred since recoverability of such expenditures is uncertain.

Leases

The Company recognizes its leases with a term of greater than a year on the balance sheet by recording right-of-use assets and lease liabilities. Leases can be classified as either operating leases or finance leases. Operating leases will result in straight-line lease expense, while finance leases will result in front-loaded expense. The Company's leases consists of operating leases for office space for terms of 12 months or less. The Company does not recognize a lease liability or right-of-use asset on the balance sheet for short-term leases. Instead, the Company recognizes short-term lease payments as an expense on a straight-line basis over the lease term. A short-term lease is defined as a lease that, at the commencement date, has a lease term of 12 months or less and does not include an option to purchase the underlying asset that the lessee is reasonably certain to exercise.

Fair Value of Financial Instruments

The Company's financial instruments primarily include cash, short-term investments, and stock appreciation rights. Due to the short-term nature of cash and accounts payable the carrying amounts of these assets and liabilities approximate their fair value.

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the reporting date. A fair value hierarchy has been established for valuation inputs that gives the highest priority to quoted prices in active markets for identical assets or liabilities and the lowest priority to unobservable inputs. The fair value hierarchy is as follows:

Level 1 Inputs - Unadjusted quoted prices in active markets for identical assets or liabilities that the reporting entity has the ability to access at the measurement date.

Level 2 Inputs - Inputs other than quoted prices included in Level 1 that are observable for the asset or liability, either directly or indirectly. These might include quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active, inputs other than quoted prices that are observable for the asset or liability (such as interest rates, volatilities, prepayment speeds, credit risks, etc.) or inputs that are derived principally from or corroborated by market data by correlation or other means.

Level 3 Inputs - Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (supported by little or no market activity).

As required by Accounting Standard Codification (ASC) Topic No. 820 - 10 *Fair Value Measurement*, financial assets and liabilities are classified based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement requires judgment and may affect the valuation of the fair value of assets and liabilities and their placement within the fair value hierarchy levels.

The Company's short-term investment instruments of $41,052,356 and $92,232,292 at December 31, 2024 and 2023, respectively, are classified using Level 1 inputs within the fair value hierarchy because they are valued using NAV. Unrealized gains and losses are recorded in the consolidated statement of operations as unrealized gain on short-term investments. The Company recorded unrealized gains of $6,735 and of $3,823,234, included in other income (expense) for the years ended December 31, 2024 and 2023, respectively.

The Company's stock appreciation rights liability is a mark-to-market liability and classified within Level 3 of the fair value hierarchy as the Company is using a Black-Scholes option pricing model. Significant unobservable inputs included expected term and volatility. The expected term was calculated using the simplified method. The volatility is calculated based on the Company's historical stock price over a period of time.

As of December 31, 2024, the stock appreciation rights liability had a fair value of $4,467. Significant inputs for Level 3 stock appreciation rights liability fair value measurement at December 31, 2024 are (1) discount rate of 4.38%, (2) expected life of 5.75 years, (3) expected volatility of 129%, (4) zero expected dividends, (5) stock price of $0.52 and (6) exercise price of $3.84 - $3.69.

There have been no transfers in and out of level 3 during the year ended December 31, 2024.

Income Taxes

The Company accounts for income taxes using the asset and liability method. Accordingly, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between financial statement carrying amounts of existing assets and liabilities and their respective tax bases. 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 the tax rate is recognized in income or expense in the period that the change is effective. Tax benefits are recognized when it is probable that the deduction will be sustained. A valuation allowance is established when it is more likely than not that all or a portion of a deferred tax asset will either expire before the Company is able to realize the benefit, or that future deductibility is uncertain. At December 31, 2024 and 2023, the Company had recognized a valuation allowance to the full extent of the Company's net deferred tax assets since the likelihood of realization of the benefit does not meet the more likely than not threshold.

The Company files a U.S. Federal income tax return and various state returns. Uncertain tax positions taken on the Company's tax returns will be accounted for as

liabilities for unrecognized tax benefits. The Company will recognize interest and penalties, if any, related to unrecognized tax benefits in general and administrative expenses in the statements of operations. There were no liabilities recorded for uncertain tax positions at December 31, 2024 and 2023. The open tax years, subject to potential examination by the applicable taxing authority, for the Company are from December 31, 2020 forward.

Research and Development

Research and development costs primarily consist of research contracts for the advancement of product development, salaries and benefits, stock-based compensation, and consultants. The Company expenses all research and development costs in the period incurred. The Company makes an estimate of costs in relation to clinical study contracts. The Company analyzes the progress of studies, including the progress of clinical studies and phases, invoices received and contracted costs when evaluating the adequacy of the amount expensed and the related prepaid asset and accrued liability.

Stock-Based Compensation

The Company measures the cost of employee services received in exchange for an award of equity instruments based on the grant-date fair value of the award. That cost is recognized over the period during which an employee is required to provide service in exchange for the award - the requisite service period. The grant-date fair value of employee share options is estimated using the Black-Scholes option pricing model adjusted for the unique characteristics of those instruments.

Stock Appreciation Rights

Pursuant to the terms of the Company's 2021 Equity Incentive Plan, the Company may grant cash-settled Stock Appreciation Rights ("SARs") that are classified as liabilities under ASC 718 (*Compensation—Stock Compensation*). These SARs allow employees to receive cash payments based on the appreciation of the Company's stock price over a specified period.

The initial fair value of SARs is determined on the grant date using the Black-Scholes option pricing model. SARs are remeasured at fair value at each reporting date using the Black-Scholes pricing model until they are exercised or expire. Changes in fair value are recognized in the income statement as a compensation expense. Compensation expense is recognized over the service period, which is the period during which employees are required to provide service in exchange for the award.

Upon exercise, the Company will settle SARs in cash based on the difference between the fair value of the underlying shares at the exercise date and the exercise price.

Net Loss per Common Share

Basic loss per common share attributable to common stockholders is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of common shares outstanding for the period, without consideration for common stock equivalents. Diluted loss per common share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common share equivalents outstanding for the period determined using the treasury-stock method. Dilutive common stock equivalents are comprised of options and warrants to purchase common stock. For all periods presented, there is no difference in the number of shares used to calculate basic and diluted shares outstanding due to the Company's net losses in each period.

The potentially dilutive securities that would be anti-dilutive due to the Company's net loss are not included in the calculation of diluted net loss per share attributable to common stockholders. The anti-dilutive securities are as follows (in common stock equivalent shares):

	Year ended December 31, 2024	Year ended December 31, 2023
Common stock warrants	1,382,613	2,381,366
Common stock options	12,263,017	17,416,192
Total	13,645,630	19,797,558

Adoption of Recent Accounting Standards

In October 2021, the FASB issued ASU 2021-08, "*Business Combinations (Topic 805): Accounting for Contract Assets and Contract Liabilities from Contracts with Customers*". The amendments in this ASU require that an entity (acquirer) recognize, and measure contract assets and contract liabilities acquired in a business combination, including contract assets and contract liabilities arising from revenue contracts with customers, as if it had originated the contracts as of the acquisition date. The amendments in this ASU were effective for annual and interim periods beginning after December 15, 2022. The Company adopted this standard effective January 1, 2023 and the standard did not have a significant impact on our consolidated financial statements.

In November 2023, The FASB issued ASU 2023-07, "*Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*" which expands annual and interim disclosures for reportable segments, primarily through enhanced disclosures about significant segment expenses. ASU 2023-07 is effective for our annual periods beginning January 1, 2024, and for interim periods beginning January 1, 2025, with early adoption permitted. The Company adopted this standard effective January 1, 2024 and the standard did not have significant impact on our consolidated financial statements.

Recent Accounting Standards

In December 2023, the FASB issued ASU 2023-09, "*Income Taxes (Topic 740): Improvements to Income Tax Disclosures*" to expand the disclosure requirements for income taxes, specifically related to the rate reconciliation and income taxes paid. ASU 2023-09 is effective for our annual periods beginning January 1, 2025, with early adoption permitted. The Company is currently evaluating the potential effect that the updated standard will have on our financial statement disclosures.

In November 2024, the FASB issued ASU 2024-03, *Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40)*. ASU 2024-03 requires specified information about certain costs and expenses be disclosed in the notes to the financial statements, including the expense caption on the face of the income statement in which they are disclosed, in addition to a qualitative description of remaining amounts not separately disaggregated. Entities will also be required to disclose their definition of "selling expenses" and the total amount in each annual period. The standard is effective for the Company for annual periods beginning January 1, 2027 and for interim periods beginning January 1, 2028, with updates applied either prospectively or retrospectively. Early adoption is

permitted. The Company is currently evaluating the impact of this guidance on its disclosures.

Subsequent Events

The Company's management reviewed all material events through the date the audited consolidated financial statements were issued for subsequent event disclosure consideration.

NOTE 4 - PREPAID EXPENSES

Prepaid expenses consisted of the following (rounded to nearest $00):

	December 31, 2024	December 31, 2023
Insurance	$ 403,100	$ 365,100
Research and Development	391,200	695,000
Other	92,200	125,000
Total	$ 886,500	$ 1,185,100

NOTE 5 - ACCRUED EXPENSES

Accrued expenses consisted of the following (rounded to nearest $00):

	December 31, 2024	December 31, 2023
Research and development	$ 4,514,800	$ 5,394,700
Professional fees	362,600	174,000
Accrued bonus	732,300	2,632,400
Accrued vacation	421,700	372,200
Other	129,400	115,500
Total	$ 6,160,800	$ 8,688,800

NOTE 6 - STOCK APPRECIATION RIGHTS

During the year ended December 31, 2024, 110,000 cash-settled stock appreciation rights have been issued to employees with an exercise price of $3.84 - $3.69 respectively with a 10-year term and vesting over a 4-year period. Variables used in the Black-Scholes option-pricing model include: (1) discount rate of 3.87 – 4.15%, (2) expected life of 6.25 years, (3) expected volatility of 113%, and (4) zero expected dividends.

At December 31, 2024, the Company revalued the cash-settled stock appreciation rights using a stock price of $0.52 and an exercise price of $3.84 - $3.69. Variables used in the Black-Scholes option-pricing model include: (1) discount rate of 4.38%, (2) expected life of 5.75 years, (3) expected volatility of 129%, and (4) zero expected dividends.

As of December 31, 2024, the total liability related to cash-settled SARs is $4,467, reflecting the fair value as of the reporting date. During the year ended December 31, 2024, the Company recorded compensation related to the cash-settled SARs in the amount of $4,467, included in research and development expenses in the accompanying consolidated statements of operations.

A summary of the changes in SARs during the nine months ended December 31, 2024 is as follows.

	Number of Cash-Settled SARS	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at December 31, 2023	-	$ -	-	$ -
Granted	110,000	$ 3.70	9.58	$ -
Outstanding at December 31, 2024	110,000	$ 3.70	9.58	$ -
SARs vested at December 31, 2024	-	$ -	-	$ -

At December 31, 2024, the Company has unrecognized compensation expense of approximately $38,000 related to unvested stock appreciation rights which will be recognized over the weighted average remaining service period of 3.58 years.

NOTE 7 - STOCKHOLDERS' EQUITY

Common Stock

During the years ended December 31, 2024 and 2023, the Company did not issue any shares of common stock for the exercise of warrants.

During the year ended December 31, 2024, the Company issued 74,999 shares of common stock for the exercise of options for proceeds of $246,747.

During the year ended December 31, 2023, the Company did not issue any shares of common stock for the exercise of options.

On April 6, 2022, the Company entered into a new Open Market Sale Agreement with Jefferies LLC, as sales agent, pursuant to which we may offer and sell, from time

to time, through Jefferies LLC, shares of our common stock, having an aggregate offering price of up to $100,000,000. We are not obligated to sell any shares under the agreement. As of December 31, 2024, no shares have been issued under this agreement.

During the years ended December 31, 2024 and 2023, there were no common stock shares issued for issuances of restricted common stock.

NOTE 8 - OPTIONS AND WARRANTS

In December 2014, the Board of Directors adopted and the Company's shareholders approved Relmada's 2014 Stock Option and Equity Incentive Plan, as amended (the "2014 Plan"), which allows for the granting of 5,152,942 common stock awards, stock appreciation rights, and incentive and nonqualified stock options to purchase shares of the Company's common stock to designated employees, non-employee directors, and consultants and advisors.

In May 2021, the Company's Board of Directors adopted and shareholders approved Relmada's 2021 Equity Incentive Plan (the "2021 Plan") which allows for the granting of 1,500,000 options or other stock awards.

In May 2022, the Company's Board of Directors adopted, and shareholders approved an amendment to the 2021 Plan to increase the shares of the Company's common stock available for issuance thereunder by 3,900,000 shares.

In May 2023, the Company's Board of Directors adopted and shareholders approved an amendment to the 2021 Plan to increase the shares of the Company's common stock available for issuance thereunder by 2,500,000 shares.

These combined plans allowed for the granting of up to 13,052,942 options or other stock awards.

Stock options are exercisable generally for a period of 10 years from the date of grant and generally vest over four years.

As of December 31, 2024, there were 789,925 shares available to be granted under either the 2014 and 2021 Plan.

The Company uses the simplified method for share-based compensation to estimate the expected term for employee option awards for share-based compensation in its option-pricing model.

From January 1, 2024 through December 31, 2024, the Company awarded a total of 487,434 options to consultants and employees with an exercise price ranging from $3.05 to $3.44 and a 10-year term vesting over a 3.56-4 year period. The options granted include time-based vesting grants. The options have an aggregate fair value of approximately $1,300,000 calculated using the Black Scholes option-pricing model. Variables used in the Black-Scholes option-pricing model include: (1) discount rate of 4.10 – 4.51% (2) expected life of 5.92- 6.25 years, (3) expected volatility of 113.5-114.1%, and (4) zero expected dividends.

From November 13, 2023 through December 15, 2023, the Company awarded a total of 5,010,000 options to consultants and employees with an exercise price ranging from $2.48 to $2.82 and a 10-year term vesting over a 4-year period. The options granted include time-based vesting grants. The options have an aggregate fair value of approximately $10,703,070 calculated using the Black Scholes option-pricing model. Variables used in the Black-Scholes option-pricing model include: (1) discount rate of 3.93 – 4.68% (2) expected life of 6.25 years, (3) expected volatility of 113-114%, and (4) zero expected dividends.

From August 1, 2023 through September 18, 2023, 10,000 options were issued to various employees with an exercise price ranging from $2.56 to $2.96 and a 10-year term, vesting over a 4-year period. The options granted include time-based vesting grants. The options have an aggregate fair value of approximately $23,840 calculated using the Black-Scholes option-pricing model. Variables used in the Black-Scholes option-pricing model include: (1) discount rate of 4.20– 4.44% (2) expected life of 6.25 years, (3) expected volatility of 113-114%, and (4) zero expected dividends.

From April 10, 2023 through June 20, 2023, 60,000 options were issued to various employees with an exercise price ranging from $2.28 to $3.32 and a 10-year term, vesting over a 4-year period. The options granted include time-based vesting grants. The options have an aggregate fair value of approximately $148,420 calculated using the Black-Scholes option-pricing model. Variables used in the Black-Scholes option-pricing model include: (1) discount rate of 3.43 – 3.91% (2) expected life of 6.25 years, (3) expected volatility of 114%, and (4) zero expected dividends.

From January 6, 2023 through February 21, 2023, 620,000 options were issued to various consultants and employees with an exercise price ranging from $3.18 to $4.30 and a 10-year term, vesting over a 4-year period. The options have an aggregate fair value of approximately $1,933,613 calculated using the Black-Scholes option-pricing model. Variables used in the Black-Scholes option-pricing model include: (1) discount rate of 3.46 – 4.12% (2) expected life of 6.25 years, (3) expected volatility of 115-116%, and (4) zero expected dividends.

Options

A summary of the changes in options outstanding for the years ended December 31, 2024 and 2023 is as follows:

	Number of Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value

Outstanding and expected to vest at December 31, 2022	12,122,606	$ 18.19	8.5	$ 417,998
Granted	5,700,000	2.61	9.9	-
Forfeited	(406,414)	-	-	-
Outstanding and expected to vest at December 31, 2023	17,416,192	$ 12.99	8.3	$ 11,183,370
Granted	487,434	3.10		
Forfeited and cancelled	(5,565,610)	-		
Exercised	(74,999)	-		
Outstanding and expected to vest at December 31, 2024	12,263,017	$ 16.61	6.01	$ -
Options exercisable at December 31, 2024	9,480,618	$ 19.02	5.44	$ -

At December 31, 2024, the Company has unrecognized stock-based compensation expense of approximately $16,289,000 related to unvested stock options over the weighted average remaining service period of 1.40 years. The weighted average fair value of options granted during the years ended December 31, 2024 and 2023 was approximately $3.10 and $2.61 per share, respectively, on the date of grant using the Black-Scholes option pricing model with the following assumptions:

	Years Ended December 31, 2024	Years Ended December 31, 2023
Risk free interest rate	4.10 to 4.51%	3.43 to 4.68%
Dividend yield	0%	0%
Volatility	113.5-114.1%	113-116%
Expected term (in years)	5.92 - 6.25	6.25

Warrants

A summary of the changes in outstanding warrants during the years ended December 31, 2024 and 2023 is as follows:

	Number of Shares	Weighted Average Exercise Price Per Share
Outstanding at December 31, 2022	3,027,441	$ 17.02
Forfeited	(646,075)	$ 1.5
Outstanding at December 31, 2023	2,381,366	$ 20.02
Forfeited	(998,753)	$ 2.31
Outstanding at December 31, 2024	1,382,613	$ 28.74
Warrants exercisable at December 31, 2024	1,372,113	$ 28.76

There were no warrants issued during the year ended December 31, 2024.

At December 31, 2024, the Company had approximately $167,300 of unrecognized stock-based compensation expense related to outstanding warrants. At December 31, 2024, the aggregate intrinsic value of warrants vested and outstanding was $0.

Stock-based compensation by class of expense

The following summarizes the components of stock-based compensation expense which includes stock options and warrants in the consolidated statements of operations (rounded to nearest $00):

	Year Ended December 31, 2024	Year Ended December 31, 2023
Research and development	$ 5,933,200	$ 7,224,000
General and administrative	24,251,200	36,587,100
Total	$ 30,184,400	$ 43,811,100

NOTE 9 - INCOME TAXES

No provision or benefit for federal or state income taxes has been recorded because the Company has incurred net losses for all periods presented and has recorded a valuation allowance against its deferred tax assets.

The components of the Company's deferred tax assets are as follows at:

	December 31, 2024	December 31, 2023
Deferred tax assets:		
Federal net operating loss	$ 26,679,000	$ 21,016,000
State net operating loss	1,554,000	3,771,000
Research and development tax credits	3,953,000	2,238,000
Capitalized R&D	42,843,000	49,581,000
Nonqualified Stock Options	29,040,000	29,305,000
Accruals	1,398,000	1,616,000
Intangibles and Fixed Assets	2,118,000	2,599,000
NUBIL-382	7,763,000	-
Other	11,000	11,000
Less: valuation allowance	(115,359,000)	(110,137,000)
Total	$ -	$ -

The Company has maintained a full valuation allowance against its deferred tax assets at December 31, 2024 and 2023. A valuation allowance is required to be recorded when it is more likely than not that some portion or all of the net deferred tax assets will not be realized. Since the Company cannot be assured of realizing the net deferred tax asset, a full valuation allowance has been provided. The valuation allowance (decreased)/increased for the years ended December 31, 2024 and 2023 by approximately $5,222,000 and $(6,259,000), respectively. Deferred tax asset for net operating loss carryforwards at December 31, 2024 was adjusted with the corresponding offset to valuation allowance.

At December 31, 2024, the Company had federal, New York State and New York City net operating loss (NOL) carryforwards of approximately $ 127,041,000, $1,068,000 and $1,068,000, respectively, which begin expiring in 2027, 2032 and 2032, respectively. Approximately $127,041,000 federal NOL can be carried forward indefinitely but it is limited to 80% of future taxable income. The Company also has federal research and development tax credit carryforwards of approximately $3,953,000 that will begin to expire in 2042.

Sections 382 and 383 of the Internal Revenue Code of 1986 subject the future utilization of net operating losses and certain other tax attributes, such as research and development tax credits, to an annual limitation in the event of certain ownership changes, as defined. The Company has undergone an ownership change and has determined that various "changes in ownership" as defined by IRS Section 382 did occur. Accordingly, about $111,168,000 of the Company's NOL carryforwards are limited. Approximately, $53,028,000 of NOLs and $7,321,000 of R&D Credits are expected to expire unused. The deferred tax assets associated with the attributes that will expire without utilization have been written-off. There are approximately $68,900,000 of NOLs available for in 2024. In subsequent years, the NOLs available from the October 13, 2022 change under section 382 are $740,000, annually.

A reconciliation of the statutory tax rate to the effective tax rate is as follows:

	Year Ended December 31, 2024	Year Ended December 31, 2023
Statutory federal income tax rate	21.00%	21.00%
State (net of federal benefit)	(14.27)%	(6.56)%
Non-deductible expenses	(2.58)%	(5.34)%
R&D Credit	2.15%	1.70%
NOL and R&D adjustment due to 382	(2.72)%	(16.27)%
NUBIL – 382 adjustment	5.23%	0.00%
Permanent true-ups	(2.28)%	(0.89)%
Other	0.00%	0.02%
Change in valuation allowance	(6.53)%	6.34%
Effective income tax rate	0%	0%

The Company does not have any uncertain tax positions at December 31, 2024 and 2023, that would affect its effective tax rate. The Company does not anticipate a significant change in the amount of unrecognized tax benefits over the next twelve months. Because the Company is in a loss carryforward position, the Company is generally subject to US federal and state income tax examinations by tax authorities for all years for which a loss carryforward is available. If and when applicable, the Company will recognize interest and penalties as part of income tax expense.

NOTE 10 - COMMITMENTS AND CONTINGENCIES

License Agreements

Third Party Licensor

Based upon a prior acquisition, the Company assumed an obligation to pay a third party (Dr. Charles E. Inturrisi and Dr. Paolo Manfredi – see below): (A) royalty payments up to 2% on net sales of licensed products that are not sold by sublicensee and (B) on each and every sublicense earned royalty payment received by licensee from its sublicensee on sales of license product by sublicensee, the higher of (i) 20% of the royalties received by licensee; or (ii) up to 2% of net sales of sublicensee. The Company will also make milestone payments of up to $4 or $2 million, for the first commercial sale of product in the field that has a single active pharmaceutical ingredient, and for the first commercial sale of product in the field of product that has more than one active pharmaceutical ingredient, respectively. As of December 31, 2024, the Company has not generated any revenue related to this license agreement.

Inturrisi / Manfredi

In January 2018, the Company entered into an Intellectual Property Assignment Agreement (the Assignment Agreement) and License Agreement (the License Agreement and together with the Assignment Agreement, the Agreements) with Dr. Charles E. Inturrisi and Dr. Paolo Manfredi (collectively, the Licensor). Pursuant to the Agreements, Relmada assigned its existing rights, including patents and patent applications, to esmethadone in the context of psychiatric use (the Existing Invention) to Licensor. Licensor then granted Relmada under the License Agreement a perpetual, worldwide, and exclusive license to commercialize the Existing Invention and certain further inventions regarding esmethadone in the context of other indications such as those contemplated above. In consideration of the rights granted to Relmada under the License Agreement, Relmada paid the Licensor an upfront, non-refundable license fee of $180,000. Additionally, Relmada will pay Licensor $45,000 every three months until the earliest to occur of the following events: (i) the first commercial sale of a licensed product anywhere in the world, (ii) the expiration or invalidation of the last to expire or be invalidated of the patent rights anywhere in the world, or (iii) the termination of the License Agreement. Relmada will also pay Licensor tiered royalties with a maximum rate of 2%, decreasing to 1.75%, and 1.5% in certain circumstances, on net sales of licensed products covered under the License Agreement. Relmada will also pay Licensor tiered payments up to a maximum of 20%, and decreasing to 17.5%, and 15% in certain circumstances, of all consideration received by Relmada for sublicenses granted under the License Agreement. As of December 31, 2024, no events have occurred, and the Company continues to pay Licensor $45,000 every three months.

Arbormentis, LLC

On July 16, 2021, the Company entered into a License Agreement with Arbormentis, LLC, a privately held Delaware limited liability company, by which the Company acquired development and commercial rights to a novel psilocybin and derivate program from Arbormentis, LLC, worldwide excluding the countries of Asia. The Company will collaborate with Arbormentis, LLC on the development of new therapies targeting neurological and psychiatric disorders, leveraging its understanding of neuroplasticity, and focusing on this emerging new class of drugs targeting the neuroplastogen mechanism of action. Under the terms of the License Agreement, the Company paid Arbormentis, LLC an upfront fee of $12.7 million, consisting of a mix of cash and warrants to purchase the Company's common stock, in addition to potential milestone payments totaling up to approximately $160 million related to pre-specified development and commercialization milestones. Arbormentis, LLC is also eligible to receive a low single digit royalty on net sales of any commercialized therapy resulting from this agreement. The license agreement is terminable by the Company but is perpetual and not terminable by the licensor absent material breach of its terms by the Company.

The new licensed program stems from an international collaboration among U.S., European and Swiss scientists that has focused on the discovery and development of compounds that may promote neural plasticity.

Leases and Subleases

On August 1, 2021, the Company relocated its corporate headquarters to 2222 Ponce de Leon, Floor 3, Coral Gables, FL 33134, pursuant to a lease agreement with monthly rent of approximately $11,000. The lease period was for five months. The lease agreement expired on December 31, 2021 and was renewed for each subsequent year with monthly rent for the years end December 31, 2024 and 2023 of approximately $7,000 and $7,000, respectively.

Beginning on January 1, 2023, we also leased office space at 880 Third Avenue, 12th Floor, New York, NY 10022 with monthly rent of approximately $14,500 that was terminated on November 30, 2023.

Beginning on December 1, 2023, we leased office space at 12 E 49th Street, New York, NY 10022 for with monthly rent of approximately $12,000 that lease was terminated on May 31, 2024.

Beginning on May 29, 2024, we leased office space at 12 E 49th Street, New York, NY 10022 with monthly rent of approximately $10,500; that lease expires on May 30, 2025.

In accordance with ASC 842, *Leases*, the Company has elected the practical expedient and recognizes rent expense evenly over the 12 months.

The Company incurred rent expense of approximately $236,900 and $283,600 for the years ended December 31, 2024 and 2023, respectively.

Legal

From time to time, the Company may become involved in lawsuits and other legal proceedings that arise in the course of business. Litigation is subject to inherent uncertainties, and it is not possible to predict the outcome of litigation with total confidence. The Company is currently not aware of any legal proceedings or potential claims against it whose outcome would be likely, individually or in the aggregate, to have a material adverse effect on the Company's business, financial condition, operating results, or cash flows.

NOTE 11 - OTHER POSTRETIREMENT BENEFIT PLAN

Relmada participates in a multiemployer 401(k) plan that permits eligible employees to contribute funds on a pretax basis subject to maximum allowed under federal tax provisions. The Company matches 100% of the first 3% of employee contributions, plus 50% of employee contributions that exceed 3% but do not exceed 5%.

The employees choose an amount from various investment options for both their contributions and the Company's matching contribution. The Company's contribution expense was $135,298 and $140,982 for the years ended December 31, 2024 and 2023, respectively.

NOTE 12 – SEGMENT REPORTING

The Company determined its reporting units in accordance with ASC 280, *Segment Reporting*. Reportable operating segments are determined based on the management approach, as defined by ASC 280, is based on the way that the chief operating decision-maker (CODM) organizes segments within the Company for making operating decisions, assessing performance, and allocating resources. Reportable segments are based on products and services, geography, legal structure, management structure, or any other manner in which management disaggregates the Company.

Management determined the Company's operations constitute a single reportable segment in accordance with ASC 280: clinical stage drug development. The Company derives all of its losses from the development of clinical stage drugs expenses. The Company's CODM is its chief executive officer and chief financial officer. The CODM assesses performance and makes operating decisions about allocating resources based on the research and development operating expenses on the Consolidated Statements of Operations. The CODM does not review assets in evaluating the results of the clinical stage development, and therefore, such information is not presented.

The following table provides the operating expenses of our clinical stage drug development segment (rounded to the nearest $00):

	December 31, 2024	December 31, 2023
Clinical Study Expense	$ 11,376,200	$ 20,043,700
Other Research Expense	23,616,000	22,367,300
Manufacturing and Drug Storage Expense	1,567,400	1,542,300
Pre-clinical Expense	328,900	-
Compensation Expense	3,349,400	3,630,100
Stock-based Compensation Expense	5,937,600	7,224,000
Total Research and Development Expense	$ 46,175,500	$ 54,807,400

NOTE 13 - SUBSEQUENT EVENTS

On January 2, 2025, 300,000 Cash-Settled Stock Appreciation Rights were granted to a consultant with an exercise price of $0.45.

On February 3, 2025, the Company entered into an Asset Purchase Agreement (the Purchase Agreement) with Asarina Pharma AB (Asarina), a Swedish corporation, pursuant to which the Company has agreed, subject to the terms and conditions set forth therein, to purchase from Asarina all right, title, and interest in Sepranolone, a phase 2b ready neurosteroid being developed for the potential treatment of Prader-Willi Syndrome, Tourette Syndrome, essential tremor and other diseases related to excessive GABAergic activity. The total purchase price for Sepranolone is €3,000,000. The Company paid Asarina $2,756,000 on February 5, 2025, which includes a credit of $250,000 for a previous payment made by the Company to Asarina pursuant to an exclusivity agreement dated October 25, 2024.

On March 24, 2025, the Company entered into an Exclusive License Agreement with Trigone Pharma, Ltd. (Trigone), an Israeli company. The license agreement is for Trigone's NDV-01 product, which is a novel, sustained-release, intravesical gemcitabine/docetaxel, ready-for-use product candidate for the treatment of NMIBC. Under the terms of the agreement, the Company made a $3,500,000 upfront payment on March 25, 2025, and issued 3,017,420 shares of common stock, which represent 10% of the Company's outstanding shares, for exclusive worldwide rights to NDV-01, excluding Israel, India and South Africa.

In addition, the Company will pay up to $200 million in development, regulatory and sales milestones pending successful commercialization. The Company will also pay a royalty of 3% on any net sales. Following the completion of the ongoing Phase 2 study, the Company will assume responsibility for NDV-01's development, manufacturing and commercialization.

On March 24, 2025, the Company awarded a total of 200,000 options to consultants with an exercise price of $0.30 and a 10-year term vesting over a four-year period.

Exhibits

Certain of the agreements filed as exhibits to this Annual Report contain representations and warranties by the parties to the agreements that have been made solely for the benefit of the parties to the agreement. These representations and warranties:

- may have been qualified by disclosures that were made to the other parties in connection with the negotiation of the agreements, which disclosures are not necessarily reflected in the agreements;
- may apply standards of materiality that differ from those of a reasonable investor; and
- were made only as of specified dates contained in the agreements and are subject to subsequent developments and changed circumstances.

Accordingly, these representations and warranties may not describe the actual state of affairs as of the date that these representations and warranties were made or at any other time. Investors should not rely on them as statements of fact.

Exhibit Number	Description
2.1	Share Exchange Agreement, dated May 20, 2014, by and among Camp Nine, Inc., Relmada Therapeutics, Inc., and the stockholders of Relmada Therapeutics, Inc. (incorporated by reference to Exhibit 2.1 of Relmada's Form 8-K filed with the SEC on May 27, 2014).
3.1	(i) Articles of Incorporation of Camp Nine, Inc. (incorporated by reference to Exhibit 3.1 of Relmada's Registration Statement on Form S-1 filed with the SEC on November 13, 2012).
	(ii) Certificate of Designation dated May 13, 2014 (incorporated by reference to Exhibit 4.1 to Relmada's Report on Form 8-K filed with the SEC on May 19, 2014).
	(iii) Nevada Certificate of Amendment to Articles of Incorporation of Camp Nine, Inc., effective May 30, 2014 (incorporated by reference to Exhibit 3.1 of Relmada's Form 8-K filed with the SEC on June 2, 2014).
	(iv) Nevada Certificate of Amendment to Articles of Incorporation of Camp Nine, Inc., effective July 8, 2014 (incorporated by reference to Exhibit 3.1 of Relmada's Form 8-K filed with the SEC on July 14, 2014).
	(v) Certificate of Change of Relmada Therapeutics, Inc. dated September 26, 2019 (incorporated by reference to Exhibit 3.1 of Relmada's Form 8-K filed with the SEC on September 27, 2019).
	(vi) Certificate of Amendment to Articles of Incorporation dated September 22, 2022 (incorporated by reference to Exhibit 3.1 of Relmada's Form 8-K filed with the SEC on September 22, 2022).
3.2	Second Amended and Restated Bylaws of Relmada Therapeutics, Inc. (incorporated by reference to Exhibit 3.2 of Relmada's Form 8-K filed with the SEC on November 25, 2015).

Exhibit Number	Description
4.1	Form of Warrants to Purchase Common Stock issued in 2012 and 2013 in connection with Relmada Therapeutics, Inc. Series A Preferred Stock (incorporated by reference to Exhibit 4.1 of Relmada's Form 8-K filed with the SEC on May 27, 2014).
4.2	Form of Warrants to Purchase Common Stock issued in 2012 and 2013 in connection with Relmada Therapeutics, Inc. 8% Senior Subordinated Promissory Notes (incorporated by reference to Exhibit 4.2 of Relmada's Form 8-K filed with the SEC on May 27, 2014).
4.3	Form of B Warrant dated May ___, 2014 issued to investors by Relmada Therapeutics, Inc. (incorporated by reference to Exhibit 4.4 of Relmada's Form 8-K filed with the SEC on May 27, 2014).
4.4	Form of B Warrant dated June 10, 2014 issued to investors by Camp Nine, Inc. (incorporated by reference to Exhibit 4.2 of Relmada's Form 8-K filed with the SEC on June 16, 2014).
4.5	Form of Convertible Promissory Note (incorporated by reference to Exhibit 4.1 of Relmada's Form 10-Q filed with the SEC on February 12, 2018).
4.6	Form of Warrant to Purchase Common Stock (incorporated by reference to Exhibit 4.2 of Relmada's Form 10-Q filed with the SEC on February 12, 2018).
4.7	Form of 2018 Warrant (incorporated by reference to Exhibit 4.1 of Relmada's Form 10-Q filed with the SEC on November 13, 2018).
4.8	Form of 2019 Warrant (incorporated by reference to Exhibit 4.1 of Relmada's Form 10-Q filed with the SEC on May 15, 2019).
4.9	Form of Exchanged Warrant [(incorporated by reference to Exhibit 4.1 of Relmada's Form 8-K filed with the SEC on September 22, 2022).]
4.10	Description of Securities (incorporated by reference to the description of the Company's common stock, par value $0.001 per share, under the heading "Description of Securities We May Offer—Authorized Capital Stock; Issued and Outstanding Capital Stock," "—Common Stock," "—Forum for Adjudication of Disputes, "—Anti-takeover Effects of Our Articles of Incorporation and By-laws, and "—Anti-takeover Effects of Nevada Law" in the Company's Registration Statement on Form S-3 (File No. 333-245054), filed with the Securities and Exchange Commission on August 12, 2020)
10.1	Agreement and Plan of Merger dated as of December 31, 2013 between Relmada Therapeutics, Inc. and Medeor, Inc. (incorporated by reference to Exhibit 10.1 of Relmada's Form 8-K filed with the SEC on May 27, 2014).
10.2	2014 Stock Option and Equity Incentive Plan (incorporated by reference to Exhibit 10.14 of Relmada's Form S-1/A filed with the SEC on December 9, 2014)
10.3	Director Agreement, dated July 14, 2015, by and between Charles J. Casamento and Relmada Therapeutics, Inc. (incorporated by reference to Exhibit 10.1 of Relmada's Form 8-K filed with the SEC on July 16, 2015)
10.4	Director Indemnity Agreement, dated July 14, 2015, by and between Charles J. Casamento and Relmada Therapeutics, Inc. (incorporated by reference to Exhibit 10.2 of Relmada's Form 8-K filed with the SEC on July 16, 2015)
10.5	Amended 2014 Stock Option and Equity Incentive Plan (incorporated by reference to Exhibit 10.1 of Relmada's Form 8-K filed with the SEC on August 7, 2015).
10.6	Form of Indemnification Agreement (incorporated by reference to Exhibit 10.2 of Relmada's Form 8-K filed with the SEC on August 7, 2015).

Exhibit Number	Description
10.7	License Agreement, dated January 16, 2018, between Relmada Therapeutics, Inc. Dr. Charles E. Inturrisi and Dr. Paolo Manfredi (incorporated by reference to Exhibit 10.1 of Relmada's Form 8-K filed with the SEC on January 19, 2018).
10.8	Intellectual Property Assignment Agreement, dated January 16, 2018, between Relmada Therapeutics, Inc. Dr. Charles E. Inturrisi and Dr. Paolo Manfredi (incorporated by reference to Exhibit 10.2 of Relmada's Form 8-K filed with the SEC on January 19, 2018).
10.9	Form of Note and Warrant Purchase Agreement (incorporated by reference to Exhibit 10.1 of Relmada's Form 10-Q filed with the SEC on February 12, 2018).
10.10	Third Amendment to the 2014 Stock Option and Equity Incentive Plan, as amended (incorporated by reference to Exhibit 10.3 of Relmada's Form 10-Q filed with the SEC on May 14, 2018).
10.11	Form of Unit Purchase Agreement among Relmada Therapeutics, Inc. and certain accredited investors (incorporated by reference to Exhibit 10.1 of Relmada's Form 10-Q filed with the SEC on November 13, 2018).
10.12	Amendment No. 4 to the Relmada Therapeutics, Inc. 2014 Stock Option and Equity Incentive Plan, as amended (incorporated by reference to Exhibit 10.1 of Relmada's Form 10-Q filed with the SEC on May 15, 2019).
10.13	Form of Share Purchase Agreement, dated September 23, 2019 and September 26, 2019, among Relmada Therapeutics, Inc. and certain accredited investors named therein (incorporated by reference to Exhibit 10.4 of Relmada's Form 10-Q filed with the SEC on November 13, 2019).

10.14	Form of Registration Rights Agreement, dated September 23, 2019 and September 26, 2019, among Relmada Therapeutics, Inc. and certain accredited investors named therein (incorporated by reference to Exhibit 10.5 of Relmada's Form 10-Q filed with the SEC on November 13, 2019).
10.15	Amended and Restated Unit Purchase Agreement dated November 27, 2019, between Relmada Therapeutics, Inc., and certain accredited investors (incorporated by reference to Exhibit 10.1 of Relmada's Form 8-K filed with the SEC on December 3, 2019).
10.16	Amendment No. 1 To License Agreement dated December 2, 2019, to the License Agreement dated January 16, 2018 between Relmada Therapeutics, Inc., and Dr. Charles E. Inturrisi and Dr. Paolo Manfredi (incorporated by reference to Exhibit 10.2 of Relmada's Form 8-K filed with the SEC on December 3, 2019).
10.17	Director Agreement, effective December 19, 2019, by and between Eric Schmidt and Relmada Therapeutics, Inc. (incorporated by reference to Exhibit 10.1 of Relmada's Form 8-K filed with the SEC on December 26, 2019).
10.18	Indemnity Agreement, effective December 19, 2019, by and between Eric Schmidt and Relmada Therapeutics, Inc. (incorporated by reference to Exhibit 10.2 of Relmada's Form 8-K filed with the SEC on December 26, 2019).
10.19	Director Agreement, effective December 19, 2019, by and between John Glasspool and Relmada Therapeutics, Inc. (incorporated by reference to Exhibit 10.3 of Relmada's Form 8-K filed with the SEC on December 26, 2019).

Exhibit Number	Description
10.20	Indemnity Agreement, effective December 19, 2019, by and between John Glasspool and Relmada Therapeutics, Inc. (incorporated by reference to Exhibit 10.4 of Relmada's Form 8-K filed with the SEC on December 26, 2019).
10.21	Employment Agreement, dated January 9, 2020, by and between Maged Shenouda and Relmada Therapeutics, Inc. (incorporated by reference to Exhibit 10.1 of Relmada's Form 8-K filed with the SEC on January 10, 2020).
10.22	Employment Agreement, dated January 9, 2020, by and between Charles Ence and Relmada Therapeutics, Inc. (incorporated by reference to Exhibit 10.2 of Relmada's Form 8-K filed with the SEC on January 10, 2020).
10.23	Amended and Restated Employment Agreement, dated January 9, 2020, by and between Sergio Traversa and Relmada Therapeutics, Inc. (incorporated by reference to Exhibit 10.3 of Relmada's Form 8-K filed with the SEC on January 10, 2020).
10.24	Amendment No. 5 to Stock Option and Equity incentive Plan (incorporated by reference to Exhibit 10.1 of Relmada's Form 8-K filed with the SEC on March 9, 2020).
10.25	Open Market Sale Agreement℠ dated as of May 15, 2020 by and between Relmada Therapeutics, Inc. and Jefferies LLC. (incorporated by reference to Exhibit 10.7 of Relmada's Form 10-Q filed with the SEC on May 15, 2020).
10.26	Relmada Therapeutics, Inc., 2021 Equity Incentive Plan (incorporated by reference to Exhibit 10.61 of Relmada's Form 10-K filed with the SEC on March 24, 2021).
10.27	License Agreement dated as of July 16, 2021, between Arbormentis, LLC and Relmada Therapeutics, Inc. (incorporated by reference to Exhibit 10.2 of Relmada's Form 10-Q filed with the SEC on August 10, 2021).
10.28	Exchange Agreement between Relmada Therapeutics, Inc., and Venrock Healthcare Capital Partners EG, L.P., Venrock Healthcare Capital Partners II, L.P., VHCP Co-Investment Holdings II, LLC, Venrock Healthcare Capital Partners III, L.P., and VHCP Co-Investment Holdings III, LLC, dated September 21, 2022 (incorporated by reference to Exhibit 10.1 of Relmada's Form 8-K filed with the SEC on September 22, 2022).

Exhibit Number	Description
10.29	Amendment No. 2 dated December 27, 2022, to the License Agreement originally dated January 16, 2018, as heretofore amended, between Relmada Therapeutics, Inc., and Dr. Charles E. Inturrisi and Dr. Paolo Manfredi (incorporated by reference to Exhibit 10.1 of Relmada's Form 8-K filed with the SEC on December 28, 2022).
10.30	Advisory Agreement dated as of January 1, 2023, between Relmada Therapeutics, Inc., and Paul Kelly (incorporated by reference to Exhibit 10.1 of Relmada's Form 8-K filed with the SEC on January 5, 2023).
10.31	Director Agreement between Relmada Therapeutics, Inc., and Fabiana Fedeli (incorporated by reference to Exhibit 99.1 of Relmada's Form 8-K filed with the SEC on January 17, 2023).
10.32	Indemnity Agreement between Relmada Therapeutics, Inc., and Fabiana Fedeli (incorporated by reference to Exhibit 99.2 of Relmada's Form 8-K filed with the SEC on January 17, 2023).
10.33	Employment Agreement, dated January 1, 2025, between Relmada Therapeutics, Inc. and Paul Kelly (incorporated by reference to Exhibit 10.1 of Relmada's Form 8-K filed with the SEC on January 6, 2025).

10.34	Amended and Restated Employment Agreement, dated January 1, 2025, by and between Sergio Traversa and Relmada Therapeutics, Inc. (incorporated by reference to Exhibit 10.2 of Relmada's Form 8-K filed with the SEC on January 6, 2025).
10.35	Amended and Restated Employment Agreement, dated January 1, 2025, by and between Maged Shenouda and Relmada Therapeutics, Inc. (incorporated by reference to Exhibit 10.3 of Relmada's Form 8-K filed with the SEC on January 6, 2025).
10.36	Amended and Restated Employment Agreement, dated January 1, 2025, by and between Charles Ence and Relmada Therapeutics, Inc. (incorporated by reference to Exhibit 10.4 of Relmada's Form 8-K filed with the SEC on January 6, 2025).
10.37	Retention Compensation Agreement, effective as of August 27, 2024, between Relmada Therapeutics, Inc. and Sergio Traversa (incorporated by reference to Exhibit 10.5 of Relmada's Form 8-K filed with the SEC on January 6, 2025).
10.38	Retention Compensation Agreement, effective as of August 27, 2024, between Relmada Therapeutics, Inc. and Maged Shenouda (incorporated by reference to Exhibit 10.6 of Relmada's Form 8-K filed with the SEC on January 6, 2025).
10.39	Retention Compensation Agreement, effective as of August 27, 2024, between Relmada Therapeutics, Inc. and Charles Ence (incorporated by reference to Exhibit 10.7 of Relmada's Form 8-K filed with the SEC on January 6, 2025).
10.40	Retention Compensation Agreement, effective as of August 27, 2024, between Relmada Therapeutics, Inc. and Paul Kelly (incorporated by reference to Exhibit 10.8 of Relmada's Form 8-K filed with the SEC on January 6, 2025).
10.41	Asset Purchase Agreement between Relmada Therapeutics, Inc. and Asarina Pharma AB, dated February 3, 2025 (incorporated by reference to Exhibit 10.1 of Relmada's Form 8-K filed with the SEC on February 6, 2025)
19.1*	Insider Trading Policy, effective November 10, 2020.

Exhibit Number	Description
21.1	List of Subsidiaries (incorporated by reference to Exhibit 21.1 of Relmada's Form 10-K filed with the SEC on September 9, 2014).
23.1*	Consent of Marcum LLP
31.1*	Certification of Principal Executive Officer, pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial and Accounting Officer, pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1†	Certification of Principal Executive Officer, pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2†	Certification of Principal Financial and Accounting Officer, pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
97.1*	Clawback Policy, effective November 21, 2023.
101.INS*	Inline XBRL Instance Document.
101.SCH*	Inline XBRL Taxonomy Extension Schema Document.
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

* Filed herewith
† Furnished herewith

ITEM 16. FORM 10-K SUMMARY

None.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following person on behalf of the Registrant.

Dated: March 27, 2025

RELMADA THERAPEUTICS, INC.

By: /s/ Sergio Traversa
Sergio Traversa
Chief Executive Officer
(Duly Authorized Officer and
Principal Executive Officer)

By: /s/ Maged Shenouda
Maged Shenouda
Chief Financial Officer
(Duly Authorized Officer and
(Principal Financial and Accounting Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following person on behalf of the Registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Sergio Traversa Sergio Traversa	Chief Executive Officer, and Director	March 27, 2025
/s/ Maged Shenouda Maged Shenouda	Chief Financial Officer	March 27, 2025
/s/ Charles J. Casamento Charles J. Casamento	Chairman of the Board	March 27, 2025
/s/ Paul Kelly Paul Kelly	Director	March 27, 2025
/s/ John Glasspool John Glasspool	Director	March 27, 2025
/s/ Fabiana Fedeli Fabiana Fedeli	Director	March 27, 2025