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

# FORM 10-K

**☒ Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**
**For the annual period ended: December 31, 2024**
**OR**
**☐ Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

**For the transition period from ___ to ___**
**Commission File Number 001-38286**

# ENVERIC BIOSCIENCES, INC.
(Exact name of registrant as specified in its charter)

| **Delaware** | **95-4484725** |
|---|---|
| (State or other jurisdiction of incorporation or organization) | (IRS Employer Identification No.) |
| **4851 Tamiami Trail N, Suite 200 Naples, FL** | **34103** |
| (Address of principal executive offices) | (Zip code) |

**(239) 302-1707**
(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, $0.01 par value per share | ENVB | The Nasdaq Stock Market LLC |

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 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act:

| | |
|---|---|
| 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 of its management's assessment of the effectiveness of its internal controls 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 the 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 Exchange Act). Yes ☐ No ☒

As of June 30, 2024, the last 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, based on a closing price of $9.39 per share, was approximately $4.9 million.

As of March 27, 2025, there were 2,471,656 shares outstanding of Registrant's Common Stock (par value $0.01 per share).

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Company's proxy statement for the Annual Meeting of Stockholders to be held May 29, 2025 are incorporated by reference into Part III of this report. Such proxy statement will be filed with the Securities and Exchange Commission within 120 days of the registrant's fiscal year ended December 31, 2024. Additionally, portions of the Annual Report are incorporated by reference in this Form 10-K in response to Items within Part II.

**ENVERIC BIOSCIENCES, INC. AND SUBSIDIARIES**

**FORM 10-K**

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## CAUTIONARY NOTE REGARDING FORWARD LOOKING STATEMENTS; RISK FACTOR SUMMARY

This Annual Report on Form 10-K, including the documents that we incorporate by reference herein, contains forward-looking statements within the meaning of Section 27A of the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Any statements about our expectations, beliefs, plans, objectives, assumptions or future events or performance are not historical facts and may be forward-looking. These statements are often, but are not always, made through the use of words or phrases such as "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "seek," "should," "target," "will," "would," and similar expressions, or the negative of these terms, or similar expressions. Accordingly, these statements involve estimates, assumptions and uncertainties which could cause actual results to differ materially from those expressed in them. Any forward-looking statements are qualified in their entirety by reference to the factors discussed throughout this Annual Report on Form 10-K, and in particular those factors referenced in the section entitled "Risk Factors."

These forward-looking statements are based on our management's belief and assumptions and on information currently available to our management. These statements relate to future events or our future financial performance, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. Numerous factors could cause our actual results to differ materially from those described in forward-looking statements.

A summary of the principal risk factors that make investing in our securities risky and might cause our actual results to differ materially from those projected in these forward-looking statements is set forth below. If any of the following risks occur, our business, financial condition, results of operations, cash flows, cash available for distribution, ability to service our debt obligations and prospects could be materially and adversely affected:

- our dependence on the success of our prospective product candidates, which are in early stages of development and may not reach a particular stage in development, receive regulatory approval or be successfully commercialized;
- potential difficulties that may delay, suspend, or scale back our efforts to advance additional early research programs through preclinical development and investigational new drug ("IND") application filings and into clinical development;
- the risk that the cost savings, synergies and growth from our combination with MagicMed Industries Inc. and the successful use of the rights and technologies acquired in the combination may not be fully realized or may take longer to realize than expected;
- the limited study on the effects of psychedelics, and the chance that future clinical research studies may lead to conclusions that dispute or conflict with our understanding and belief regarding the medical benefits, viability, safety, efficacy, dosing, and social acceptance of psychedelics;
- the expensive, time-consuming, and uncertain nature of clinical trials, which are susceptible to change, delays, termination, and differing interpretations;
- the ability to establish that potential products are efficacious or safe in preclinical or clinical trials;
- the fact that our current and future preclinical and clinical studies may be conducted outside the United States, and the United States Food and Drug Administration may not accept data from such studies to support any new drug applications we may submit after completing the applicable developmental and regulatory prerequisites;
- our ability to effectively and efficiently build, maintain and legally protect our molecular derivatives library so that it can be an essential building block from which those in the biotech industry can develop new patented products;
- our ability to establish or maintain collaborations on the development of therapeutic candidates;
- our ability to obtain appropriate or necessary governmental approvals to market potential products;
- our ability to manufacture product candidates on a commercial scale or in collaborations with third parties;
- our significant and increasing liquidity needs and potential requirements for additional funding;
- our ability to obtain future funding for developing products and working capital and to obtain such funding on commercially reasonable terms;
- our ability to continue as a going concern;
- legislative changes related to and affecting the healthcare system, including, without limitation, changes and proposed changes to the Patient Protection and Affordable Care Act ("PPACA");

- the intense competition we face, often from companies with greater resources and experience than us;
- our ability to retain key executives and scientists;
- the ability to secure and enforce legal rights related to our products, including intellectual property rights and patent protection;
- political, economic, and military instability in Israel which may impede our development programs; and
- other factors described in the "Risk Factors" section of this Annual Report on Form 10-K.

We have included important factors in the cautionary statements included in this Annual Report on Form 10-K and the documents we incorporate by reference herein and, particularly in the "Risk Factors" sections of these documents, that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make. No forward-looking statement is a guarantee of future performance.

You should read this Annual Report on Form 10-K and the documents that we incorporate by reference herein completely and with the understanding that our actual future results may be materially different from what we expect. The forward-looking statements in this Annual Report on Form 10-K and the documents we incorporate by reference herein represent our views as of the date of this Annual Report on Form 10-K. We anticipate that subsequent events and developments will cause our views to change. However, we undertake no obligation to publicly update or revise any forward-looking statements, whether from new information, future events or otherwise, except as required by law. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Annual Report on Form 10-K.

## PART I

*Unless the context indicates otherwise, references in this Annual Report on Form 10-K to the "Company," "Enveric," "we," "us," "our" and similar terms refer to Enveric Biosciences, Inc. and its subsidiaries.*

### Item 1. Business

#### Background

We were incorporated under the laws of the State of Delaware in February 1994 as Spatializer Audio Laboratories, Inc., which was a shell company immediately prior to the completion of a "reverse merger" transaction on May 26, 2015, whereby Ameri100 Acquisition, Inc., a Delaware corporation and newly created, wholly owned subsidiary, was merged with and into Ameri and Partners Inc., a Delaware corporation (the "2015 Merger"). In connection with the 2015 Merger, we changed our name to "AMERI Holdings, Inc."

The Ameri business ceased to be part of the Company on December 30, 2020, pursuant to a spin-off transaction. On December 30, 2020, we completed a tender offer to purchase all of the outstanding common shares of Jay Pharma Inc., a Canada corporation, for shares of Company common stock or certain preferred stock, and changed our name to "Enveric Biosciences, Inc."

On May 24, 2021, the Company entered into an Amalgamation Agreement (the "Amalgamation Agreement") with 1306432 B.C. Ltd., a corporation existing under the laws of the Province of British Columbia and a wholly-owned subsidiary of the Company ("HoldCo"), 1306436 B.C. Ltd., a corporation existing under the laws of the Province of British Columbia and a wholly-owned subsidiary of HoldCo ("Purchaser"), and MagicMed Industries Inc., a corporation existing under the laws of the Province of British Columbia ("MagicMed"), pursuant to which, among other things, the Company, indirectly through Purchaser, acquired all of the outstanding securities of MagicMed in exchange for securities of the Company by way of an amalgamation under the British Columbia Business Corporations Act, upon the terms and conditions set forth in the Amalgamation Agreement, such that, upon completion of the amalgamation, the amalgamated corporation ("Amalco") became an indirect wholly-owned subsidiary of the Company. The amalgamation was completed on September 16, 2021.

On March 21, 2023, the Company established Enveric Therapeutics Pty. Ltd., an Australia-based subsidiary ("Enveric Therapeutics"), to support the Company's plans to advance the EVM201 Series, comprised of the next generation synthetic prodrugs of the active metabolite, psilocin, towards the clinic. Enveric Therapeutics was established to oversee the Company's intended preclinical, clinical, and regulatory activities in Australia, including interactions with the local Human Research Ethics Committees ("HREC") and the Therapeutic Goods Administration, Australia's regulatory authority. Enveric has since out-licensed the EVM201 Series asset to MycoMedica Life Sciences, Inc. and is not currently performing activities in Australia.

#### Available Information

We are required to file Annual Reports on Form 10-K and Quarterly Reports on Form 10-Q with the Securities and Exchange Commission (the "SEC") on a regular basis, and are required to disclose certain material events in Current Reports on Form 8-K. The SEC maintains an Internet website that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC. The SEC's Internet website is located at http://www.sec.gov. We also make available, free of charge, our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to these reports on our website at https://www.enveric.com/ as soon as reasonably practicable after those reports and other information is electronically filed with, or furnished to, the SEC.

Our internet address is https://www.enveric.com/, and the information included in, or linked to our website is not part of this Annual Report on Form 10-K. We have included our website address in this Annual Report on Form 10-K solely as a textual reference.

#### Business Overview

We are a biotechnology company dedicated to the development of novel neuroplastogenic small-molecule therapeutics for the treatment of depression, anxiety, addiction, and other psychiatric disorders. Leveraging our unique discovery and development platform, the Psybrary™, which houses proprietary information on the use and development of existing and novel molecules for specific mental health indications, Enveric seeks to develop a robust intellectual property portfolio of novel drug candidates.

Enveric's lead program, the EVM301 Series, and its lead drug candidate, EB-003, are intended to offer a first-in-class, new approach to the treatment of difficult-to-address mental health disorders, mediated by the promotion of neuroplasticity and without also inducing hallucinations in the patient. Enveric unveiled its EVM401 Series on February 25, 2025, which is intended to broaden Enveric's pipeline with additional non-hallucinogenic molecules and strengthen its ability to target addiction and neuropsychiatric disorders for patients with limited options. Previously, Enveric was developing the EVM201 Series, and its lead drug candidate EB-002 (formerly EB-373), for the treatment of neuropsychiatric disorders. The EVM201 Series comprised next generation synthetic prodrugs of the active metabolite, psilocin. Recently, Enveric out-licensed the EVM201 Series program to MycoMedica Life Sciences, who will seek to develop, manufacture, and commercialize EB-002, in exchange for certain development and milestone payments to Enveric.

*Neuroplastogens*

Following our amalgamation with MagicMed in September 2021, we have continued to pursue the development of MagicMed's proprietary library, the Psybrary™, which we believe will help us to identify and develop the right drug candidates needed to address mental health challenges, including depression, anxiety, and addiction disorders. We synthesize novel phenylalkylamines and indolethylamines, using a mixture of chemistry and synthetic biology, resulting in the expansion of the Psybrary™, which currently includes 20 patent families with claims covering a million potential molecular structures, over one thousand of which we have so far synthesized in sufficient quantities to identify and hundreds of which we have screened for receptor binding and other relevant activities.

The Company developed certain intellectual property rights around the trademark PsyAI™ for potential use. On March 6, 2025, Enveric announced it is soliciting Requests-For Proposals ("RFPs") for the license or sale of its PsyAI™ trademark portfolio as a means of maximizing value for an asset which is no longer strategic given the Company's focus on drug development. This limited portfolio of US and Canadian trademark assets is held by its subsidiary, Enveric Biosciences Canada, Inc. Enveric expects the period for RFPs to remain open until August 31, 2025, with a decision to follow within three (3) months thereafter.

At this stage, we have entered into several non-binding term sheets with strategic partners to out-license certain molecules from the Psybrary™. Going forward, in order to build a pipeline of product candidates, we intend to both continue to internally develop new drug candidates with associated intellectual property and to acquire, through in-licensing, additional intellectual property from pharmaceutical and biotechnology companies and research institutions. The in-licensed assets could include both research stage and clinical stage drug candidates.

While we intend to pursue development of the EVM401 Series, our primary focus is to develop our lead asset EB-003 in the EVM301 Series. The development status of EB-003 is shown in the table below:

| Product Candidates | Targeted Indications | Status | Expected Next Steps |
|---|---|---|---|
| **EB-003**<br>*Psychedelic-inspired drug candidate* | Mental health indication | Preclinical Development | IND Filing |

**Intellectual Property**

We are a party to certain license agreements as described below, to build a pipeline of product candidates going forward, we intend to both continue to internally develop new drug candidates with associated intellectual property and to acquire, through in-licensing, additional intellectual property from pharmaceutical and biotechnology companies and research institutions. The in-licensed assets could include both research stage and clinical stage drug candidates.

The current focus of Enveric's intellectual property is in neuroplastogens, including multiple portfolios of psychedelic-inspired compounds and formulations and methods of making, using, and treating mental and neurological disorders. In addition, Enveric has intellectual property related to computer assisted methods of discovering promising novel psychedelic-inspired compounds.

***Psychedelic-Inspired Compounds***

We own rights to 20 active patent families related to compounds that are phenylalkylamine and indolethylamine derivatives. The 20 patent families are represented by a total of 17 issued United States patents and 47 pending United States and non-United States patent applications for treatment of mental disorders, such as depression, anxiety, addiction, and other neuropsychiatric conditions.

The patent portfolio includes the following published and unpublished applications:

- *Glycosylated Psilocybin Derivatives and Methods of Using (WO 2022/040802)*
- *Halogenated Psilocybin Derivatives and Methods of Using (WO2022/047579)*
- *Hydroxylated Psilocybin Derivatives and Methods of Using (WO2022/047580)*
- *Nitrated Psilocybin Derivatives and Methods of Using (WO 2022/047583)*
- *Aminated Psilocybin Derivatives and Methods of Using (WO2023/044556)*
- *Nitrilated Psilocybin Derivatives and Methods of Using (WO2022/104475)*
- *Carboxylated Psilocybin Derivatives and Methods of Using (WO2022/115944)*
- *Aldehyde and Ketone Derivatives of Psilocybin and Methods of Using (WO2022/115960)*
- *Prenylated Psilocybin Derivatives and Methods of Using (WO2022/155751)*
- *Multi-substituent Psilocybin Derivatives and Methods of Using (WO2022/170438)*
- *N-Heterocycle Substituted Tryptamine Derivatives and Methods of Using (Unpublished PCT/CA2024/050312)*
- *Tri-Halo-Alkoxy-Substituted Tryptamine Derivatives (Unpublished PCT/CA2024/050242)*
- *C-4 Substituted Tryptamine Derivatives and Methods of Using (WO2023/173227)*
- *C-4 Carboxylic Acid Substituted Tryptamine Derivatives and Methods of Using (WO2023/173196)*
- *C-4 Carbanothioate Substituted Tryptamine Derivatives and Methods of Using (WO2023/173197)*
- *Salts of C4-Carboxylic Acid and C4-Carbonothioate-substituted Tryptamine Derivatives and Methods of Using (WO 2023/173229)*
- *Fused Heterocyclic Mescaline Derivatives* (*WO2024/026568A1)*
- *C1-Substituted Isopropylamine Fused Heterocyclic Mescaline Derivatives (WO2024/086933)*
- *Substituted N- Propylamine Fused Heterocyclic Mescaline Derivatives (WO2024/103185)*
- *Substituted Ethylamine Fused Heterocyclic Mescaline Derivatives (WO2024/124353)*

***Cannabinoid Conjugates and Formulations***

We own rights held by our wholly-owned subsidiary Akos Biosciences, Inc. to 2 active patent families related to cannabinoids. One patent family relates to cannabinoid crème formulations for treatment of radiation dermatitis and is licensed to Aries Science & Technology, LLC, and comprises 1 United States patent and 2 pending non-United States patents applications. The other patent family relates to cannabinoid conjugates in combination with COX-2 inhibitors for treatment of pain and joint disease and is the subject of a pending license term sheet with a third party and comprises 3 United States patents, and 3 pending United States and non-United States patent applications.

- *Compositions for topical treatment of radiation dermatitis (WO2023154264)*
- *Cannabinoid Conjugate Molecules (WO2023150057)*

***Diverse Biotech, Inc. In-License***

We hold limited rights to patent applications owned by Diverse Biotech, Inc. for the use of cannabinoids in conjugate form with five existing, standard-of-care drugs (celecoxib and four selected steroids) via Diverse Biotech's patent pending conjugate drug delivery platform. Our rights extend to all fields of use. The intended target for development of such conjugates is alleviating pain, specifically the pain of osteoarthritis, rheumatoid arthritis, and cancer, with the goal of achieving improved and novel therapeutic outcomes for patients.

The in-licensed Diverse Biotech, Inc. portfolio includes two patent families comprising 2 issued United States patents and 13 pending United States and non-United States applications. Those patents and applications disclose conjugate chemistry that combines cannabinoids with existing drugs in conjugate form that we believe will provide differentiation in use and efficacy from combination therapy of drugs and cannabinoids. The license extends for as long as Enveric intends to develop and commercialize the licensed Agents and Products. The patent applications, should they issue, may expire as late as 2040.

**Research & Development**

In view of the urgent need for new and more effective mental health treatments, we intend to combine innovative scientific discoveries and bio-chemical synthesis, along with accelerated clinical development plans to create, develop and progress novel therapies using psychedelic-inspired medications and similar compounds. Our current research and development efforts are focused on developing novel molecules structurally related to certain naturally occurring psychedelics with improved pharmaceutical characteristics. Some of the naturally occurring psychedelic molecules are currently being investigated by researchers around the world as potential treatments for a broad range of psychiatric and neurologic disorders.

***Clinical Studies***

We are currently pursuing drug discovery and preclinical activities in order to advance a number of novel psychedelic-inspired molecules towards the clinic. Enveric's lead development candidate is EB-003. EB-003 is a novel derivative of DMT. It is the lead drug candidate from the EVM301 Series currently advancing through preclinical studies with the aim of initiating first-in-human studies to assess safety and tolerability including non-hallucinogenic properties, followed by clinical trials targeting the treatment of depression or other neuropsychiatric disorders.

We intend to assemble a team of clinical experts and principal investigators with experience across multiple mental health and central nervous system indications to be responsible for the management, monitoring, and integrity of the clinical research.

We plan to submit filings including Clinical Trial Applications ("CTA"), Investigational New Drug ("IND") applications and, eventually, new drug applications ("NDA") to seek approval with the US FDA and with responsible regulatory agencies in other jurisdictions, in connection with our product candidates. The selection, timing, duration, and design of any prospective studies are subject to regulatory filings, approval and finalization of commercial plans.

Our next step is to advance EB-003 into formal preclinical development studies in support of a future IND filing.

***Scientific Advisory Board***

We have established a scientific advisory board and plan to seek advice and input from these experienced clinical leaders on matters related to our research and development programs. The members of our scientific advisory board consist of experts across a range of key disciplines relevant to our programs. We intend to continue to leverage the broad expertise of our advisors by seeking their counsel on important topics relating to our product development and clinical development programs.

Our scientific advisors are not our employees and do have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. In addition, our scientific advisors may have arrangements with other companies to assist those companies in developing products or technologies that may compete with us. All of our scientific advisors are affiliated with other entities and devote a limited portion of their time to us.

Enveric's current scientific advisors are set forth in the table below:

| Name | Title | Specialization |
|---|---|---|
| Maurizio Fava, M.D. | Executive Director of the Clinical Trials Network and Institute | Clinical Research |
| Stephen M. Stahl, M.D., Ph.D. | Director of Psychopharmacology for the California Department of State Hospitals | Clinical Research |
| John Krystal, M.D. | Director of Yale Center for Clinical Investigation | Clinical Research |
| Michael Liebowitz, M.D. | Professor of Psychiatry; Director at Medical Research Network | Clinical Research |

*Maurizio Fava, M.D.* has served as a Scientific Advisor of Enveric since 2022. Dr. Maurizio Fava is Chair, Mass General Brigham Academic Centers Psychiatry Department, Psychiatrist-in-Chief of the Massachusetts General Hospital (MGH), executive director of the Clinical Trials Network and Institute, (MGH), associate dean for clinical and translational research, and the Slater Family Professor of Psychiatry at Harvard Medical School. Dr. Fava is a world leader in the field of depression. He has edited eight books and authored or co-authored more than 900 original articles published in medical journals with international circulation, articles which have been cited more than 95,000 times in the literature and with an H index

greater than 150. Dr. Fava founded and was director of MGH's Depression Clinical and Research Program from 1990 until 2014. Under Dr. Fava's direction, the Depression Clinical and Research Program became one of the most highly regarded depression programs in the country, a model for academic programs that link, in a bi-directional fashion, clinical and research work. In 2007, he also founded and is now the executive director of the MGH Psychiatry Clinical Trials Network and Institute, the first academic CRO specialized in the coordination of multi-center clinical trials in psychiatry.

*Stephen M. Stahl, M.D., Ph.D.* has served as a Scientific Advisor of Enveric since 2022. Dr. Stephen Stahl has held faculty positions at Stanford University, the University of California at Los Angeles, the Institute of Psychiatry London, the Institute of Neurology London, and, currently, as Clinical Professor of Psychiatry and Neuroscience at the University of California Riverside, Adjunct Professor of Psychiatry at the University of California San Diego and as Honorary Fellow in Psychiatry at the University of Cambridge. Dr. Stahl serves as editor-in-chief of CNS Spectrums and is Senior Academic Advisor and Director of Psychopharmacology for the California Department of State Hospitals (DSH) where he has a leadership role in addressing violence and decriminalization of the seriously mentally ill. Author of over 575 articles and chapters with an H index of 69, and more than 2000 scientific presentations and abstracts, Dr. Stahl is an internationally renowned clinician, researcher, and teacher in psychiatry with subspecialty expertise in psychopharmacology. Dr. Stahl has written over 50 textbooks and edited 15 others, including the best-selling and award-winning textbook, Stahl's Essential Psychopharmacology, now in its fifth edition, and the best-selling and award-winning clinical manual, Essential Psychopharmacology Prescriber's Guide, now in its seventh edition.

*John Krystal, M.D.* has served as a Scientific Advisor of Enveric since 2022. Dr. John Krystal is the Robert L. McNeil, Jr., Professor of Translational Research; Professor of Psychiatry, Neuroscience, and Psychology; Chair of the Department of Psychiatry at Yale University; and Chief of Psychiatry and Behavioral Health at Yale-New Haven Hospital. He is a graduate of the University of Chicago, Yale School of Medicine, and the Yale Psychiatry Residency Training Program. He has published extensively on the neurobiology and treatment of schizophrenia, alcoholism, PTSD, and depression. Notably, his laboratory discovered the rapid antidepressant effects of ketamine in humans. Dr. Krystal directs/co-directs the Yale Center for Clinical Investigation (CTSA), NIAAA Center for the Translational Neuroscience of Alcoholism, and Clinical Neuroscience Division of the National Center for PTSD (VA). He is a member of the U.S. National Academy of Medicine; co-director of the Neuroscience Forum of the U.S. National Academies of Sciences, Engineering, and Medicine; Fellow of the American Association for the Advancement of Science (AAAS); and editor of Biological Psychiatry (IF=13.382). Previously, Dr. Krystal chaired the NIMH Board of Scientific Counselors and has served as a member of the NIMH National Mental Health Advisory Council and the NIAAA National Alcohol Advisory Council. He also previously served as the president of the American College of Neuropsychopharmacology (ACNP) and the International College of Neuropsychopharmacology (CINP).

*Michael Liebowitz, M.D.* has served as a Scientific Advisor of Enveric since 2022. Dr. Michael Liebowitz is a Professor of Psychiatry at Columbia University and New York State Psychiatric Institute (NYSPI) and is currently Director at Medical Research Network where he is engaged in clinical trials for depression, anxiety, binge eating, ADHD, PTSD, and borderline personality disorders. Dr. Liebowitz completed his fellowship in psychopharmacology at the Depression Evaluation Service at NYSPI, where he helped develop and validate the DSM criteria for atypical depression. Dr. Liebowitz established the Anxiety Disorders Clinic at NYSPI, the first research clinic to specialize in anxiety disorders in the United States. Over the next two decades, Dr. Liebowitz and colleagues helped refine treatments for panic disorder, broadened the diagnostic criteria and established medication treatment for social anxiety disorder, and collaborated in clinical trials comparing medications and behavioral treatments for several anxiety disorders. Dr. Liebowitz developed the Liebowitz Social Anxiety Scale (LSAS) which has been the primary outcome measure for several registration programs in social anxiety disorder and is used worldwide as a research and clinical measure.

***Academic Partners***

We have also established relationships with certain academic partners, who we believe have the potential to accelerate our product development, market entry, data collection, analysis and advancement of clinical trials.

Our primary academic partner is the University of Calgary which brings excellence into advancing brain and mental health research and education.

**Competition**

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition, and a strong emphasis on proprietary products. While we believe that our scientific knowledge and technology and development experience provide us with competitive advantages, we face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions, governmental agencies, and public and private research institutions. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future.

We intend to focus on the development of novel and viable psychedelic-inspired drug candidates for mental illnesses and unmet medical needs, and partner with pharmaceutical and other drug development and biotechnology companies in developing and commercializing psychedelic-inspired medicines for diverse psychological and neuropsychiatric indications, which will be fundamentally composed of the psychedelic-inspired drug candidates contained in the Psybrary™. While we believe that our technology, knowledge and experience as well as the scientific resources at our disposal provide us with significant competitive advantages, we face potential competition from many different sources. Any product candidates we successfully identify will compete not only with existing therapies but also new therapies that may become available in the future

Our commercial opportunities could be reduced or eliminated if our competitors develop and commercialize medicines that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any product candidates that we may develop. Our competitors also may obtain approval from the FDA or other regulatory agencies for their medicines more rapidly than us, which could result in our competitors establishing a strong market position before we are able to enter the market.

Regarding our Psybrary™ and the intellectual property kept and developed therein, our success depends on our ability to protect our intellectual property and our ability to achieve and maintain key partnerships aimed at the development, licensing and marketing of psychedelic-inspired medicines without infringing on the proprietary rights of others. Patent positions within the pharmaceutical field can be highly uncertain and involve complex legal, scientific and factual questions for which important legal principles remain unresolved. Patents issued to us may be challenged, invalidated or circumvented.

**Government Regulation and Product Approvals**

Pharmaceutical companies are subject to extensive regulation by the federal government, principally by the FDA under the Federal Food, Drug and Cosmetic Act, or the FDCA, and, to a lesser extent, by state and local governments. Before our prescription products may be marketed in the U.S., they must be approved by the FDA for commercial distribution. Certain OTC products must comply with applicable FDA regulations, known as OTC Monographs, in order to be marketed, but do not have the benefit of FDA review and approval before marketing. We are also subject to regulation under federal, state and local laws, including requirements regarding occupational safety, laboratory practices, environmental protection and hazardous substance control, and may be subject to other present and future local, state, federal and foreign regulations. We cannot predict the extent to which we may be affected by legislative and other regulatory developments concerning our products and the healthcare industry in general.

The FDCA and other federal and state statutes and regulations govern the testing, manufacture, quality control, export and import, labeling, storage, record keeping, approval, pricing, advertising, promotion, sale and distribution of pharmaceutical products. Noncompliance with applicable requirements both before and after approval, can subject us, our third party manufacturers and other collaborative partners to administrative and judicial sanctions, such as, among other things, warning letters, fines and other monetary payments, recall or seizure of products, criminal proceedings, suspension or withdrawal of regulatory approvals, interruption or cessation of clinical trials, total or partial suspension of production or distribution, injunctions, limitations on or the limitation of claims we can make for our products, and refusal of the government to enter into supply contracts for distribution directly by governmental agencies, or delay in approving or refusal to approve new drug applications. The FDA also has the authority to revoke or withhold approvals of new drug applications.

FDA approval is required before any "new drug," can be marketed. Our products are new drugs and require prior FDA approval. Such approval must be based on extensive information and data submitted in a NDA, including, but not limited to, adequate and well controlled laboratory and clinical investigations to demonstrate the safety and effectiveness of the drug product for its intended use(s) as well as the manufacturing suitability of the product. In addition to providing required safety and effectiveness data for FDA approval, a drug manufacturer's practices and procedures must comply with current Good Manufacturing Practices ("cGMPs"), which apply to manufacturing, receiving, holding and shipping, and include, among other things, demonstration of product purity, consistent manufacturing and quality and at least six months of data supporting product expiration dating based on clinical registration batches. Accordingly, manufacturers must continue to expend time, money and effort in all applicable areas relating to quality assurance and regulatory compliance, including production and quality control to comply with cGMPs. Failure to so comply risks delays in approval of drug products and possible FDA enforcement actions, such as an injunction against shipment of products, the seizure of non-complying products, criminal prosecution and/or any of the other possible consequences described above. We are subject to periodic inspection by the FDA and the Drug Enforcement Administration ("DEA"), which inspections may or may not be announced in advance.

The intellectual property kept and developed in our Psybrary™ is focused solely on developing and commercializing non-hallucinogenic synthetic derivatives of psychedelic substances. While we use psychedelic-inspired compounds and classic psychedelics as our starting point for our research and identification of compounds, we do not have any direct or indirect involvement in the illegal selling, production or distribution of any substances in the jurisdictions in which we operate. Enveric is a neuro-pharmaceutical scientific company and as such we do not advocate for the legalization of psychedelic substances nor do we deal with psychedelic substances except within laboratory and clinical trial settings conducted within approved regulatory frameworks. Our products will not be commercialized prior to applicable regulatory approval and this approval will only be granted if clinical evidence of safety and efficacy for the specific intended use is successfully developed.

Successful execution of our strategy is in part contingent upon compliance with regulatory requirements enacted by governmental authorities and obtaining regulatory approvals for the development and license of our psychedelic-inspired drug candidates. The psychedelic-inspired medicine industry is a new and emerging industry with ambiguous existing regulations and uncertainty as to future regulations; we cannot predict the impact of the ever-evolving compliance regime in respect of this industry. The impact of compliance regimes, any delays in obtaining, or failure to obtain regulatory approvals may significantly delay or impact our development of markets, our business, psychedelic-inspired medicines, and licensing initiatives and could have a material adverse effect on our business, financial condition and operating results.

***FDA New Drug Approval Process***

In the U.S., pharmaceutical products are subject to extensive regulation by the FDA. The Federal Food, Drug, and Cosmetic Act, or the FDCA, 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 imposition of clinical holds, FDA refusal to approve pending NDAs, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement, civil penalties and criminal prosecution.

Pharmaceutical product development in the U.S. typically involves pre-clinical laboratory and animal tests and the submission to the FDA of an IND, which must become effective before clinical testing may commence. For commercial approval, the sponsor must submit adequate tests by all methods reasonably applicable to show that the drug is safe for use under the conditions prescribed, recommended or suggested in the proposed labeling. The sponsor must also submit substantial evidence, generally consisting of adequate, well-controlled clinical trials to establish that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended or suggested in the proposed labeling. In certain cases, the FDA may determine that a drug is effective based on one clinical study plus confirmatory evidence. Satisfaction of FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity and novelty of the product or disease.

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

A 30-day waiting period after the submission of each IND application is required prior to the commencement of clinical testing in humans. If the FDA has not imposed a clinical hold on the IND application or otherwise commented or questioned the IND application within this 30-day period, the clinical trial proposed in the IND application may begin.

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

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

Clinical trials to support NDAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap. In general, 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 on effectiveness. Phase 2 usually involves trials in a limited patient population to determine the effectiveness of the drug for a particular indication, dosage tolerance and optimum dosage, and to identify common adverse effects and safety risks.

If a compound demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 trials are undertaken to obtain the additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit the FDA to evaluate the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the drug. In most cases, the FDA requires two adequate and well-controlled Phase 3 clinical trials to demonstrate the efficacy of the drug. The FDA may, however, determine that a drug is effective based on one clinical study plus confirmatory evidence. Only a small percentage of investigational drugs complete all three phases and obtain marketing approval. In some cases, the FDA may require post-market studies, known as Phase 4 studies, to be conducted as a condition of approval in order to gather additional information on the drug's effect in various populations and any side effects associated with long-term use. Depending on the risks posed by the drugs, other post-market requirements may be imposed.

After completion of the required clinical testing, an NDA is prepared and submitted to the FDA. The 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 pre-clinical, clinical, and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture, and controls. The cost of preparing and submitting an NDA is substantial. Under federal law, the submission of most NDAs is additionally subject to a substantial application user fee.

The FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review. Under the statute and implementing regulations, the FDA has 180 days (the initial review cycle) from the date of filing to issue either an approval letter or a complete response letter, unless the review period is adjusted by mutual agreement between the FDA and the applicant or as a result of the applicant submitting a major amendment. In practice, the performance goals established pursuant to the Prescription Drug User Fee Act have effectively extended the initial review cycle beyond 180 days. The FDA's current performance goals call for the FDA to complete review of 90 percent of standard (non-priority) NDAs within 10 months of receipt and within six months for priority NDAs, but two additional months of review are added to standard and priority NDAs for a new molecular entity (NME).

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

After the 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 the FDA to reconsider the application. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing 90 percent of resubmissions within two to 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, the FDA may require a risk evaluation and mitigation strategy, or REMS, to help ensure that the benefits of the drug outweigh the potential risks. REMS can include medication guides, communication plans for health care professionals, and elements to assure safe use, or 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.

***Disclosure of Clinical Trial Information***

Sponsors of clinical trials of certain FDA-regulated products, including prescription drugs, are required to register and disclose certain clinical trial information on a public website maintained by the U.S. National Institutes of Health. Information related to the product, patient population, phase of investigation, study sites and investigator, and other aspects of the clinical trial is made public as part of the registration. Sponsors are also obligated to disclose the results of these trials after completion. Disclosure of the results of these trials can be delayed for up to two years if the sponsor certifies that it is seeking approval of an unapproved product or that it will file an application for approval of a new indication for an approved product within one year. Competitors may use this publicly available information to gain knowledge regarding the design and progress of our development programs.

***Special Protocol Assessment***

A company may reach an agreement with the FDA under the Special Protocol Assessment, or "SPA", process as to the required design and size of clinical trials intended to form the primary basis of an efficacy claim. According to its performance goals, the FDA is supposed to evaluate the protocol within 45 days of the request to assess whether the proposed trial is adequate, and that evaluation may result in discussions and a request for additional information. A SPA request must be made before the proposed trial begins, and all open issues must be resolved before the trial begins. If a written agreement is reached, it will be documented and made part of the administrative record. Under the FDCA and FDA guidance implementing the statutory requirement, an SPA is generally binding upon the FDA except in limited circumstances, such as if the FDA identifies a substantial scientific issue essential to determining safety or efficacy after the study begins, public health concerns emerge that were unrecognized at the time of the protocol assessment, the sponsor and the FDA agree to the change in writing, or if the study sponsor fails to follow the protocol that was agreed upon with the FDA.

***Advertising and Promotion***

Pre-approval promotion of investigational drug candidates is prohibited by the FDA. Therefore, sponsors must ensure that any pre-approval communications disseminated about its drug candidates do not state or imply that such candidates have been proven safe or effective for the applicable use(s) or that they have been approved for commercialization in the United States. Further, once an NDA for a given candidate is approved, if ever, the product will be subject to certain post-approval requirements. For instance, the FDA closely regulates the post-approval marketing and promotion of drugs.

Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved labeling. 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 the FDA uses the same procedures and actions in reviewing NDA supplements as it does in reviewing NDAs.

***Adverse Event Reporting and GMP Compliance***

Adverse event reporting and submission of periodic reports is required following FDA approval of an NDA. The FDA also may require post-marketing testing, known as Phase 4 testing, may require under a REMS special communication regarding the safety of the drug or heightened surveillance to monitor the effects of an approved product, or the FDA may place conditions on an approval that could restrict the distribution or use of the product. In addition, quality-control, drug manufacture, packaging, and labeling procedures must continue to conform to GMP, after approval. Drug manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies. Registration with the FDA subjects entities to periodic unannounced inspections by the FDA, during which the agency inspects

manufacturing facilities to assess compliance with GMP. Accordingly, manufacturers must continue to expend time, money and effort in the areas of production and quality control to maintain compliance with GMP. 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.

***Pediatric Exclusivity and Pediatric Use***

The Best Pharmaceuticals for Children Act, or "BPCA", provides NDA holders a six-month period of exclusivity attached to any other exclusivity listed with the FDA — patent or non-patent — for a drug, if certain conditions are met. Conditions for pediatric exclusivity include a determination by the FDA that information relating to the use of a new drug in the pediatric population may produce health benefits in that population; a written request by the FDA for pediatric studies; and agreement by the applicant to perform the requested studies and the submission to the FDA, completion of the studies in accordance with the written request, and the acceptance by the FDA, of the reports of the requested studies within the statutory time frame. Applications under the BPCA are treated as priority applications.

In addition, under the Pediatric Research Equity Act, or "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, unless the sponsor has received a deferral or waiver from the FDA. Unless otherwise required by regulation, PREA does not apply to any drug for an indication for which orphan designation has been granted. The sponsor or the FDA may request a deferral of pediatric studies for some or all of the pediatric subpopulations. A deferral may be granted for several reasons, including a finding that the drug is ready for approval for use in adults before pediatric studies are complete or that additional safety or effectiveness data need to be collected before the pediatric studies begin. Under PREA, the FDA must send a noncompliance letter requesting a response within 45 days to any sponsor that fails to submit the required assessment, keep a deferral current or fails to submit a request for approval of a pediatric formulation.

***Controlled Substances***

The federal Controlled Substances Act of 1970, or "CSA", and its implementing regulations establish a "closed system" of regulations for controlled substances. The CSA imposes registration, security, recordkeeping and reporting, storage, manufacturing, distribution, importation and other requirements under the oversight of the Drug Enforcement Agency ("DEA"). The DEA is the federal agency responsible for regulating controlled substances, and requires those individuals or entities that manufacture, import, export, distribute, research, or dispense controlled substances to comply with the regulatory requirements in order to prevent the diversion of controlled substances to illicit channels of commerce.

The DEA categorizes controlled substances into one of five schedules — Schedule I, II, III, IV or V — with varying qualifications for listing in each schedule. 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. Marijuana and psychedelics such as psilocybin, DMT, mescaline and MDMA are currently Schedule I controlled substances, which means that no preclinical or clinical studies of product candidates containing these substances may be conducted in the United States without the required DEA registration(s) and related approvals, as applicable. Pharmaceutical products having a currently accepted medical use that are otherwise approved for marketing may be listed as Schedule II, III, IV or V substances, with Schedule II substances presenting the highest potential for abuse and physical or psychological dependence, and Schedule V substances presenting the lowest relative potential for abuse and dependence.

Facilities that manufacture, distribute, import, or export any controlled substance must register annually with the DEA. The DEA registration is specific to the particular location, activity(ies) and controlled substance schedule(s). For example, separate registrations are required for importation and manufacturing activities, and each registration authorizes which schedules of controlled substances the registrant may handle. However, certain coincidental activities are permitted without obtaining a separate DEA registration, such as distribution of controlled substances by the manufacturer that produces them.

The DEA inspects all manufacturing facilities to review security, recordkeeping, reporting, and handling prior to issuing a controlled substance registration. The specific security requirements vary by the type of business activity and the schedule and quantity of controlled substances handled. The most stringent requirements apply to manufacturers of Schedules I and Schedule II substances. Required security measures commonly include background checks on employees and physical control of controlled substances through storage in approved vaults, safes and cages, and through use of alarm systems and surveillance cameras. An application for a manufacturing registration as a bulk manufacturer (not a dosage form manufacturer or a repacker/relabeler) for a Schedule I or II substance must be published in the Federal Register, and is open for 60 days to

permit interested persons to submit comments, objections or requests for a hearing. A copy of the notice of the Federal Register publication is simultaneously forwarded by DEA to all those registered, or applicants for registration, as bulk manufacturers of that substance.

Once registered, manufacturing facilities must maintain records documenting the manufacture, receipt and distribution of all controlled substances. Manufacturers must submit periodic reports to the DEA of the distribution of Schedules I and II controlled substances, Schedule III narcotic substances, and other designated substances. Registrants must also report any controlled substance thefts or significant losses, and must obtain authorization to destroy or dispose of controlled substances.

As with applications for registration as a bulk manufacturer, an application for an importer registration for a Schedule I or II substance must also be published in the Federal Register, which remains open for 30 days for comments. Imports of Schedules I and II controlled substances for commercial purposes are generally restricted to substances not already available from a domestic supplier or where there is not adequate competition among domestic suppliers. In addition to an importer or exporter registration, importers and exporters must obtain a permit for every import or export of a Schedules I and II substance or Schedules III, IV and V narcotic, and submit import or export declarations for Schedules III, IV and V non-narcotics. In some cases, Schedule III non-narcotic substances may be subject to the import/export permit requirement, if necessary to ensure that the U.S. complies with its obligations under international drug control treaties.

For drugs manufactured in the U.S., the DEA establishes annually an aggregate quota for the amount of substances within Schedules I and II that may be manufactured or 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 states also maintain separate controlled substance laws and regulations, including licensing, recordkeeping, security, distribution, and dispensing requirements. State Authorities, including Boards of Pharmacy, regulate use of controlled substances in each state. Failure to maintain compliance with applicable requirements, particularly as manifested in the loss or diversion of controlled substances, can result in enforcement action that could have a material adverse effect on our business, operations and financial condition. The DEA may seek civil penalties, refuse to renew necessary registrations, or initiate proceedings to revoke those registrations. In certain circumstances, violations could lead to criminal prosecution.

*Europe/Rest of World Government Regulation*

In addition to regulations in the U.S., we are and will be subject, either directly or through our distribution partners, to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales (including pricing and reimbursement) and distribution of our product candidates, if approved.

Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in non-U.S. countries prior to the commencement of clinical trials or marketing of the product in those countries.

In the European Union, medicinal products are subject to extensive pre- and post-marketing regulation by regulatory authorities at both the European Union and national levels. Additional rules also apply at the national level to the manufacture, import, export, storage, distribution and sale of controlled substances. In many European Union member states the regulatory authority responsible for medicinal products is also responsible for controlled substances. Responsibility is, however, split in some member states. Generally, any company manufacturing or distributing a medicinal product containing a controlled substance in the European Union will need to hold a controlled substances license from the competent national authority and will be subject to specific record-keeping and security obligations. Separate import or export certificates are required for each shipment into or out of the member state.

*Clinical Trials and Marketing Approval*

Whether or not we obtain FDA approval for a product, we would need to obtain the necessary approvals by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others.

Certain countries outside of the U.S. have a process that requires the submission of a clinical trial application much like an IND application prior to the commencement of human clinical trials. In Europe, for example, a clinical trial application, or "CTA", must be submitted to the competent national health authority and to independent ethics committees in each country in which a company intends to conduct clinical trials. Once the CTA is approved in accordance with a country's requirements and a company has received favorable ethics committee approval, clinical trial development may proceed in that country.

The requirements and process governing the conduct of clinical trials, product licensing, pricing, and reimbursement vary from country to country, even though there is already some degree of legal harmonization in the European Union member states resulting from the national implementation of underlying European Union legislation. In all cases, the clinical trials must be conducted in accordance with the International Conference on Harmonization, or "ICH", guidelines on GCP and other applicable regulatory requirements.

To obtain regulatory approval to place a drug on the market in European Union countries, Enveric must submit a marketing authorization application. This application is similar to the NDA in the U.S., with the exception of, among other things, country-specific document requirements. All application procedures require an application in the common technical document, or CTD, format, which includes the submission of detailed information about the manufacturing and quality of the product, and nonclinical and clinical trial information. Drugs can be authorized in the European Union by using (i) the centralized authorization procedure, (ii) the mutual recognition procedure, (iii) the decentralized procedure, or (iv) national authorization procedures.

The European Commission created the centralized procedure for the approval of human drugs to facilitate marketing authorizations that are valid throughout the European Union and, by extension (after national implementing decisions) in Iceland, Liechtenstein and Norway, which, together with the European Union Member States, comprise the European Economic Area, or "EEA". Applicants file marketing authorization applications with the EMA (European Medicines Agency), where they are reviewed by a relevant scientific committee, in most cases the Committee for Medicinal Products for Human Use (the "CHMP"). The EMA forwards CHMP opinions to the European Commission, which uses them as the basis for deciding whether to grant a marketing authorization. This procedure results in a single marketing authorization granted by the European Commission that is valid across the European Union, as well as in Iceland, Liechtenstein and Norway. The centralized procedure is compulsory for human drugs that are: (i) derived from biotechnology processes, such as genetic engineering, (ii) contain a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative diseases, autoimmune and other immune dysfunctions and viral diseases, (iii) officially designated "orphan drugs" (drugs used for rare human diseases), and (iv) advanced-therapy medicines, such as gene-therapy, somatic cell-therapy or tissue-engineered medicines. The centralized procedure may at the voluntary request of the applicant also be used for human drugs that do not fall within the above-mentioned categories if the CHMP agrees that the human drug (a) contains a new active substance not yet approved on November 20, 2005; (b) constitutes a significant therapeutic, scientific or technical innovation, or (c) authorization under the centralized procedure is in the interests of patients at the European Union level.

Under the centralized procedure in the European Union, the maximum time frame for the evaluation of a marketing authorization application by the EMA is 210 days (excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP), with adoption of the actual marketing authorization by the European Commission thereafter.

Accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of a major public health interest from the point of view of therapeutic innovation, defined by three cumulative criteria: the seriousness of the disease to be treated; the absence of an appropriate alternative therapeutic approach, and anticipation of exceptional high therapeutic benefit. In this circumstance, EMA ensures that the evaluation for the opinion of the CHMP is completed within 150 days and the opinion issued thereafter.

For those medicinal products for which the centralized procedure is not available, the applicant must submit marketing authorization applications to the national medicines regulators through one of three procedures: (i) the mutual recognition procedure (which must be used if the product has already been authorized in at least one other European Union member state, and in which the European Union member states are required to grant an authorization recognizing the existing authorization in the other European Union member state, unless they identify a serious risk to public health), (ii) the decentralized procedure (in which applications are submitted simultaneously in two or more European Union member states), or (iii) national authorization procedures (which results in a marketing authorization in a single European Union member state).

***Mutual Recognition Procedure***

The mutual recognition procedure, or "MRP", for the approval of human drugs is an alternative approach to facilitate individual national marketing authorizations within the European Union. Fundamentally, the MRP may be applied for all human drugs for which the centralized procedure is not obligatory. The MRP is applicable to the majority of conventional medicinal products, and must be used if the product has already been authorized in one or more European Union member states.

The MRP functions by building on an already-existing marketing authorization in a member state of the European Union which is used as a reference in order to obtain marketing authorizations in other European Union member states. Under the MRP, if a marketing authorization for a drug already exists in one or more member states of the European Union and subsequently marketing authorization applications are made in other European Union member states by referring to the initial marketing authorization. The member state in which the marketing authorization was first granted will then act as the reference member state. The member states where the marketing authorization is subsequently applied for act as concerned member states. The concerned member states are required to grant an authorization recognizing the existing authorization in the reference member state, unless they identify a serious risk to public health.

The MRP is based on the principle of the mutual recognition by European Union member states of their respective national marketing authorizations. Based on a marketing authorization in the reference member state, the applicant may apply for marketing authorizations in other member states. In such case, the reference member state shall update its existing assessment report about the drug in 90 days. After the assessment is completed, copies of the report are sent to all member states, together with the approved summary of product characteristics, labeling and package leaflet. The concerned member states then have 90 days to recognize the decision of the reference member state and the summary of product characteristics, labeling and package leaflet. National marketing authorizations shall be granted within 30 days after acknowledgement of the agreement.

Should any European Union member state refuse to recognize the marketing authorization by the reference member state, on the grounds of potential serious risk to public health, the issue will be referred to a coordination group. Within a time frame of 60 days, member states shall, within the coordination group, make all efforts to reach a consensus. If this fails, the procedure is submitted to an EMA scientific committee for arbitration. The opinion of this EMA Committee is then forwarded to the European Commission, for the start of the decision-making process. As in the centralized procedure, this process entails consulting various European Commission Directorates General and the Standing Committee on Human Medicinal Products.

***Data Exclusivity***

In the European Union, marketing authorization applications for generic medicinal products do not need to include the results of pre-clinical and clinical trials, but instead can refer to the data included in the marketing authorization of a reference product for which regulatory data exclusivity has expired. If a marketing authorization is granted for a medicinal product containing a new active substance, that product benefits from eight years of data exclusivity, during which generic marketing authorization applications referring to the data of that product may not be accepted by the regulatory authorities, and a further two years of market exclusivity, during which such generic products may not be placed on the market. The two-year period may be extended to three years if during the first eight years a new therapeutic indication with significant clinical benefit over existing therapies is approved.

***Orphan Medicinal Products***

The EMA's Committee for Orphan Medicinal Products ("COMP") may recommend orphan medicinal product designation to promote the development of products that are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions affecting not more than 5 in 10,000 persons in the European Union. Additionally, designation is granted for products intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition and when, without incentives, it is unlikely that sales of the product in the European Union would be sufficient to justify the necessary investment in developing the medicinal product. The COMP may only recommend orphan medicinal product designation when the product in question offers a significant clinical benefit over existing approved products for the relevant indication. Following a positive opinion by the COMP, the European Commission adopts a decision granting orphan status. The COMP will reassess orphan status in parallel with EMA review of a marketing authorization application and orphan status may be withdrawn at that stage if it no longer fulfills the orphan criteria (for instance because in the meantime a new product was approved for the indication and no convincing data are available to demonstrate a significant benefit over that product). Orphan medicinal product designation entitles a party to financial incentives such as reduction of fees or fee waivers and ten years of market exclusivity is granted following marketing

authorization. During this period, the competent authorities may not accept or approve any similar medicinal product, unless it offers a significant clinical benefit. This period may be reduced to six years if the orphan medicinal product designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity.

***Pediatric Development***

In the European Union, companies developing a new medicinal product must agree to a Pediatric Investigation Plan, or "PIP", with the EMA and must conduct pediatric clinical trials in accordance with that PIP unless a waiver applies, for example, because the relevant disease or condition occurs only in adults. The marketing authorization application for the product must include the results of pediatric clinical trials conducted in accordance with the PIP, unless a waiver applies, or a deferral has been granted, in which case the pediatric clinical trials must be completed at a later date. Products that are granted a marketing authorization on the basis of the pediatric clinical trials conducted in accordance with the PIP are eligible for a six-month extension of the protection under a supplementary protection certificate (if the product covered by it qualifies for one at the time of approval). This pediatric reward is subject to specific conditions and is not automatically available when data in compliance with the PIP are developed and submitted.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension of clinical trials, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

In addition, most countries are parties to the Single Convention on Narcotic Drugs 1961, which governs international trade and domestic control of narcotic substances. Countries may interpret and implement their treaty obligations in a way that creates a legal obstacle to us obtaining marketing approval for our product candidates in those countries. These countries may not be willing or able to amend or otherwise modify their laws and regulations to permit our product candidates to be marketed, or achieving such amendments to the laws and regulations may take a prolonged period of time. In that case, we would be unable to market our product candidates in those countries in the near future or perhaps at all.

**Employees**

We have consolidated our employee base to save capital and focus on development of our leading candidates EB-003. As of the date of this report, we employ five full-time employees and one part-time employee. We also work with scientific advisors, consultants and service providers, mainly through academic institutions and contract research organizations.

We have never had a work stoppage and none of its employees are covered by collective bargaining agreements or represented by a labor union. We believe that we have good relationships with our employees.

**Item 1A. Risk factors**

**Risks Related to Our Business and Financial Condition**

***Our management and independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern as of December 31, 2024. We will be unable to continue to operate for the foreseeable future without additional capital.***

Our independent registered public accounting firm issued a report dated March 28, 2025 in connection with the audit of our consolidated financial statements as of December 31, 2024, which included an explanatory paragraph describing the existence of conditions that raise substantial doubt about our ability to continue as a going concern including our recurring losses, cash used in operations, and need to raise additional funds to meet our obligations and sustain our operations. In addition, the notes to our financial statements for the year ended December 31, 2024, included in this Annual Report on Form 10-K, contain a disclosure describing the existence of conditions that raise substantial doubt about our ability to continue as a going concern. Our ability to continue as a going concern is dependent upon our ability to obtain substantial additional funding in connection with our continuing operations. Adequate additional financing may not be available to us in the necessary timeframe, in the amounts we require, on terms that acceptable to us, or at all. If we are unable to raise additional capital our business, prospectus, financial condition and results of operations will be materially and adversely affected and we may be unable to continue as a going concern. If we are not able to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our consolidated financial statements and/or seek protection under federal bankruptcy law, and it is likely that holders of our common stock and holders of securities convertible into our common stock will lose all of their investment. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding on commercially reasonable terms or at all.

As such, there is uncertainty regarding our ability to maintain liquidity sufficient to operate our business effectively, which raises substantial doubt about our ability to continue as a going concern.

***We are dependent on the success of our prospective product candidates, which are in early stages of development, and there can be no assurances that any such prospects will reach a particular stage in development, receive regulatory approval or be successfully commercialized.***

Our success will depend on our ability to successfully develop and commercialize our prospective product candidates through our development programs. We intend to develop at least one product candidate, EB-003, by undergoing the long, costly clinical-trial process under an IND application and, eventually, obtaining FDA approval under an NDA before proceeding to market. In order to proceed with development of our pharmaceutical product candidates under the NDA pathway, we must obtain the FDA's approval of our IND application and conduct preclinical and clinical trials in compliance with the applicable IND regulations, clinical-study protocols, and other applicable regulations and related requirements. We may never be able to develop products which are commercially viable or receive regulatory approval in the U.S. or elsewhere. There can be no assurance that the FDA or any other regulatory authority will approve of our current or future product candidates.

In the United States, the FDA regulates drugs under the Federal Food, Drug and Cosmetic Act, or "FDCA," and implementing regulations. Drugs are also subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. The process required by the FDA before a new drug or biological product may be marketed in the United States generally involves the following:

- Completion of preclinical laboratory tests, animal studies, and formulation studies according to Good Laboratory Practices and other applicable regulations;
- Submission to the FDA of an IND application, which must become effective before human clinical trials may begin in the United States;
- Performance of adequate and well-controlled human clinical trials according to the FDA's current good clinical practices, or GCPs, which sufficiently demonstrate the safety and efficacy of the proposed drug or biologic for its intended uses;
- Submission to the FDA of a New Drug Application, or an NDA, for a new drug product;
- Satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the drug or biologic is to be produced to assess compliance with the FDA's current good manufacturing practice standards, or cGMP, to assure that the facilities, methods and controls are adequate to preserve the drug's or biologic's identity, strength, quality and purity;
- Potential FDA audit of the nonclinical and clinical trial sites that generated the data in support of the NDA or biologics license application; and
- FDA review and, potentially, approval of the NDA.

The lengthy process of seeking required approvals and the continuing need for compliance with applicable statutes and regulations require the expenditure of substantial resources. There can be no certainty that approvals will be granted.

***We may encounter difficulties that may delay, suspend or scale back our efforts to advance additional early research programs through preclinical development and IND application filings and into clinical development.***

We intend to advance early research programs through preclinical development and to file an IND application for human clinical trials evaluating the prospective product candidates in our pipeline. The preparation and submission of IND applications requires rigorous and time-consuming preclinical testing, the results of which must be sufficiently documented to establish, among other things, the toxicity, safety, manufacturing, chemistry and clinical protocol of the product candidates. We may experience unforeseen difficulties that could delay or otherwise prevent us from successfully executing our current development strategy. In addition, our ability to complete and file certain IND applications may depend on the support of our partners and the timely performance of their obligations under relevant collaboration agreements. If our relevant partners are not able to perform such obligations, or if they otherwise delay the progress, we may not be able to prepare and file the intended IND applications on a timely basis or at all. Any delay, suspension or reduction of our efforts to pursue our preclinical and IND strategy could have a material adverse effect on our business and cause our share price to decline.

***Catastrophic events could have a material adverse effect on our business, including current plans for product development, as well as any currently ongoing preclinical studies and clinical trials and any future studies or other development or commercialization activities.***

Our operations and business could be disrupted by natural disasters; industrial accidents; public health issues and global pandemics such as COVID 19; cybersecurity incidents; interruptions of service from utilities, transportation restrictions or disruptions, telecommunications, or IT systems providers; manufacturing equipment failures; geopolitical conflict; tariff wars; terrorism; or other catastrophic events.

Catastrophic events could severely impact our business, including, but not limited to, our current or future preclinical studies, clinical trials, regulatory progress, or any other development or commercialization activities, including (among others):

- delays or difficulties in enrolling patients in clinical trials, specifically since many of the patients are considered immunocompromised;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others;
- limitations in employee resources that would otherwise be focused on the conduct of our clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- delays in receiving approval from local regulatory authorities to initiate our planned clinical trials;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials;
- interruption in global shipping that may affect the transport of clinical trial materials, such as investigational drug product used in our clinical trials
- changes in local regulations as part of a response to a catastrophic event which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;
- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees;
- delay in the timing of interactions with the FDA due to absenteeism by federal employees or by the diversion of their efforts and attention to approval of other therapeutics or other activities related; and
- refusal of the FDA to accept data from clinical trials in affected geographies outside the United States.

In addition, a catastrophic event could disrupt our operations due to absenteeism by infected or ill members of management or other employees, or absenteeism by members of management and other employees who elect not to come to work due to the illness affecting others in our office or laboratory facilities, or due to quarantines. A catastrophic event could also impact members of our board of directors, resulting in absenteeism from meetings of the directors or committees of directors, and making it more difficult to convene the quorums of the full board of directors or our committees needed to conduct meetings for the management of our affairs.

***We have significant and increasing liquidity needs and may require additional funding.***

Research and development, management and administrative expenses and cash used for operations will continue to be significant and may increase substantially in the future in connection with new and continued research and development initiatives and our pursuit of IND authorization(s) for some or all of our product candidates, as is required to initiate clinical trials in human subjects in the United States. We will need to raise additional capital to fund our operations, continue to conduct clinical trials to support potential regulatory approval of marketing applications, and to fund commercialization of our current and future product candidates.

The amount and timing of our future funding requirements will depend on many factors, including, but not limited to:

- the scope, number, initiation, progress, timing, costs, design, duration, delays (if any), and results of preclinical and clinical studies for our current or future product candidates;
- the outcome, timing and cost of regulatory reviews, approvals or other actions to meet regulatory requirements established by the FDA, and comparable foreign regulatory authorities;
- the timing and amount of revenue generated or received, including any revenue from grants or other sources;
- the rate of progress and cost of our clinical trials and other product development programs;
- costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights associated with our current and future product candidates;
- the effect of competing technological and market developments;
- personnel, facilities and equipment requirements; and
- the terms and timing of any additional collaborative, licensing, co-promotion or other arrangements that we may establish.

While we expect to fund our future capital requirements from financing arrangements, we cannot assure you that any such financing arrangements will be available to it on favorable terms, or at all. In the first quarter of 2025, we engaged in a best efforts public offering, which locked-up our ability to issue securities or file registration statements for a period of 60 days following February 3, 2025, and engage in variable-rate transactions for a period of one year following February 3, 2025, each subject to limited exceptions. Even if we can raise funds from financing arrangements, the amounts raised may not be sufficient to meet our future capital requirements. Additionally, the Company does not have sufficient unreserved, authorized shares to secure an equity investment of a sufficient amount, based on the Company's currently traded price per share, and the Company will require shareholder approval to increase the amount of authorized shares. If we are not able to raise capital, we could be required to postpone, scale back or eliminate some, or all, of our development objectives or commercialization efforts.

***We depend on our current key personnel.***

We have consolidated our employee base to save capital and focus on development of our leading candidate EB-003. As of the date of this report, we employ five full-time employees and one part-time employee. We are highly dependent on our current management and scientific personnel, including Joseph Tucker, Peter Facchini, and Kevin Coveney. The inability to hire or retain experienced management personnel could adversely affect our ability to execute our business plan and harm our operating results. Due to the specialized scientific and managerial nature of our business, we rely heavily on our ability to attract and retain qualified scientific, technical and managerial personnel. The competition for qualified personnel in the pharmaceutical field is intense and we may be unable to continue to attract and retain qualified personnel necessary for the development of our business or to recruit suitable replacement personnel.

***There has been limited study on the effects of psychedelic- inspired drug candidates, and future clinical research studies may lead to conclusions that dispute or conflict with our understanding and belief regarding the medical benefits, viability, safety, efficacy, dosing, and social acceptance of psychedelics.***

Research relating to the medical benefits, viability, safety, efficacy, and dosing of psychedelic-inspired drug candidates remains in relatively early stages. There have been few clinical trials on the benefits of psychedelic-inspired drug candidates conducted by us or by others. Future research and clinical trials may draw opposing conclusions to statements contained in the articles, reports and studies we have relied on, or could reach different or negative conclusions regarding the medical benefits, viability, safety, efficacy, dosing or other facts and perceptions related to psychedelic-inspired drug candidates, which could adversely affect social acceptance of such molecules and the demand for our product candidates.

***Our limited resources have lead us to focus on a particular candidate. As a result, we may fail to capitalize on product candidates that may be more profitable or for which there is a greater likelihood of medical and commercial success.***

As a result of our limited financial, managerial and scientific leadership resources we have focused on developing product candidates that we have identified as most likely to succeed. As such, we have elected to forego or delay for the time being the development of other candidates that may prove to have greater potential. Our resource allocation decisions may cause us to fail to capitalize on viable medical solutions, therapeutic enhancements and commercial potentials for viable markets when our spending on our current and future defined candidates with the indications specified therein may not yield any commercially viable products. Inaccurate evaluation of potential may result in relinquishment of valuable product candidate opportunity.

***We expect to face intense competition, often from companies with greater resources and experience than us.***

The pharmaceutical industry is highly competitive, with an emphasis on proprietary products and subject to rapid change. The industry continues to expand and evolve as an increasing number of competitors and potential competitors enter the market. Many of these competitors and potential competitors have substantially greater financial, technological, managerial and research and development resources and experience than us. Some of these competitors and potential competitors have more experience than us in the development of pharmaceutical products, including validation procedures and regulatory matters. In addition, our future product candidates, if successfully developed, will compete with product offerings from large and well-established companies that have greater marketing and sales experience and capabilities than us or our collaboration partners have. Other companies with greater resources than we may announce similar plans in the future. In addition, small or early stage companies may prove to be competitors, particularly through collaborative arrangements with large and established companies. If we are unable to compete successfully, our commercial opportunities will be reduced and our business, results of operations and financial conditions may be materially harmed. In addition, we compete with these companies in recruiting and retaining scientific personnel as well as establishing clinical trial sites and patient registration for clinical trials.

***Our current and future preclinical and clinical studies may be conducted outside the United States, and the FDA may not accept data from such studies to support any NDAs we may submit after completing the applicable developmental and regulatory prerequisites.***

We are conducting, or may conduct, preclinical and/or clinical studies outside the United States. To the extent we do not conduct these clinical trials in accordance under an IND application, the FDA may not accept data from such trials. Although the FDA may accept data from clinical trials conducted outside the United States that are not conducted under an IND application, the FDA's acceptance of the data is subject to certain conditions. For example, the clinical trial must be well designed and conducted and performed by qualified investigators in accordance with ethical principles and all applicable FDA regulations. The trial population must also adequately represent the intended U.S. population, and the data must be applicable to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful. In general, the patient population for any clinical trials conducted outside of the United States must be representative of the population for whom we intend to market the product candidate in the United States, if approved. In addition, while these clinical trials are subject to the applicable local laws, FDA acceptance of the data will be dependent upon our ability to verify the data and our determination that the trials also complied with all applicable U.S. laws and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state and foreign statutes and regulations requires the expenditure of substantial time and financial resources.

We cannot guarantee that the FDA will accept data from trials conducted outside of the United States. If the FDA does not accept the data from such clinical trials, we would likely result in the need for additional trials and the completion of additional regulatory steps, which would be costly and time-consuming and could delay or permanently halt our development of our product candidates.

***Because the results of preclinical studies and earlier clinical trials are not necessarily predictive of future results, we may not have favorable results in our planned and future clinical trials.***

Successful development of therapeutic products is highly uncertain and is dependent on numerous factors, many of which are beyond our control. Drug development involves long lead times and involves many variables of uncertainty. Product candidates that appear promising in the early phases of development may fail to reach the market for several reasons including, without limitation:

- preclinical study results that may show the product to be less effective than desired (e.g., the study failed to meet our primary objectives) or to have harmful or problematic side effects;
- failure to receive the necessary regulatory approvals or a delay in receiving such approvals. Among other things, such delays may be caused by slow enrollment in clinical studies, length of time to achieve study endpoints, additional time requirements for data analysis or an IND and later NDA, preparation, discussions with the FDA, an FDA request for additional preclinical or clinical data or unexpected safety or manufacturing issues;
- manufacturing costs, pricing, or reimbursement issues or other factors that make the product not economical; and
- the proprietary rights of others and their competing products and technologies that may prevent the product from being commercialized.

Any positive results from our preclinical testing of our prospective product candidates may not necessarily be predictive of the results from planned or future clinical trials for such product candidates. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in clinical trials after achieving positive results in preclinical and early clinical development, and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, preclinical findings while clinical trials were underway or safety or efficacy observations in clinical trials, including adverse events. Moreover, our interpretation of clinical data or our conclusions based on the preclinical in vitro and in vivo models may prove inaccurate, as preclinical and clinical data can be susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain FDA or other regulatory approvals. Similarly, undesirable side effects caused by our product candidates could cause us or regulatory authorities to limit dosage in development or interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. Restrictive label applications may include but are not limited to a Boxed Warning, Risk Evaluation and Mitigation Strategies, or REMS, or other limitations of use. Drug-related side effects during one clinical trial furthermore could affect patient recruitment or the ability of enrolled patients to complete the trial, result in potential product liability claims or our ability to ensure enrollment for future trials. Any of these occurrences may harm our business, financial condition and prospects significantly.

***Regulatory approval is limited by the FDA to those specific indications and conditions for which clinical safety and efficacy have been demonstrated, and we may be subject to fines, penalties or injunctions if we are determined to be promoting the use of our products for unapproved or "off-label" uses.***

When the FDA or comparable foreign regulatory authorities issue regulatory approval for a product candidate, the regulatory approval is limited to those specific indications for which a product is approved. If we are not able to obtain FDA approval for any desired future indications for our products and product candidates, our ability to effectively market and sell our products may be reduced and our business may be adversely affected. While physicians may choose to prescribe drugs for uses that are not described in the product's labeling and for uses that differ from those tested in clinical studies and approved by the regulatory authorities, we are prohibited from marketing and promoting the products for indications that are not specifically approved by the FDA.

These "off-label" uses are common across medical specialties and may constitute an appropriate treatment for some patients in varied circumstances. Regulatory authorities in the United States generally do not restrict or regulate the behavior of physicians in their choice of treatment within the practice of medicine. Regulatory authorities do, however, restrict communications by pharmaceutical companies on off-label use. If the FDA determines that our promotional activities constitute promotion of an off-label use, it could request that we modify our promotional materials or subject us to regulatory or enforcement actions by other agencies, including issuance of warning letters, suspension or withdraw an approved product from the market, additional reporting requirements and/or oversight if we become subject to a corporate integrity agreement or similar agreement, any of which could significantly harm our business.

***Business interruptions could delay us in the process of developing our product candidates.***

Loss of our stored materials or facilities through fire, theft, or other causes could have an adverse effect on our ability to continue product development activities and to conduct our business. Even if we obtain insurance coverage to compensate us for such business interruptions, such coverage may prove insufficient to fully compensate us for the damage to our business resulting from any significant property or casualty loss.

***Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and legal requirements.***

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA, SEC or Office of Inspector General of the Department of Health and Human Services, or regulations of any other applicable regulatory authority, failure to provide accurate information to the FDA or the SEC, comply with applicable manufacturing standards, other federal, state or foreign laws and regulations, report information or data accurately or disclose unauthorized activities. Employee misconduct could also involve the improper use of confidential or protected information, including information obtained in the course of clinical trials, or illegal pre-approval promotion of drug candidates, which could result in government investigations, enforcement actions and serious harm to our reputation. We have adopted a Corporate Code of Conduct and Ethics and Whistleblower Policy, but employee misconduct is not always possible to identify and deter.

The precautions we take to detect and prevent these prohibited activities may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending our Company or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

***Our proprietary information, or that of our customers, suppliers and business partners, may be lost or we may suffer security breaches.***

In the ordinary course of our business, we expect to collect and store sensitive data, including valuable and commercially sensitive intellectual property, clinical trial data, our proprietary business information and that of our future customers, suppliers and business partners, and personally identifiable information of our customers, clinical trial subjects and employees, patients, in our data centers and on our networks. The secure processing, maintenance and transmission of this information is critical to our operations. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions.

Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, regulatory penalties, disrupt our operations, damage our reputation, and cause a loss of confidence in our products and our ability to conduct clinical trials, which could adversely affect our business and reputation and lead to delays in gaining regulatory approvals for our future product candidates. Although we may obtain business interruption insurance coverage in the future, our insurance might not cover all losses from any future breaches of our systems.

***Failure of our information technology systems, including cybersecurity attacks or other data security incidents, could significantly disrupt the operation of our business.***

Our business depends on the use of information technologies. Our ability to execute our business plan and to comply with regulators' requirements with respect to data control and data integrity, depends, in part, on the uninterrupted performance of our information technology systems, or IT systems and the IT systems supplied by third-party service providers. Our IT systems are vulnerable to damage from a variety of sources, including telecommunications or network failures, malicious human acts, natural disasters and more sophisticated and targeted cyber-related attacks that pose a risk to the security of our information systems and networks and the confidentiality, availability and integrity of data and information. A successful cybersecurity attack or other data security incident could result in the misappropriation and/or loss of confidential or personal information, create system interruptions, or deploy malicious software that attacks our systems. It is also possible that a cybersecurity attack might not be noticed for some period of time. In addition, sustained or repeated system failures or problems arising during the upgrade of any of our IT systems that interrupt our ability to generate and maintain data could adversely affect our ability to operate our business. The occurrence of a cybersecurity attack or incident could result in business interruptions from the disruption of our IT systems, or negative publicity resulting in reputational damage with our shareholders and other stakeholders and/or increased costs to prevent, respond to or mitigate cybersecurity events. In addition, the unauthorized dissemination of sensitive personal information or proprietary or confidential information could expose us or other third-parties to regulatory fines or penalties, litigation and potential liability, or otherwise harm our business.

***Security breaches, loss of data and other disruptions could compromise sensitive information related to our business, prevent it from accessing critical information or expose it to liability, which could adversely affect our business and its reputation.***

In the ordinary course of our business, we expect to collect and store sensitive data, including legally protected patient health information, credit card information, personally identifiable information about our employees, intellectual property, and proprietary business information. We expect to manage and maintain this data utilizing on-site systems. This data includes a wide variety of business-critical information including research and development information, commercial information and business and financial information.

The secure processing, storage, maintenance and transmission of this critical information is vital to our operations and business strategy, and we devote significant resources to protecting such information. Although we take measures to protect sensitive information from unauthorized access or disclosure, our information technology and infrastructure may be vulnerable to attacks by hackers, or viruses, breaches or interruptions due to employee error, malfeasance or other disruptions, or lapses in compliance with privacy and security mandates. Any such virus, breach or interruption could compromise our networks and the information stored there could be accessed by unauthorized parties, publicly disclosed, lost or stolen. In the future, any such

access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, such as the Health Insurance Portability and Accountability Act (HIPPA) and European Union General Data Protection Regulation, government enforcement actions and regulatory penalties. Unauthorized access, loss or dissemination could also disrupt our operations, including our ability to process samples, provide test results, share and monitor safety data, bill payors or patients, provide customer support services, conduct research and development activities, process and prepare company financial information, manage various general and administrative aspects of our business and may damage our reputation, any of which could adversely affect our business, financial condition and results of operations.

***Our operating results may vary significantly in future periods.***

We are in the early stages of product development and expect to focus substantial efforts for, at least, the next several years on preclinical and clinical trials and other research and development activities. We have not obtained regulatory approval for any product candidates. Our revenues, expenses and operating results are likely to fluctuate significantly in the future. We expect to incur substantial additional operating expenses over the next several years as our research, development, and preclinical and clinical study activities increase. Our financial results are unpredictable and may fluctuate, for among other reasons, due to:

- the scope, number, progress, duration, endpoints, cost, results, and timing of our preclinical testing and clinical studies of current or potential future product candidates;
- our ability to obtain additional funding to develop product candidates; and
- delays in the commencement, enrollment and timing of clinical studies.

A high portion of our costs are predetermined on an annual basis, due in part to our significant research and development costs. Thus, small declines in revenue could disproportionately affect financial results in a quarter.

***Significant ongoing costs and obligations.***

As a neuro-pharmaceutical drug discovery and development platform company, the Company expects to spend substantial funds on the research, development and testing of psychedelic-inspired drug candidates. In addition, the Company expects to incur significant ongoing costs and obligations related to its investment in infrastructure and growth and for regulatory compliance, which could have a material adverse impact on the Company's results of operations, financial condition and cash flows. The Company will also require significant additional funds if it expands the scope of current plans for research and development or if it were to acquire any other assets and advance their development. It is possible that future financing will not be available or, if available, may not be on favorable terms. The availability of financing will be affected by the achievement of the Company's corporate goals, the results of scientific and clinical research, the need and ability to obtain regulatory approvals and the state of the capital markets generally. If adequate funding is not available, the Company may be required to delay, reduce or eliminate one or more of its research and development programs, or obtain funds through corporate partners or others who may require the Company to relinquish significant rights to its psychedelic-inspired drug candidates or obtain funds on less favorable terms than the Company would otherwise accept. To the extent that external sources of capital become limited or unavailable or available on onerous terms, the Company's intangible assets and its ability to continue its business plans may become impaired, and the Company's assets, liabilities, business, financial condition and results of operations may be materially or adversely affected.

In addition, future changes in regulations, changes in legal status of psychedelic and/or psychedelic-inspired products, more vigorous enforcement thereof or other unanticipated events could require extensive changes to the Company's operations, increased compliance costs or give rise to material liabilities, which could have a material adverse effect on the business, results of operations and financial condition of the Company. The Company's efforts to grow its business may be costlier than expected.

***We may rely on third parties to plan and conduct preclinical and clinical trials.***

We may rely on third parties to conduct preclinical development activities and intend to partner with third parties who may conduct clinical development activities with our psychedelic-inspired drug candidates and other product candidates. Preclinical activities include "in vivo" studies providing access to specific disease models, pharmacology and toxicology studies, and assay development. Clinical development activities include trial design, regulatory submissions, clinical patient recruitment, clinical trial monitoring, clinical data management and analysis, safety monitoring and project management. If there is any dispute or disruption in its relationship with third parties, or if such third parties are unable to provide quality services in a timely manner and at a feasible cost, or if such third parties fail to meet certain development milestones, our active development programs may face delays.

Further, if any of these third parties fails to perform as we expect or if their work fails to meet regulatory requirements, the testing and eventual development of viable drug candidates could be delayed, cancelled or rendered ineffective.

***Our reliance on third-party contract manufacturers.***

For completion of the "in vitro" portion of the preclinical testing we intend to conduct, when only lab-grade and lab-scale drug candidate molecules are required, we intend to synthesize the required psychedelic molecules in our laboratories in Calgary or at other third-party contract research organizations ("CROs") that provide synthetic chemistry services. We have limited control over these third-party CROs. When larger quantities and higher quality psychedelic molecules are required (e.g., for animal model testing), we intend to contract with appropriate third-party contract manufacturing organizations ("CMOs"), over which we may have limited control to, among other things, supply the active pharmaceutical ingredient ("API") used in our drug candidates. We intend to rely on CMOs to supply APIs and formulated drug products in compliance with GMP regulations.

All applicable jurisdictions, including Health Canada, and the FDA, ensure the quality of drug candidates by carefully monitoring drug manufacturers' compliance with GMP regulations. The GMP regulations for drug candidates contain minimum requirements for the methods, facilities and controls used in manufacturing, processing and packing of APIs and formulated a drug products. There can be no assurances that CMOs will be able to meet our timetable and requirements or carry out their contractual obligations in accordance with the applicable regulations. In addition, the API and/or formulated drug product that they supply to us may not meet our specifications and quality policies and procedures or they may not be able to supply the API and/or formulated drug product in commercial quantities. If we are unable to arrange for alternative third-party supply sources on commercially reasonable terms or in a timely manner, it may delay the development of our drug candidates and could have a material adverse effect on our business operations and financial condition.

Further, the failure of CMOs to operate in compliance with GMP regulations could result in, among other things, certain product liability claims in the event such failure to comply results in defective products (containing our drug candidates) that caused injury or harm. In general, our dependence upon third parties for the supply of our APIs and formulated drug products may adversely affect profit margins and our ability to develop and deliver viable drug candidates on a timely and competitive basis.

***Termination or non-renewal of key licenses and agreements.***

Our business is highly dependent on key licenses and agreements which expire in a short time period. Specifically, in conducting research and preclinical studies in compliance with current legislation, we substantially rely on the Facchini Drug License, which expires on December 31, 2025. Health Canada renews drug licenses annually and Dr. Facchini has held the Facchini Drug License since October 5, 1995 and it has been renewed each year without issue. Until Enveric obtains its own Dealer's License or Section 56 Exemption necessary for its business, the termination, non-renewal or hindrance of use of the Facchini Drug License would have a material adverse effect on Enveric's ability to develop psychedelic-inspired drug candidate, conduct research or operate its business as it currently does. This could have a material adverse impact on Enveric's financial condition.

***Negative results from clinical trials or studies of others and adverse safety events involving our drug candidates.***

From time to time, studies or clinical trials on various aspects of biopharmaceutical or natural health products ("NHPs") are conducted by academic researchers, competitors or others. The results of these studies or trials, when published, may have a significant effect on the market for the biopharmaceutical or NHP that is the subject of the study. The publication of negative results of studies or clinical trials or adverse safety events related to the psychedelic compounds similar to those used by us in the development of our psychedelic-inspired drug candidates, or the therapeutic areas in which our drug candidates compete, could adversely affect our share price and our ability to finance future development of our drug candidates, and our business and financial results could be materially and adversely affected.

***Clinical trials of our drug candidates may fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or not otherwise produce positive results.***

Before we or third parties (who may license or acquire our drug candidates) are able to obtain marketing approval from regulatory authorities for the sale of products containing our drug candidates, the completion of preclinical studies in animals and extensive clinical trials in humans to demonstrate the safety and efficacy of the drug candidates will be required. Clinical testing is expensive and difficult to design and implement, can take many years to complete and has uncertain

outcomes. The outcome of preclinical studies and early clinical trials may not predict the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. A number of companies in the pharmaceutical, NHP and biotechnology industries have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety profiles, notwithstanding promising results in earlier trials. We do not know whether the clinical trials that we or third parties may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market any products containing our drug candidates in any jurisdiction. A product/compound candidate may fail for safety or efficacy reasons at any stage of the testing process. A major risk we face is the possibility that none of the products containing our drug candidates will successfully gain market approval from Health Canada, the FDA or other regulatory authorities, resulting in our inability to derive any royalty-based revenue from them.

***Raw materials requiring regulatory approval***

Some raw materials used by us will require regulatory approval by Health Canada and the FDA because the plant or fungi may contain a controlled substance. While we believe that we can acquire, or indirectly make use of, the requisite licenses to conduct our intended research and development activities, there is a risk that Health Canada and the FDA can either reject or require further action to approve the requisite licenses which would cause delays or result in losses for us and could result in the abandonment of a specific research programs. Raw materials and supplies are generally available in quantities to meet the needs of our business. An inability to obtain raw materials or product supply could have a material adverse impact on our business, financial condition, and results of operations.

***Possible increase in costs beyond what is currently expected as a result of regulatory review***

Health Canada, the FDA or other regulatory authorities in foreign jurisdictions have not yet determined whether our psychedelic-inspired drug candidates will be scheduled as controlled substances. Based on preclinical and/or clinical abuse liability studies, Health Canada, the FDA or other regulatory authorities may determine that our products are controlled substances and therefore, require additional regulatory controls. Such additional regulatory requirements may increase our costs and cause a delay in our operations. Further, if Health Canada, the FDA or other regulatory authorities require that we perform additional preclinical or clinical studies, or if we determine that additional preclinical or clinical studies are required for our drug candidates, our expenses would further increase beyond what is currently expected and the anticipated timing of any potential approval of our drug candidates or licensing out agreements would likely be delayed.

***We have never been profitable, have no products approved for commercial sale, and to date have not generated any revenue.***

We have never been profitable and we do not expect to be profitable in the foreseeable future. Neither us, nor any third-party partner, have submitted any products containing our products for approval by regulatory authorities in Canada, the United States or elsewhere. As of December 31, 2024, we had an accumulated deficit of $106.1 million and accumulated other comprehensive losses of $0.6 million. To date, we have devoted most of our financial resources to research and development, including drug discovery research, preclinical development activities, patent application filings and prosecution, and media relation efforts, as well as corporate overhead.

We generated no reportable revenues since inception through December 31, 2024, we expect to continue to incur losses for the foreseeable future, and expect these losses to increase as we continue our product development activities. If our drug candidates and other products developed do not achieve market acceptance, we may never become profitable. As a result of the foregoing, we expect to continue to experience net losses and negative cash flows for the foreseeable future. These net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital.

Because of the numerous risks and uncertainties associated with drug development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. In addition, our expenses could increase if we are required by the FDA, Health Canada or other regulatory authorities in foreign jurisdictions to perform preclinical studies or clinical trials in addition to those currently expected, or if there are any delays in completing our preclinical studies or the development of any of our drug candidates or other products. The amount of future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenues.

***We have no licensing, marketing or distribution experience and will have to invest significant resources to develop those capabilities or enter into acceptable third-party sales and marketing transactions.***

We have no commercial licensing, marketing or distribution experience. To develop commercial licensing, distribution and marketing capabilities, we will have to invest significant amounts of financial and management resources, some of which will need to be committed prior to any confirmation that our drug candidates will be approved by the FDA, Health Canada or other regulatory authorities in foreign jurisdictions. Where we decide to perform commercial licensing, marketing and distribution functions itself or through third parties, we could face a number of additional risks, including that we or our third-party collaborators may not be able to build and maintain an effective marketing or sales force. If we use third parties to market and distribute any products arising from our drug candidates, we may have limited or no control over our commercial licensing, marketing and distribution activities on which our future revenues may depend.

***We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights.***

We may from time to time seek to enforce our intellectual property rights against infringers when we determine that a successful outcome is probable and may lead to an increase in the value of the intellectual property. If we choose to enforce our patent rights against a party, then that individual or company has the right to ask the court to rule that such patents are invalid or should not be enforced. Additionally, the validity of our patents and the patents we have licensed may be challenged if a petition for post grant proceedings such as inter-partes review and post grant review is filed within the statutorily applicable time with the Canadian Intellectual Property Office or the United States Patent and Trademark Office. These lawsuits and proceedings are expensive and would consume time and resources and divert the attention of managerial and scientific personnel even if we were successful in stopping the infringement of such patents.

In addition, there is a risk that the court will decide that such patents are not valid and that we do not have the right to stop the other party from using the inventions. There is also the risk that, even if the validity of such patents is upheld, the court will refuse to stop the other party on the ground that such other party's activities do not infringe our intellectual property rights.

***Changes in patent law and its interpretation could diminish the value of patents in general, thereby impairing our ability to protect our drug candidates.***

As is the case with other NHP, biotechnology and pharmaceutical companies, our success is heavily dependent on intellectual property rights, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves technological and legal complexity, and obtaining and enforcing biopharmaceutical patents is costly, time consuming and inherently uncertain. The Supreme Court of Canada and the U.S. Supreme Court have ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the Canadian House of Representative, the Federal Court of Canada, the Canadian Intellectual Property Office, U.S. Congress, the federal courts, and the U.S. Patent and Trademark Office and international treaties entered into by these nations, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain patents or to enforce patents we may obtain in the future.

***Failure to manage growth***

As we advance our drug candidates through preclinical studies and early clinical development and seek business arrangements and partnerships with third parties to advance our drug candidates through later stage clinical development, we will need to increase our research and development personnel, scientific, management, and administrative headcount to manage these programs and partnerships. In addition, to meet obligations as a public company, we may need to increase our general and administrative capabilities and improve our operational and financial controls and reporting procedures. Our management, personnel and systems currently in place may not be adequate to support this future growth. In managing our growing operations, we are also subject to the risks of over-hiring and/or overcompensating our employees and over-expanding our operating infrastructure. As a result, we may be unable to manage our expenses effectively in the future, which may negatively impact our gross profit or operating expenses.

***Insurance and uninsured risks***

Our business is subject to a number of risks and hazards generally, including adverse preclinical trial results, accidents, labor disputes and changes in the regulatory environment. Such occurrences could result in damage to assets, personal injury or death, environmental damage, delays in operations, monetary losses and possible legal liability.

Our insurance may not cover all the potential risks associated with our operations. We may also be unable to maintain insurance to cover these risks at economically feasible premiums. Insurance coverage may not be available or may not be adequate to cover any resulting liability. Moreover, insurance against risks such as environmental pollution or other hazards encountered in our operations is not generally available on acceptable terms. We might also become subject to liability for pollution or other hazards which may not be insured against or which we may elect not to insure against because of premium costs or other reasons. Losses from these events or any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our financial position and results of operations.

***Litigation***

We may become party to litigation from time to time in the ordinary course of business which could adversely affect our business. Should any litigation in which we become involved be determined against us such a decision could adversely affect our ability to continue operating and the market price for our shares and could use significant resources. Even if we are involved in litigation and win, litigation can redirect significant company resources.

***Conflicts of interest***

Certain of our directors and officers do not devote their full time to the affairs of the Company and certain of our directors and officers are also directors, officers and shareholders of other biotechnology and research and development companies or other public companies in general, and as a result they may find themselves in a position where their duty to another company conflicts with their duty to the Company. There is no assurance that any such conflicts will be resolved in favor of the Company. If any such conflicts are not resolved in our favor we may be adversely affected.

***The psychedelic- inspired medicines industry and market are relatively new in this industry and the market may not continue to exist or grow as anticipated.***

We operate our business in a relatively new industry and market. In addition to being subject to general business risks, we must continue to build brand awareness in this industry and market through significant investments in our strategy, our operational capacity, quality assurance and compliance with regulations. In addition, there is no assurance that the industry and market will continue to exist and grow as currently estimated or anticipated or function and evolve in the manner consistent with management's expectations and assumptions. Any event or circumstance that adversely affects the psychedelic-inspired medicines industry and market could have a material adverse effect on our business, financial conditions and results of operations.

The psychedelic and psychedelic-inspired medicine market will face specific marketing challenges given the psychedelic products' status as a controlled substance which resulted in past and current public perception that the products have negative health and lifestyle effects and have the potential to cause physical and social harm due to psychoactive and potentially addictive effects. Any marketing efforts by us would need to overcome this perception to build consumer confidence, brand recognition and goodwill

***The psychedelics-inspired medicines industry and market are relatively new, and the industry may not succeed in the long term.***

We operate our business in a relatively new industry and market. The use of psychedelic-inspired medicines for medicinal purposes has shown promise in various studies and we believe that both regulators and the public have an increasing awareness and acceptance of this promising field. Nevertheless, psychedelics remain a controlled substance in the United States, Canada, and most other jurisdictions and their use for research and therapeutic purposes remains highly regulated and narrow in scope. There is no assurance that the industry and market will continue to grow as currently estimated or anticipated or function and evolve in the manner consistent with management's expectations and assumptions. Any event or circumstance that adversely affects the psychedelic manufacturing and medicines industry and market could have a material adverse effect on our business, financial condition and results of operations. We have committed and expect to continue committing significant resources and capital to the development of psychedelic-inspired products for therapeutic uses. As a category of products,

medical-grade psychedelics raw materials and psychedelic-derived APIs, and research into such substances, represent relatively untested offerings in the marketplace, and we cannot provide assurance that psychedelics as a category, or that our prospective psychedelic-inspired products, in particular, will achieve market acceptance. Moreover, as a relatively new industry, there are not many established players in the psychedelic-inspired medicines industry whose business model we can emulate. Similarly, there is little information about comparable companies available for potential investors to review in making a decision about whether to invest in our common shares.

***Our psychedelic-inspired drug candidates may generate public controversy. Adverse publicity or public perception regarding the psychedelic-inspired APIs we intend to utilize may negatively influence our success and that of our prospective investigational therapies.***

Our ability to establish and grow our business is substantially dependent on the success of the emerging market for psychedelic-inspired medicines, which will depend upon, among other matters, pronounced and rapidly changing public preferences, factors which are difficult to predict and over which we have little, if any, control. We and our clients will be highly dependent upon consumer perception of psychedelic-inspired medicines and other products.

Therapies containing controlled substances may generate public controversy. Political and social pressures and adverse publicity could lead to delays in approval of, and increased expenses for any future therapeutic candidates we may develop. Opponents of these therapies 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 therapies. For example, we may face media-communicated criticism directed at our clinical development program. Adverse publicity from psilocybin misuse may adversely affect the commercial success or market penetration achievable by our product candidates. Anti-psychedelic protests have historically occurred and may occur in the future and generate media coverage. Political pressures and adverse publicity could lead to delays in, and increased expenses for, and limit or restrict the introduction and marketing of any future therapeutic candidates.

***The expansion of the use of psychedelic-inspired medicines in the medical industry may require new clinical research into effective medical therapies.***

Research in United States and internationally regarding the medical benefits, viability, safety, efficacy, addictiveness, dosing and social acceptance of psychedelic-inspired products remains in early stages. There have been relatively few clinical trials on the benefits of such products. Although we believe that the articles, reports and studies support our beliefs regarding the medical benefits, viability, safety, efficacy, dosing and social acceptance of psychedelic-inspired products, future research and clinical trials may prove such statements to be incorrect, or could raise concerns regarding, and perceptions relating to, psychedelic-inspired products. Given these risks, uncertainties and assumptions, readers should not place undue reliance on such articles and reports. Future research studies and clinical trials may draw opposing conclusions to those stated in this Annual Report or reach negative conclusions regarding the medical benefits, viability, safety, efficacy, dosing, social acceptance or other facts and perceptions related to psychedelic-inspired products, which could have a material adverse effect on the demand for our drug candidates with the potential to lead to a material adverse effect on the Company's business, financial condition and results of operations.

***The psychedelic-inspired medicine industry is difficult to quantify and investors will be reliant on their own estimates of the accuracy of market data.***

Because the psychedelic-inspired medicine industry is in a nascent stage with uncertain boundaries, there is a lack of information about comparable companies available for potential investors to review in deciding about whether to invest in us and, few, if any, established companies whose business model we can follow or upon whose success we can build. Accordingly, investors will have to rely on their own estimates in deciding about whether to invest in us. There can be no assurance that our estimates are accurate or that the market size is sufficiently large for our business to grow as projected, which may negatively impact our financial results.

***The psychedelic-inspired medicine and biotechnology industries are experiencing rapid growth and increased competition.***

The psychedelic-inspired medicine and biotechnology industries are undergoing rapid growth and substantial change, which has resulted in an increase in competitors, consolidation and formation of strategic relationships. Acquisitions or other consolidating transactions could harm us in a number of ways, including, without limitation, by losing strategic partners if they are acquired by or enter into relationships with a competitor, losing customers, revenue and market share, or forcing us to expend greater resources to meet new or additional competitive threats, all of which could harm our operating results.

Additionally, the biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. We have competitors in Canada, the United States, Europe and other jurisdictions, including, without limitation, major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical and generic drug companies and universities and other research institutions. Many of our competitors have greater financial and other resources, such as larger research and development staff and more experienced marketing and manufacturing organizations than we do. Large pharmaceutical companies, in particular, have extensive experience in, and substantial capital resources for, conducting research, molecular derivative development, obtaining regulatory approvals, obtaining intellectual property protection and establishing key relationships. These companies also have significantly greater sales and marketing capabilities and experience in completing collaborative transactions in our target markets with leading companies and research institutions.

Our competitors may introduce new psychedelic-inspired medicines or develop technological advances that compete with us. We cannot predict the timing or impact of competitors introducing new psychedelic-inspired medicines or technological advances. Such competing psychedelic-inspired medicines may be safer, more effective, more effectively marketed, licensed or sold or have lower prices or superior performance features than our psychedelic-inspired drug candidates, and this could negatively impact our business and results of operations. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make the psychedelic-inspired drug candidates that we develop obsolete. As a result of all of these factors, our competitors may succeed in obtaining patent protection or discovering, developing and commercializing psychedelic-inspired medicines before we do or may develop psychedelic-inspired medicines that are deemed to be more effective or gain greater market acceptance than those of the Company.

Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative transactions with large, established companies. In addition, many universities and private and public research institutes may become active in the development of novel compounds. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis, technologies and psychedelic-inspired medicines that are more effective or less costly than any of the psychedelic-inspired drug candidates that we are currently developing or that we may develop, which could render our psychedelic-inspired drug candidates obsolete or non-competitive. If our competitors market psychedelic-inspired medicines that are more effective, safer or less expensive or that reach the market sooner than our psychedelic-inspired drug candidates, if any, we may not achieve commercial success. In addition, because of our limited resources, it may be difficult for us to stay abreast of the rapid changes in each technology. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Technological advances or products developed by our competitors may render our technologies or psychedelic-inspired drug candidates obsolete, less competitive or not economical.

***Changes in legislation, regulations and guidelines.***

Our operations are subject to various laws, regulations and guidelines relating to, among other things, drug research, development, marketing practices, health and safety, the conduct of operations and preclinical trials. In addition to FDA or Health Canada restrictions on the marketing of pharmaceutical products, several other types of state and federal laws have been applied to restrict certain marketing practices in the pharmaceutical and medical industries in recent years, as well as consulting or other service agreements with physicians or other potential referral sources. While to the knowledge of management, we are currently in compliance with all such laws, changes to applicable laws, regulations and guidelines may cause adverse effects to its operations. The risks to the business of the Company represented by this or similar risks are that they could significantly reduce the addressable market for our psychedelic-inspired drug candidates and could materially and adversely affect the business, financial condition and results of our operations.

**Risks Related to Regulatory Matters**

***Our current and prospective product candidates, and the development thereof, are or will be subject to the various federal and state laws and regulations relating to the safety and efficacy of health products, such as drugs and medical devices.***

We are in the process of developing investigational new drugs for which we intend to pursue FDA approval via the NDA process. In these product candidates and synthetic molecules based on psychedelics, such as psilocybin, mescaline and MDMA, will be the active pharmaceutical ingredients.

In connection with our development and future commercialization (if applicable) of our prospective products, we, and each contemplated product candidate, are subject to the Federal Food Drug and Cosmetic Act (FDCA). The FDCA is intended to assure the consumer, in part, that drugs and devices are safe and effective for their intended uses and that all labeling and packaging is truthful, informative, and not deceptive. The FDCA and the U.S. Food and Drug Administration (FDA) regulations define the term "drug," in part, by reference to its intended use, as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease" and "articles (other than food) intended to affect the structure or any function of the body of man or other animals." The definition also includes components of drugs, such as active pharmaceutical ingredients. To be lawfully marketed in the United States, drugs must generally either receive premarket approval by FDA through the NDA process or conform to a "monograph" for a particular drug category, as established by FDA's Over-the-Counter (OTC) Drug Review. If the FDA does not award premarket approval for our product candidates through the NDA process, this will have a material adverse effect on our business, financial condition and results of operations.

Additionally, the nature of the active ingredients we intend to utilize in our product candidates subjects us and our development and future commercialization (as applicable) activities to additional regulatory scrutiny and oversight. In connection with our development and future commercialization (if applicable) of psychedelic-based product candidates, we and each contemplated product candidate will be subject to the federal Controlled Substances Act (CSA) and the Controlled Substances Import and Export Act in the United States and analogous state and foreign laws.

There is no guarantee that any of our investigational drugs will ever be approved as medicines in any jurisdiction in which the Company operates, as there are currently very few FDA-approved drugs containing the psychedelic ingredients we intend to utilize as active ingredients. And, the laws and regulations generally applicable to the industry in which the Company is involved are subject to constant evolution and may change in ways currently unforeseen. Any amendment to or replacement of existing laws or regulations, including the re-classification of the substances the Company is developing or with which it is working, which are matters beyond the Company's control, may cause the Company's business, financial condition, results of operations and prospects to be adversely affected or may cause the Company to incur significant costs in complying with such changes or it may be unable to comply therewith. A violation of any applicable laws and regulations of the jurisdictions in which the Company operates could result in significant fines, penalties, administrative sanctions, convictions or settlements arising from civil proceedings initiated by either government entities in the jurisdictions in which the Company operates, or private citizens or criminal charges.

***The psychedelic-inspired drug candidates we are developing or may develop in the future may be subject to controlled substance laws and regulations in the United States and other countries where the product will be marketed, and failure to comply with these laws and regulations, or the cost of compliance with these laws and regulations, may adversely affect the results of our business operations and our financial condition.***

In the United States, psychedelics, such as psilocybin (and its active metabolite, psilocin), N,N-Dimethyltryptamine ("DMT"), mescaline and MDMA, are classified by the DEA as a Schedule I substances under the CSA. The DEA regulates chemical compounds as Schedule I, II, III, IV or V substances. 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. Pharmaceutical products approved for use in the United States may be listed as Schedule II, III, IV or V, with Schedule II substances considered to present the highest potential for abuse or dependence and Schedule V substances the lowest relative risk of abuse among such substances. Schedule I and II substances are subject to the strictest controls under the CSA, including manufacturing and procurement quotas, security requirements and criteria for importation. In addition, dispensing of Schedule II substances is further restricted. For example, they may not be refilled without a new prescription and may have a black box warning. For any product containing active ingredients that are Schedule I controlled substances to be available for commercial marketing in the United States, the product must be scheduled by the DEA to Schedule II, III, IV or V, which requires scheduling-related legislative or administrative action, which can further delay the path to market. There can be no assurance that the DEA will make a favorable scheduling decision about our psychedelic-inspired drug candidates. 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.

FDA approval is also a prerequisite to commercialization, and the controlled-substance status, currently undetermined, of our psychedelic-inspired APIs may negatively impact the FDA's decision regarding whether to approve the applicable product candidates.

During the pre-market review process, the FDA may determine that additional data is needed for one or more of our psychedelic-inspired drug candidates, either from non-clinical or clinical studies, including with respect to whether, or to what extent, the substance has abuse potential. This may introduce a delay into the approval and any potential rescheduling process.

In addition, therapeutic candidates containing controlled substances are subject to DEA regulations relating to manufacturing, storage, distribution and physician prescription procedures, including:

- DEA registration and inspection of facilities. Facilities conducting research, manufacturing, distributing, importing or exporting, or dispensing controlled substances must be registered (licensed) to perform these activities and have the security, control, recordkeeping, reporting and inventory mechanisms required by the DEA to prevent drug loss and diversion. All these facilities must renew their registrations annually, except dispensing facilities, which must renew every three years. The DEA conducts periodic inspections of certain registered establishments that handle controlled substances. Obtaining and maintaining the necessary registrations may result in delay of the importation, manufacturing or distribution of product candidates. Furthermore, failure to maintain compliance with the CSA, particularly non-compliance resulting in loss or diversion, can result in regulatory action that could have a material adverse effect on our business, financial condition and results of operations. The DEA may seek civil penalties, refuse to renew necessary registrations, or initiate proceedings to restrict, suspend or revoke those registrations. In certain circumstances, violations could lead to criminal proceedings.
- 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 may separately schedule product candidates. While some states automatically schedule a drug based on federal action, other states schedule drugs through rule making or a legislative action. State scheduling may delay commercial sale of any product for which we obtain federal regulatory approval and adverse scheduling could have a material adverse effect on the commercial attractiveness of such product. We or any partners 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 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. The abuse liability potential of our psychedelic-inspired drug candidates has not yet been studied. A Human Abuse Potential (HAP) study or an equivalent study may determine that, upon regulatory approval, our drug candidate will be a Schedule I controlled substance. Therefore, any future research or development activities with the approved drug may require submission of a preclinical or clinical protocols to the DEA and obtaining and maintaining a DEA license for each site that uses the approved drug. In that situation, if the DEA delays or denies the grant of a researcher registration to one or more research sites, future clinical trials could be significantly delayed, and we could lose clinical trial sites.
- Importation. If any of our product candidates is approved and classified as a Schedule II, III or IV substance, an importer can only import it for commercial purposes if it obtains an importer registration and files an application for an import permit for each import. The DEA provides annual assessments/estimates to the International Narcotics Control Board, which guides the DEA in the amounts of controlled substances that the DEA authorizes to be imported. The failure to identify an importer or obtain the necessary import authority, including specific quantities, could affect the availability of our product candidates and have a material adverse effect on our business, results of operations and financial condition. In addition, an application for a Schedule II importer registration must be published in the Federal Register, and there is a waiting period for third-party comments to be submitted. It is always possible that adverse comments may delay the grant of an importer registration.
- Manufacture. If, because of a Schedule II classification or voluntarily, we were to conduct manufacturing or repackaging/relabeling in the United States, our contract manufacturers would be subject to the DEA's annual manufacturing and procurement quota requirements.
- Distribution. If any of our product candidates is approved for marketing and scheduled under Schedule II, III or IV, we would also need to identify wholesale distributors with the appropriate DEA registrations and authority to possess and distribute or dispense such products.

***If the psychedelic-inspired APIs and formulated drug products that we intend to utilize in the future are determined to be Schedule I controlled substances under the CSA in the United States and under similar controlled-substance legislation in other countries, any significant violations of these laws and regulations, or changes in the laws and regulations, may result in interruptions to our development activity or business continuity.***

The psychedelic-inspired APIs we intend to utilize have not yet been studied in preclinical or clinical abuse liability studies and may be categorized as Schedule I controlled substances under the CSA or the state or foreign equivalent and would likely be. illegal without the requisite regulatory authorizations (e.g., to allow for the use of such substances in clinical trials under an IND and in compliance with all applicable FDA, DEA, and other regulatory requirements). Violations of any federal, state or foreign laws and regulations could result in significant fines, penalties, administrative sanctions, convictions or settlements arising from civil proceedings conducted by either the federal government or private citizens, or criminal charges

and penalties, including, but not limited to, disgorgement of profits, cessation of business activities, divestiture or prison time. If such were to occur, this could have a material adverse effect on us, including on our reputation and ability to conduct business, our financial position, operating results, profitability or liquidity, the potential listing of our shares or the market price of our shares. In addition, it is difficult for us to estimate the time or resources that would be needed for the investigation or defense of any such matters or our final resolution because, in part, the time and resources that may be needed are dependent on the nature and extent of any information requested by the applicable authorities involved, and such time or resources could be substantial. It is also illegal to aid or abet such activities or to conspire or attempt to engage in such activities. An investor's contribution to and involvement in such activities may result in federal civil and/or criminal prosecution, including, but not limited to, forfeiture of his, her or its entire investment, fines and/or imprisonment.

Various federal, state, provincial and local laws govern our business in any jurisdictions in which we may operate, and to which we may export our products, including laws relating to health and safety, the conduct of our operations, and the production, storage, sale and distribution of our products. Complying with these laws requires that we comply concurrently with complex federal, state, provincial and/or local laws. These laws change frequently and may be difficult to interpret and apply. To ensure our compliance with these laws, we will need to invest significant financial and managerial resources. It is impossible for us to predict the cost of such laws or the effect they may have on our future operations. A failure to comply with these laws could negatively affect our business and harm our reputation. Changes to these laws could negatively affect our competitive position and the markets in which we operate, and there is no assurance that various levels of government in the jurisdictions in which we operate will not pass legislation or regulation that adversely impacts our business.

In addition, even if we or third parties were to conduct activities in compliance with U.S. state or local laws or the laws of other countries and regions in which we conduct activities, potential enforcement proceedings could involve significant restrictions being imposed upon us or third parties, while diverting the attention of key executives. Such proceedings could have a material adverse effect on our business, revenue, operating results and financial condition as well as on our reputation and prospects, even if such proceedings conclude successfully in our favor. In the extreme case, such proceedings could ultimately involve the criminal prosecution of our key executives, the seizure of corporate assets, and consequently, our inability to continue business operations. Strict compliance with state and local laws with respect to psilocybin and psilocin does not absolve us of potential liability under U.S. federal law, the Canadian law or EU law, nor provide a defense to any proceeding which may be brought against us. Any such proceedings brought against us may adversely affect our operations and financial performance.

***Our prospective products will be subject to the various federal and state laws and regulations relating to health and safety.***

We are in the process of developing investigational new drugs for which we intend to pursue FDA approval via the NDA process. In connection with our development and future commercialization (if applicable) of our products, we and each contemplated product candidate are subject to the Federal Food Drug and Cosmetic Act (FDCA). The FDCA is intended to assure the consumer, in part, that drugs and devices are safe and effective for their intended uses and that all labeling and packaging is truthful, informative, and not deceptive. The FDCA and FDA regulations define the term "drug," in part, by reference to its intended use, as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease" and "articles (other than food) intended to affect the structure or any function of the body of man or other animals." Therefore, almost any ingested or topical or injectable product that, through its label or labeling (including internet websites, promotional pamphlets, and other marketing material), that is claimed to be beneficial for such uses will be regulated by FDA as a drug. The definition also includes components of drugs, such as active pharmaceutical ingredients. Drugs must generally either receive premarket approval by FDA through the NDA process or conform to a "monograph" for a particular drug category, as established by FDA's Over-the-Counter (OTC) Drug Review. If the FDA does not award premarket approval for our product candidates through the NDA process, this could have a material adverse effect on our business, financial condition and results of operations.

***Clinical trials are expensive, time-consuming, uncertain and susceptible to change, delay or termination. The results of clinical trials are open to differing interpretations.***

We currently have one drug candidate that is in preclinical development for indications such as depression and anxiety. We intend to develop additional drug candidates targeting other indications, including, for example, addiction and PTSD. After completing the requisite preclinical testing, submissions to the FDA (namely IND applications), internal review board ("IRB") review, and any other applicable obligations that must be completed before clinical testing may begin in the United States, we must conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates. Clinical testing is expensive, time consuming, and uncertain as to outcome. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, or at all. Failures in connection with one or more clinical trials can occur at any stage of testing.

The FDA and other applicable regulatory agencies may analyze or interpret the results of clinical trials differently than us. Even if the results of our clinical trials are favorable, the clinical trials for a number of our product candidates are expected to continue for several years and may take significantly longer to complete. Events that may prevent successful or timely completion of clinical development include (without limitation):

- delays in reaching a consensus with regulatory authorities on trial design;
- delays in reaching agreement on acceptable terms with prospective contract research organization ("CRO") and clinical trial sites;
- delays in sourcing materials and research animals for preclinical testing and correlated testing windows at the appropriate CRO facilities;
- delays in opening clinical trial sites or obtaining required IRB or independent ethics committee approval at each clinical trial site;
- actual or perceived lack of effectiveness of any product candidate during clinical trials;
- discovery of serious or unexpected toxicities or side effects experienced by trial participants or other safety issues, such as drug interactions, including those which cause confounding changes to the levels of other concomitant medications;
- slower than expected rates of subject recruitment and enrollment rates in clinical trials;
- difficulty in retaining subjects for the entire duration of applicable clinical studies (as study subjects may withdraw at any time due to adverse side effects from the therapy, insufficient efficacy, fatigue with the clinical trial process or for any other reason);
- delays or inability in manufacturing or obtaining sufficient quantities of materials for use in clinical trials due to regulatory and manufacturing constraints;
- inadequacy of or changes in our manufacturing process or product candidate formulation;
- delays in obtaining regulatory authorizations, such as INDs and any others that must be obtained, maintained, and/or satisfied to commence a clinical trial, including "clinical holds" or delays requiring suspension or termination of a trial by a regulatory agency, such as the FDA, before or after a trial is commenced;
- changes in applicable regulatory policies and regulation, including changes to requirements imposed on the extent, nature or timing of studies;
- delays or failure in reaching agreement on acceptable terms in clinical trial contracts or protocols with prospective clinical trial sites;
- uncertainty regarding proper dosing;
- delay or failure to supply product for use in clinical trials which conforms to regulatory specification;
- unfavorable results from ongoing preclinical studies and clinical trials;
- failure of our CROs, or other third-party contractors to comply with all contractual requirements or to perform their services in a timely or acceptable manner;
- failure by us, our employees, our CROs or their employees to comply with all applicable FDA or other regulatory requirements relating to the conduct of clinical trials;
- scheduling conflicts with participating clinicians and clinical institutions;
- failure to design appropriate clinical trial protocols;
- regulatory concerns with psychedelics or psychedelic-inspired drug candidates, generally, and the potential for abuse;
- insufficient data to support regulatory approval;
- inability or unwillingness of medical investigators to follow our clinical protocols;
- difficulty in maintaining contact with patients during or after treatment, which may result in incomplete data;
- any clinical holds placed on company by regulatory agencies during review process;
- delay or failure to supply psychedelic-inspired drug candidate for use in clinical trials due to cross-border or inter-continental shipment or customs handling and processing of controlled substances; or
- difficulty finding clinical trials sites whose investigators possess the requisite credentials to oversee clinical trials involving a Schedule I substance, should such be required.

***Certain third-parties we rely on to conduct our operations are subject to regulatory requirements.***

We rely on third parties to conduct our preclinical studies and expect to use clinical studies in the future. We rely on CROs and clinical data management organizations to design, conduct, supervise and monitor our preclinical studies and clinical trials. We and our CROs are required to comply with various regulations, including GCP, which are enforced by regulatory agencies, to ensure that the health, safety and rights of patients are protected in clinical development and clinical trials, and that trial data integrity is assured. Regulatory authorities ensure compliance with these requirements through periodic inspections of trial sponsors, principal investigators and trial sites. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. If we or any of our CROs fail to comply with applicable requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or other comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. Because we rely on third parties, our internal capacity to perform these functions is limited. Outsourcing these functions involves risk that third parties may not perform to our standards, may not produce results in a timely manner or may fail to perform at all.

We rely on third parties to supply the materials for, and manufacture, our research and development, and preclinical and clinical trial supplies and APIs, and 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.

***Difficulty or delays in enrolling patients in clinical trials may result in delay or prevention of necessary regulatory approvals.***

If we are unable to locate and enroll a sufficient number of eligible patients to participate in our clinical trials for our product candidates as required by the FDA or similar regulatory authorities outside the United States, we may not be able to initiate or conduct our trials. Our inability to enroll a sufficient number of patients for our trials would result in significant delays could require us to postpone or abandon clinical trials. Enrollment delays may result in increased development costs for our product candidates.

***Any failure by us to comply with existing regulations could harm our reputation and operating results.***

We are subject to extensive regulation by U.S. federal and state and foreign governments in each of the U.S., European and Canadian markets, in which we plan to sell our product candidates. We must adhere to all regulatory requirements, including FDA's Good Laboratory Practice ("GLP"), GCP, and GMP requirements, pharmacovigilance requirements, advertising and promotion restrictions, reporting and recordkeeping requirements, and their European equivalents. If we or our suppliers fail to comply with applicable regulations, including FDA pre-or post-approval requirements, then the FDA or other foreign regulatory authorities could sanction our Company. Even if a drug is approved by the FDA or other competent authorities, regulatory authorities may impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly post-marketing trials.

Any of our product candidates which may be approved in the U.S. will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, distribution, import, export, advertising, promotion, sampling, recordkeeping and submission of safety and other post-market information, including both federal and state requirements. In addition, manufacturers and manufacturers' facilities are required to comply with extensive FDA requirements, including ensuring that quality control and manufacturing procedures conform to GMP. As such, we and our contract manufacturers (in the event contract manufacturers are appointed in the future) are subject to continual review and periodic inspections to assess compliance with GMP. Accordingly, we and others with whom we work will have to spend time, money and effort in all areas of regulatory compliance, including manufacturing, production, quality control and quality assurance. We will also be required to report certain adverse reactions and production problems, if any, to the FDA, and to comply with requirements concerning advertising and promotion for our products. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved label. Similar restrictions and requirements exist in the European Union and other markets where we operate.

If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of the product, it may impose restrictions on that product or on us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may:

- issue warning letters;

- impose civil or criminal penalties;
- suspend regulatory approval;
- suspend any of our ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications submitted by us;
- impose restrictions on our operations, including by requiring us to enter in to a Corporate Integrity Agreement or closing our contract manufacturers' facilities, if any; or
- seize or detain products or require a product recall.

***We may be subject to federal, state and foreign healthcare laws and regulations and implementation of or changes to such healthcare laws and regulations could adversely affect our business and results of operations.***

If we successfully complete the requisite preclinical and clinical testing, make the required regulatory submissions and obtain any corresponding authorizations or licenses (as applicable), fulfill all other applicable development-related regulatory obligations, and, eventually, obtain FDA approval to market one or more of our current or future product candidates in the United States, we may be subject to certain healthcare laws and regulations. In both the U.S. and certain foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the healthcare system in ways that could impact our ability to sell our future product candidates. If we are found to be in violation of any of these laws or any other federal, state or foreign regulations, we may be subject to administrative, civil and/or criminal penalties, damages, fines, individual imprisonment, exclusion from federal health care programs and the restructuring of our operations. Any of these could have a material adverse effect on our business and financial results. Since many of these laws have not been fully interpreted by the courts, there is an increased risk that we may be found in violation of one or more of their provisions. Any action against us for violation of these laws, even if we are ultimately successful in our defense, will cause us to incur significant legal expenses and divert our management's attention away from the operation of our business. In addition, in many foreign countries, particularly the countries of the European Union, the pricing of prescription drugs is subject to government control.

In some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, some European Union jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines but monitor and control company profits. Such differences in national pricing regimes may create price differentials between European Union member states. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products.

Historically, products launched in the European Union do not follow price structures of the U.S.. In the European Union, the downward pressure on healthcare costs in general, particularly prescription medicines, has become intense. As a result, barriers to entry of new products are becoming increasingly high and patients are unlikely to use a drug product that is not reimbursed by their government.

We may face competition from lower-priced products in foreign countries that have placed price controls on pharmaceutical products. In addition, the importation of foreign products may compete with any future product that we may market, which could negatively impact our profitability.

An expansion in the government's role in the U.S. healthcare industry may cause general downward pressure on the prices of prescription drug products, lower reimbursements or any other product for which we obtain regulatory approval, reduce product utilization and adversely affect our business and results of operations. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of such cost containment measures and other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize any of our future product candidates for which we may receive regulatory approval.

***There is a high rate of failure for drug candidates proceeding through clinical trials.***

We have no products on the market. None of our prospective products or investigational candidates have ever been tested in a human subject. Our ability to achieve and sustain profitability with respect to our product candidates depends on obtaining regulatory approvals for and, if approved, successfully commercializing our product candidates, either alone or with third parties. Before obtaining regulatory approval for the commercial distribution of our product candidates, we or an existing or future collaborator must conduct extensive preclinical tests and clinical trials to demonstrate the safety, purity and potency of our product candidates.

Generally, there is a high rate of failure for drug candidates proceeding through clinical trials. We may suffer significant setbacks in our clinical trials similar to the experience of a number of other companies in the pharmaceutical and biotechnology industries, even after receiving promising results in earlier trials. Further, even if we view the results of a clinical trial to be positive, the FDA or other regulatory authorities may disagree with our interpretation of the data. In the event that we obtain negative results from clinical trials for product candidates or other problems related to potential chemistry, manufacturing and control issues or other hurdles occur and our future product candidates are not approved, we may not be able to generate sufficient revenue or obtain financing to continue our operations, our ability to execute on our current business plan may be materially impaired, and our reputation in the industry and in the investment community might be significantly damaged. In addition, our inability to properly design, commence and complete clinical trials may negatively impact the timing and results of our clinical trials and ability to seek approvals for our drug candidates.

The testing, marketing and manufacturing of any new drug product for use in the United States will require approval from the FDA. We cannot predict with any certainty the amount of time necessary to obtain such FDA approval and whether any such approval will ultimately be granted. Preclinical and clinical trials may reveal that one or more products are ineffective or unsafe, in which event further development of such products could be seriously delayed or terminated. Moreover, obtaining approval for certain products may require testing on human subjects of substances whose effects on humans are not fully understood or documented. Delays in obtaining FDA or any other necessary regulatory approvals of any proposed drug and failure to receive such approvals would have an adverse effect on the drug's potential commercial success and on our business, prospects, financial condition and results of operations. In addition, it is possible that a proposed drug may be found to be ineffective or unsafe due to conditions or facts that arise after development has been completed and regulatory approvals have been obtained. In this event, we may be required to withdraw such proposed drug from the market. To the extent that our success will depend on any regulatory approvals from government authorities outside of the United States that perform roles similar to that of the FDA, uncertainties similar to those stated above will also exist.

***Serious adverse events or other safety risks could require us to abandon development and preclude, delay or limit approval of our prospective products or current or future product candidates, limit the scope of any approved label or market acceptance, or cause the recall or loss of marketing approval of products that are already marketed.***

If any of our prospective products or current or future product candidates, prior to or after any approval for commercial sale, cause serious or unexpected side effects, or are associated with other safety risks such as misuse, abuse or diversion, a number of potentially significant negative consequences could result, including:

- regulatory authorities may interrupt, delay or halt clinical trials;
- regulatory authorities may deny regulatory approval of our future product candidates;
- regulatory authorities may require certain labeling statements, such as warnings or contraindications or limitations on the indications for use, and/or impose restrictions on distribution in the form of a Risk Evaluation and Mitigation Strategy ("REMS") in connection with approval or post-approval;
- regulatory authorities may withdraw their approval, require more onerous labeling statements, impose a more restrictive REMS, or require it to recall any product that is approved;
- we may be required to change the way the product is administered or conduct additional clinical trials;
- our relationships with our collaboration partners may suffer;
- we could be sued and held liable for harm caused to patients; or
- our reputation may suffer. The reputational risk is heightened with respect to those of our future product candidates that are being developed for pediatric indications.

Additionally, in light of the recent budget and staffing cuts at the FDA, the FDA may experience delays reviewing or approving our prospective products or current or future product candidates, which could impair our ability to commercialize our prospective products or current or future product candidates and have a material adverse effect on the business, financial condition and operating results of the Company.

***We may voluntarily suspend or terminate our clinical trials if at any time we believe that the product candidates present an unacceptable risk to participants, or if preliminary data demonstrates that our future product candidates are unlikely to receive regulatory approval or unlikely to be successfully commercialized.***

After completing preclinical testing and obtaining the requisite regulatory authorizations, as applicable, we may voluntarily suspend or terminate our clinical trials for any number of reasons, including if we believe that a product's use, or a person's exposure to it, may cause adverse health consequences or death. In addition, regulatory agencies, IRBs or data safety monitoring boards may at any time recommend the temporary or permanent discontinuation of our clinical trials or request that we cease using investigators in the clinical trials if they believe that the clinical trials are not being conducted in accordance with applicable regulatory requirements, or that they present an unacceptable safety risk to participants. Although we have never been asked by a regulatory agency, IRB or data safety monitoring board to temporarily or permanently discontinue a clinical trial, if we elect or are forced to suspend or terminate a clinical trial of any of our future product candidates, the commercial prospects for that product will be harmed and our ability to generate product revenue from that product may be delayed or eliminated. Furthermore, any of these events may result in labeling statements such as warnings or contraindications.

In addition, such events or labeling could prevent us or our partners from achieving or maintaining market acceptance of the affected product and could substantially increase the costs of commercializing our future product candidates and impair our ability to generate revenue from the commercialization of these products either by us or by our collaboration partners.

***Regulatory risks related to psychedelic-inspired drug candidates***

Successful execution of our strategy is contingent, in part, upon compliance with regulatory requirements from time to time enacted by governmental authorities and obtaining all regulatory approvals, where necessary, for the development of our psychedelic-inspired drug candidates. The abuse liability potential of our psychedelic-inspired drug candidates has not yet been studied in preclinical or clinical studies. Therefore, Health Canada or the FDA have not yet determined whether our psychedelic-inspired drug candidates will be scheduled as controlled substances. Based on the studies Health Canada or the FDA or other regulatory authorities may determine that our psychedelic-inspired drug candidates are controlled substances and therefore, would require classification as a controlled substance with all the requisite controls.

Further, we may not be able to predict the time required to secure all appropriate regulatory approvals for our psychedelic-inspired drug candidates, or the extent of testing and documentation that may, from time to time, be required by governmental authorities. The impact of compliance regimes, any delays in obtaining, or failure to obtain regulatory approvals may significantly delay or impact the development of markets, our business and psychedelic-inspired drug candidates, and licensing initiatives and could have a material adverse effect on the business, financial condition and operating results of the Company.

We will incur ongoing costs and obligations related to regulatory compliance. Failure to comply with regulations may result in additional costs for corrective measures, penalties or result in restrictions on our operations. In addition, changes in regulations, more vigorous enforcement thereof or other unanticipated events could require extensive changes to our operations, increased compliance costs or give rise to material liabilities, which could have a material adverse effect on the business, financial condition and operating results of the Company.

***Our management will be required to devote a substantial time to comply with public company regulations.***

As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act"), the Dodd-Frank Wall Street Reform and Consumer Protection Act as well as rules implemented by the SEC and Nasdaq, impose various requirements on public companies, including those related to corporate governance practices. Our management and other personnel must devote a substantial amount of time to these requirements. Moreover, these rules and regulations increase our legal and financial compliance costs and make some activities more time consuming and costly.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal control over financial reporting and disclosure controls and procedures. In particular, we must perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. Our compliance with these requirements will require that we incur substantial accounting and related expenses and expend significant management efforts. We have engaged third party consultants to help satisfy the ongoing requirements of Section 404 of the Sarbanes-Oxley Act. The costs of this outsourcing may be material and there can be no assurance that such staff will be immediately available to us. Moreover, if we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act, or if we identify deficiencies in our

internal control over financial reporting that are deemed to be material weaknesses, investors could lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities, which could require additional financial and management resources.

***We have identified a material weakness in our internal control over financial reporting. If we are unable to remediate the material weakness, or if we experience additional material weaknesses in the future, our business may be harmed.***

Our management is responsible for establishing and maintaining adequate internal control over financial reporting and for evaluating and reporting on the effectiveness of our system of internal control. Internal control over financial reporting is a process used to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of our financial statements for external purposes in accordance with generally accepted accounting principles in the United States. As a public company, we are required to comply with the Sarbanes-Oxley Act and other rules that govern public companies. In particular, we are required to certify our compliance with Section 404 of the Sarbanes-Oxley Act, which requires us to furnish annually a report by management on the effectiveness of our internal control over financial reporting.

Our management performed an assessment of the Company's significant processes and key controls. Based on this assessment, management concluded that our internal control over financial reporting was not effective as of December 31, 2024 and December 31, 2023 due to the material weakness related to segregation of duties. As of December 31, 2024 and December 31, 2023, there were control deficiencies which constituted a material weakness in our internal control over financial reporting. Management has taken, and is taking steps to strengthen our internal control over financial reporting: we have conducted evaluation of the material weakness to determine the appropriate remedy and have established procedures for documenting disclosures and disclosure controls.

Due to the small size of our Company, we do not maintain sufficient segregation of duties to ensure the processing, review and authorization of all transactions including non-routine transactions. While we have taken certain actions to address the material weaknesses identified, additional measures including engaging third-party consultants may be necessary as we work to improve the overall effectiveness of our internal controls over financial reporting.

Remediation efforts place a significant burden on management and add increased pressure to our financial resources and processes. If we are unable to successfully remediate our existing material weakness or any additional material weaknesses in our internal control over financial reporting that may be identified in the future in a timely manner, the accuracy and timing of our financial reporting may be adversely affected; our liquidity, our access to capital markets, the perceptions of our creditworthiness may be adversely affected; we may be unable to maintain or regain compliance with applicable securities laws, the listing requirements of the Nasdaq Stock Market; we may be subject to regulatory investigations and penalties; investors may lose confidence in our financial reporting; our reputation may be harmed; and our stock price may decline.

***Tax risk***

We are subject to various taxes in either the United States, Canada and Australia, or all three, including, without limitation, the following: income taxes, payroll taxes, workers compensation, goods and services tax, sales tax, and land transfer tax. Our tax filings will be subject to audit by various taxation authorities. While we intend to base its tax filings and compliance on the advice of our tax advisors, there can be no assurance that our tax filing positions will never be challenged by a relevant taxation authority resulting in a greater than anticipated tax liability.

**Risks Related to Our Intellectual Property**

***We may not be able to adequately protect or enforce our intellectual property rights, which could harm our competitive position.***

Our success will depend, in part, on our ability to obtain and maintain additional patents, protect our trade secrets and operate without infringing on the proprietary rights of others. We rely upon a combination of patents, trade secret protection (i.e., know-how), and confidentiality agreements to protect the intellectual property of our future product candidates. The strengths of patents in the pharmaceutical field involve complex legal and scientific questions and can be uncertain. Where appropriate, we seek patent protection for certain aspects of our products and technology. Filing, prosecuting and defending patents globally can be prohibitively expensive.

Our policy is to look to patent technologies with commercial potential in jurisdictions with significant commercial opportunities. However, patent protection may not be available for some of the products or technology we are developing. If we must spend significant time and money protecting, defending or enforcing our patents, designing around patents held by others or licensing, potentially for large fees, patents or other proprietary rights held by others, our business, results of operations and financial condition may be harmed. We may not develop additional proprietary products that are patentable.

The patent positions of pharmaceutical products are complex and uncertain. The scope and extent of patent protection for our future product candidates are particularly uncertain. Although we have sought, and will continue to seek, patent protection in the U.S., Europe and other countries for our proprietary technologies, future product candidates, their methods of use, and methods of manufacture, any or all of them may not be subject to effective patent protection. If any of our products is approved and marketed for an indication for which we do not have an issued patent, our ability to use our patents to prevent a competitor from commercializing a non-branded version of our commercial products for that non-patented indication could be significantly impaired or even eliminated.

Publication of information related to our future product candidates by us or others may prevent us from obtaining or enforcing patents relating to these products and product candidates. Furthermore, others may independently develop similar products, may duplicate our products, or may design around our patent rights. In addition, any of our issued patents may be opposed and/or declared invalid or unenforceable. If we fail to adequately protect our intellectual property, we may face competition from companies who attempt to create a generic product to compete with our future product candidates. We may also face competition from companies who develop a substantially similar product to our future product candidates that is not covered by any of our patents.

Many companies have encountered significant problems in protecting, defending and enforcing intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property rights, particularly those relating to pharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

***Our success depends on our ability to obtain additional intellectual property and operate without infringing the proprietary rights of others. Infringement claims by third parties may result in liability for damages or prevent or delay our developmental and commercialization efforts.***

Our success and ability to compete depend in part on our ability to obtain additional patents, protect our trade secrets, and operate without infringing on the proprietary rights of others. If we fail to adequately protect our intellectual property, we may face competition from companies who develop a substantially similar product to our future product candidates that is not covered by any of our intellectual property. Many companies have encountered significant problems in protecting, defending, and enforcing intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property rights, particularly those relating to pharmaceuticals, which could make it difficult for us to stop the infringement of our intellectual property and other proprietary rights. There is also a substantial amount of litigation, both within and outside the U.S., involving patient and other intellectual property rights in the pharmaceutical industry. We may, from time to time, be notified of claims that we are infringing upon the proprietary rights of third parties, and we cannot provide assurances that other companies will not, in the future, pursue such infringement claims against it, our commercial partners, or any third-party proprietary technologies we have licensed.

***We may be unsuccessful in licensing additional intellectual property to develop new product candidates.***

We may in the future seek to in-license additional intellectual property that we believe could complement or expand our product candidates or otherwise offer growth opportunities. The pursuit of such licenses may cause us to incur various expenses in identifying, investigating and pursuing suitable intellectual property. If we acquire additional intellectual property to develop new therapeutic product candidates, we may not be able to realize anticipated cost savings or synergies.

***If third parties claim that intellectual property used by us infringes upon their intellectual property, our operating profits could be adversely affected.***

There is a substantial amount of litigation, both within and outside the U.S., involving patent and other intellectual property rights in the pharmaceutical industry. We may, from time to time, be notified of claims that we are infringing upon patents, trademarks, copyrights or other intellectual property rights owned by third parties, and we cannot provide assurances

that other companies will not, in the future, pursue such infringement claims against us, our commercial partners or any third-party proprietary technologies we have licensed. If we were found to infringe upon a patent or other intellectual property right, or if we failed to obtain or renew a license under a patent or other intellectual property right from a third party, or if a third party that we were licensing technologies from was found to infringe upon a patent or other intellectual property rights of another third party, we may be required to pay damages, including damages of up to three times the damages found or assessed, if the infringement is found to be willful, suspend the manufacture of certain products or reengineer or rebrand our products, if feasible, or we may be unable to enter certain new product markets. Any such claims could also be expensive and time-consuming to defend and divert management's attention and resources. Our competitive position could suffer as a result. In addition, if we have declined or failed to enter into a valid non-disclosure or assignment agreement for any reason, we may not own the invention or our intellectual property, and our products may not be adequately protected. Thus, we cannot guarantee that any of our future product candidates, or our commercialization thereof, does not and will not infringe any third party's intellectual property.

***If we are not able to adequately prevent disclosure of trade secrets and other proprietary information, the value of our technology and products could be significantly diminished.***

We rely on trade secrets to protect our proprietary technologies, especially where it does not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our current and former employees, consultants, outside scientific collaborators, sponsored researchers, contract manufacturers, vendors and other advisors to protect our trade secrets and other proprietary information. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, we cannot guarantee that we have executed these agreements with each party that may have or have had access to our trade secrets. Any party with whom we or they have executed such an agreement may breach that agreement and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches.

Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they disclose such trade secrets, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third-party, our competitive position would be harmed.

***We may not be able to protect our intellectual property rights effectively outside of the United States.***

Filing, prosecuting and defending patents on all of our product candidates throughout the world would be prohibitively expensive. Therefore, we choose to file applications and/or obtained patents only in key markets. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may be able to export otherwise infringing products to territories where we have patent protection but where enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued patents and/or our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to pharmaceuticals, which could make it difficult to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in certain foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business and could be unsuccessful.

***Our financial condition would be adversely impacted if our intangible assets become impaired***

Intangibles are evaluated quarterly and are tested for impairment at least annually or when events or changes in circumstances indicate the carrying value of each segment, and collectively the Company taken as a whole, might exceed its fair value. If we determine that the value of our intangible assets is less than the amounts reflected on our balance sheet, we will be required to reflect an impairment of our intangible assets in the period in which such determination is made. An impairment of our intangible assets would result in our recognizing an expense in the amount of the impairment in the relevant period, which would also result in the reduction of our intangible assets and a corresponding reduction in our stockholders' equity in the relevant period.

**Risks Related to the Ownership of Our Common Stock**

***Our common stock could be delisted from The Nasdaq Capital Market.***

Our common stock is currently listed on Nasdaq. However, we cannot assure you that we will be able to comply with the continued listing standards of Nasdaq. If we fail to comply with the continued listing standards of Nasdaq, our common stock may become subject to delisting. If Nasdaq delists our common stock from trading on its exchange for failure to meet the continued listing standards, we and our stockholders could face significant material adverse consequences including, without limitation:

- a limited availability of market quotations for our securities;
- a determination that our common stock is a "penny stock" which will require brokers trading in our common stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our securities;
- a limited amount of analyst coverage; and
- a decreased ability for us to issue additional securities or obtain additional financing in the future.

***The market price of our common stock may be subject to significant fluctuations and volatility, and our stockholders may be unable to resell their shares at a profit and incur losses.***

The market price of our common stock could be subject to significant fluctuation. Market prices for securities of life sciences and biopharma companies in particular have historically been particularly volatile and have shown extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. Broad market and industry factors, as well as general economic, political and market conditions such as recessions or interest rate changes, may seriously affect the market price of our common stock, regardless of our actual operating performance. Some of the factors that may cause the market price of our common stock to fluctuate include, without limitation:

- investors react negatively to the effect on our business and prospects;
- the announcement of new products, new developments, services or technological innovations by us or our competitors;
- actual or anticipated quarterly increases or decreases in revenue, gross margin or earnings, and changes in our business, operations or prospects;
- announcements relating to strategic relationships, mergers, acquisitions, partnerships, collaborations, joint ventures, capital commitments, or other events by us or our competitors;
- conditions or trends in the life sciences and biopharma industries;
- changes in the economic performance or market valuations of other life sciences and biopharma companies;
- general market conditions or domestic or international macroeconomic and geopolitical factors unrelated to our performance or financial condition;
- sale of our common stock by stockholders, including executives and directors;
- volatility and limitations in trading volumes of our common stock;
- volatility in the market prices and trading volumes of companies in the life sciences and biopharma industries;
- our ability to finance our business;
- ability to secure resources and the necessary personnel to pursue our plans;
- failures to meet external expectations or management guidance;
- changes in our capital structure or dividend policy, future issuances of securities, sales or distributions of large blocks of common stock by stockholders;
- our cash position;
- announcements and events surrounding financing efforts, including debt and equity securities;
- analyst research reports, recommendation and changes in recommendations, price targets, and withdrawals of coverage;
- departures and additions of key personnel;
- disputes and litigation related to intellectual properties, proprietary rights, and contractual obligations;
- investigations by regulators into our operations or those of our competitors;

- changes in applicable laws, rules, regulations, or accounting practices and other dynamics; and
- other events or factors, many of which may be out of our control.

In the past, following periods of volatility in the overall market and the market prices of particular companies' securities, securities class action litigations have often been instituted against these companies. Litigation of this type, if instituted against us, could result in substantial costs and a diversion of our management's attention and resources. Any adverse determination in any such litigation or any amounts paid to settle any such actual or threatened litigation could require that we make significant payments.

***We may issue additional equity securities in the future, which may result in dilution to existing investors.***

To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may, from time to time, sell additional equity securities in one or more transactions at prices and in a manner we determine. If we sell additional equity securities, existing stockholders may be materially diluted. New investors could gain rights superior to existing stockholders, such as liquidation and other preferences. In addition, the number of shares available for future grant under our equity compensation plans may be increased in the future. Also, the exercise or conversion of outstanding options or warrants to purchase shares of capital stock may result in dilution to our stockholders upon any such exercise or conversion.

***Certain stockholders could attempt to influence changes within our Company which could adversely affect our operations, financial condition and the value of our common stock.***

Our stockholders may from time to time seek to acquire a controlling stake in our Company, engage in proxy solicitations, advance stockholder proposals or otherwise attempt to effect changes. Campaigns by stockholders to effect changes at publicly-traded companies are sometimes led by investors seeking to increase short-term stockholder value through actions such as financial restructuring, increased debt, special dividends, stock repurchases or sales of assets or the entire company. Responding to proxy contests and other actions by activist stockholders can be costly and time-consuming and could disrupt our operations and divert the attention of our board of directors and senior management from the operation of our business. These actions could adversely affect our operations, financial condition and the value of our common stock.

***If securities analysts do not publish research or reports about our business, or if they publish negative evaluations, the price of our common stock could decline.***

The trading market for our common stock will rely in part on the availability of research and reports that third-party industry or financial analysts publish about our Company. There are many large, publicly traded companies active in the life sciences and biopharma industries, which may mean it will be less likely that we receive widespread analyst coverage. Furthermore, if one or more of the analysts who do cover us downgrade our stock, our stock price would likely decline. If one or more of these analysts cease coverage of our Company, we could lose visibility in the market, which in turn could cause our stock price to decline.

***Anti-takeover provisions under Delaware corporate law may make it difficult for our stockholders to replace or remove our board of directors and could deter or delay third parties from acquiring our Company, which may be beneficial to our stockholders.***

Under our Amended and Restated Certificate of Incorporation, we are subject to the anti-takeover provisions of the Delaware General Corporation Law ("DGCL"), including Section 203 of the DGCL. Under these provisions, if anyone becomes an "interested stockholder," we may not enter into a "business combination" with that person for three (3) years without special approval, which could discourage a third party from making a takeover offer and could delay or prevent a change of control. For purposes of Section 203 of the DGCL, "interested stockholder" means, generally, someone owning fifteen percent (15%) or more of our outstanding voting stock or an affiliate of ours that owned fifteen percent (15%) or more of our outstanding voting stock during the past three (3) years, subject to certain exceptions as described in Section 203 of the DGCL.

***We do not anticipate paying any cash dividends in the foreseeable future.***

The current expectation is that we will retain our future earnings, if any, to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be our stockholders' sole source of gain, if any, for the foreseeable future.

***We may not be able to maintain an active trading market for our common stock.***

The listing of our common stock on Nasdaq does not assure that a meaningful, consistent and liquid trading market exists. If an active market for our common stock does continue, it may be difficult for investors to sell their shares without depressing the market price for the shares or at all.

***We maintain our cash at financial institutions, often in balances that exceed federally insured limits.***

The majority of our cash is held in accounts at U.S. banking institutions that we believe are of high quality. Cash held in non-interest-bearing and interest-bearing operating accounts may exceed the Federal Deposit Insurance Corporation ("FDIC") insurance limits. If such banking institutions were to fail, we could lose all or a portion of those amounts held in excess of such insurance limitations. While the FDIC took control of one such banking institution, Silicon Valley Bank ("SVB"), on March 10, 2023, and the FDIC also took control of Signature Bank ("Signature Bank") on March 12, 2023, we did not have any accounts with SVB or Signature Bank and therefore did not experience any specific risk of loss. The FDIC also announced that account holders would be made whole. Thus, we do not view the risk as material to our financial condition. However, if such a situation arises again with a financial institution we bank with, the risk of loss in excess of insurance limitations has generally increased. Any material loss that we may experience in the future could have an adverse effect on our ability to pay our operational expenses or make other payments and may require us to move our accounts to other banks, which could cause a temporary delay in making payments to our vendors and employees and cause other operational inconveniences.

***We may acquire businesses or products, or form strategic alliances, in the future, and may not realize the benefits of such acquisitions.***

We may acquire additional businesses or products, form strategic alliances, or create joint ventures with third parties that we believe will complement or augment our existing business. If we acquire businesses with promising markets or technologies, we may not be able to realize the benefit of acquiring such businesses if we are unable to successfully integrate them with our existing operations and company culture. We may encounter numerous difficulties in developing, manufacturing, and marketing any new products resulting from a strategic alliance or acquisition that delay or prevent us from realizing their expected benefits or enhancing our business. There is no assurance that, following any such acquisition, we will achieve the synergies expected in order to justify the transaction, which could result in a material adverse effect on our business and prospects.

**Item 1B. Unresolved Staff Comments**

Not applicable.

**Item 1C. Cybersecurity**

*Cybersecurity Risk Management and Strategy*

We have established certain processes for assessing, identifying, and managing material risk from cybersecurity threats, and have integrated these processes into our overall risk management strategy. Such processes include physical, procedural and technical safeguards, response methods, regular tests on our systems, and routine review of our processes to identify risks and enhance our practices. We also use technology-based tools to mitigate cybersecurity risks and to bolster our employee-based cybersecurity programs. We engage certain external parties, including consultants and computer security firms to enhance our cybersecurity oversight and provide monthly trainings to our employees. We consider the internal risk oversight programs of third-party service providers before engaging them in order to help protect our company from any related vulnerabilities. At this time, we are not aware of any material cybersecurity incidents that have impacted the Company. For a description of the risks from cybersecurity threats that may materially affect us and how they may do so, see our risk factors under Part 1. Item 1A. Risk Factors in this Annual Report.

*Governance*

Our board of directors is involved in the oversight of our risk management activities, and cybersecurity represents an important element of our overall approach to risk management. Our board of directors has delegated authority to the Audit Committee to serve as the cybersecurity oversight body, which works with the chief financial officer to assess and respond to cybersecurity threats. The chief financial officer meets with the third-party vendors regularly to discuss any issues and updates related to the Company's information technology environment and reports to the Audit Committee on a quarterly basis.

**Item 2. Properties**

Our principal corporate office is located at 4851 Tamiami Trail N, Suite 200 Naples, FL 34103. The Company believes our office is in good condition and is sufficient to conduct our operations. Our principal corporate office is held under a month-to-month operating lease.

**Item 3. Legal proceedings**

The Company may periodically be involved in legal proceedings, legal actions and claims arising in the ordinary course of business. In the opinion of management, we do not have any pending litigation that, separately or in the aggregate, have a material adverse effect on our financial position, results of operations or cash flows.

**Item 4. Mine Safety Disclosures**

Not applicable.

## PART II. OTHER INFORMATION

### Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

***Market Information***

Our common stock is traded on the Nasdaq Capital Markets under the symbol "ENVB".

***Holders***

On March 24, 2025 the Company had approximately 183 stockholders of record. The number of holders of record is based on the actual number of holders registered on the books of our transfer agent and does not reflect holders of shares in "street name" or persons, partnerships, associations, corporations, or other entities identified in security position listings maintained by depository trust companies.

***Dividends***

The Company has never declared or paid cash dividends on its common stock and has no intention to do so in the foreseeable future.

***Recent Sales of Unregistered Securities***

None.

***Issuer Purchases of Equity Securities***

None.

### Item 6. [Reserved]

### Item 7. Management's discussion and analysis of financial condition and results of operations

*References to the "Company," "our," "us," or "we" in this section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations of Enveric" refer to Enveric Biosciences, Inc. The following discussion and analysis of our financial condition and results of operations should be read together with our financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements involving risks and uncertainties and should be read together with the "Risk Factors" and the "Cautionary Statement Regarding Forward-Looking Statements" sections of this Annual Report on Form 10-K. Such risks and uncertainties could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.*

**Business Overview**

We are a biotechnology company dedicated to the development of novel neuroplastogenic small-molecule therapeutics for the treatment of depression, anxiety, addiction, and other psychiatric disorders. Leveraging our unique discovery and development platform, the Psybrary™, which houses proprietary information on the use and development of existing and novel molecules for specific mental health indications, Enveric seeks to develop a robust intellectual property portfolio of novel drug candidates.

Enveric's lead program, the EVM301 Series, and its lead drug candidate, EB-003, are intended to offer a first-in-class, new approach to the treatment of difficult-to-address mental health disorders, mediated by the promotion of neuroplasticity and without also inducing hallucinations in the patient. Enveric unveiled its EVM401 Series on February 25, 2025, which is intended to broaden Enveric's pipeline with additional non-hallucinogenic molecules and strengthen its ability to target addiction and neuropsychiatric disorders for patients with limited options. Previously, Enveric was developing the EVM201 Series, and its drug candidate EB-002 (formerly EB-373), for the treatment of neuropsychiatric disorders. The EVM201 Series comprised next generation synthetic prodrugs of the active metabolite, psilocin. Recently, Enveric out-licensed the EVM201 Series program to MycoMedica Life Sciences, who will seek to develop, manufacture, and commercialize EB-002, in exchange for certain development and milestone payments to Enveric (discussed below).

*Neuroplastogens*

Following our amalgamation with MagicMed in September 2021, we have continued to pursue the development of MagicMed's proprietary library, the Psybrary™, which we believe will help us to identify and develop the right drug candidates needed to address mental health challenges, including depression, anxiety, and addiction disorders. We synthesize novel phenylalkylamines and indolethylamines, using a mixture of chemistry and synthetic biology, resulting in the expansion of the Psybrary™, which currently includes 20 patent families with claims covering a million potential molecular structures, over one thousand of which we have so far synthesized in sufficient quantities to identify and hundreds of which we have screened for receptor binding and other relevant activities.

The Company developed certain intellectual property rights around the trademark PsyAI™ for potential use. On March 6, 2025, Enveric announced it is soliciting Requests-For Proposals ("RFPs") for the license or sale of its PsyAI™ trademark portfolio as a means of maximizing value for an asset which is no longer strategic given the Company's focus on drug development. This limited portfolio of US and Canadian trademark assets is held by its subsidiary, Enveric Biosciences Canada, Inc. Enveric expects the period for RFPs to remain open until August 31, 2025, with a decision to follow within three (3) months thereafter.

At this stage, we have entered into several non-binding term sheets with strategic partners to out-license certain molecules from the Psybrary™. Going forward, in order to build a pipeline of product candidates, we intend to both continue to internally develop new drug candidates with associated intellectual property and to acquire, through in-licensing, additional intellectual property from pharmaceutical and biotechnology companies and research institutions. The in-licensed assets could include both research stage and clinical stage drug candidates.

While we intend to pursue development of the EVM401 Series, our primary focus is to develop our lead asset EB-003 in the EVM301 Series. The development status of the product is shown in the table below:

| Product Candidates | Targeted Indications | Status | Expected Next Steps |
|---|---|---|---|
| **EB-003**<br>*Psychedelic-inspired drug candidate* | Mental health indication | Preclinical Development | IND Filing |

**Recent Developments**

***Reverse Stock Split***

We effected a 1-for-15 reverse stock split on January 27, 2025, which began trading on a split-adjusted basis on January 29, 2025, pursuant to which every 15 shares of our issued and outstanding common stock were reclassified as one share of common stock. No fractional shares were issued as a result of the reverse stock split. Any fractional shares that were to otherwise have resulted from the reverse stock split were rounded up to the next whole number. The reverse stock split had no impact on the par value of our common stock or the authorized number of shares of our common stock.

***Nasdaq Bid Price Deficiency***

On May 16, 2024, the Company received a letter from Nasdaq notifying the Company that for the prior 30 consecutive business days the bid price for the Company's common stock had closed below the minimum $1.00 per share requirement for continued listing on Nasdaq pursuant to Nasdaq Listing Rule 5550(a)(2) ("Bid Price Rule"). The deficiency letter did not result in the immediate delisting of the Company's common stock from Nasdaq. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), the Company was provided an initial period of 180 calendar days, until November 12, 2024, to regain compliance with the Bid Price Rule. On November 20, 2024, Nasdaq issued a delisting notice, indicating that the Company did not satisfy the Bid Price Rule by the compliance date and that unless the Company requested an appeal of this determination before Nasdaq's listing qualifications panel, our common stock would be scheduled for delisting from Nasdaq and trading suspended. We appealed the determination before Nasdaq's listing qualifications panel and on December 30, 2024, the Company received an extension until May 19, 2025, to regain compliance with Bid Price Rule. On March 4, 2025, the Company received notice from the Nasdaq Office of General Counsel that the Company regained compliance with the Bid Price Rule.

***License Agreement with MycoMedica Life Sciences***

On November 7, 2024, Enveric executed a licensing agreement with MycoMedica Life Sciences, PBC ("MycoMedica"), out-licensing the Company's EVM201 program, including drug candidate EB-002. Pursuant to the terms of licensing agreement, MycoMedica will seek to develop, manufacture, and commercialize EB-002, formerly EB-373, a synthetic prodrug of the active metabolite psilocin, for the treatment of neuropsychiatric disorders such as depression. MycoMedica received an exclusive, global license to the formulations, drugs, method of use, and medical devices developed by Enveric to utilize the compound. MycoMedica assumed the responsibility for all future preclinical, clinical, and commercial development on a royalty-bearing basis for all human and animal pharmaceutical applications. As part of the license agreement, Enveric received a modest upfront payment of $20,000 (recorded as other income), and if certain conditions are met, will receive development and sales milestones potentially totaling up to $62 million, plus tiered single digit royalties on all future sales. MycoMedica has the option during the license term to buyout its milestone and royalty payment obligations at a predetermined amount depending upon the stage of product development and commercialization at the time of the buyout. Further, MycoMedica has the right to purchase the licensed patents at a nominal amount upon a change of control of Enveric, although doing so does not relieve MycoMedica of any of its payment obligations. No royalties have been received to date.

***License Agreement with Aries Science and Technology***

On July 10, 2024, Akos Biosciences, Inc., a Delaware corporation ("Akos"), wholly-owned subsidiary of Enveric, entered into an exclusive license agreement with Aries Science and Technology, LLC ("Aries") pursuant to which Akos granted Aries a license of Akos's patented radiation dermatitis topical product. The license allows Aries to use the patented formulation to develop pharmaceutical or non-pharmaceutical products for treating radiation dermatitis suitable for administration to humans or animals. The license is exclusive (subject to certain exceptions contained in the Agreement), worldwide, royalty-bearing, and includes the right to sublicense. Enveric will be eligible to receive aggregate milestone payments of up to $61 million, as well as tiered royalties on future sales, if all conditions are met. Aries has the option during the license term, to purchase the rights to each licensed product (on a licensed product-by-licensed product basis) in the form of an exclusive (as to the applicable licensed product), fully paid, transferable right and license to the licensed product. No royalties have been received to date.

***Equity Distribution Agreement***

On September 1, 2023, the Company entered into a Distribution Agreement ("Distribution Agreement"), with Canaccord Genuity, LLC ("Canaccord"), pursuant to which the Company may offer and sell from time to time, through Canaccord as sales agent and/or principal, shares of common stock of the Company having an aggregate offering price of up to $10.0 million. Due to the offering limitations applicable to the Company and in accordance with the terms of the Distribution Agreement, the Company may offer common stock having an aggregate gross sales price of up to $2,392,514 pursuant to the prospectus supplement dated September 1, 2023. Subject to the terms and conditions of the Distribution Agreement, Canaccord may sell the common stock by any method permitted by law deemed to be an "at-the-market offering". The Company will pay Canaccord a commission equal to 3.0% of the gross sales price of the common stock sold through Canaccord under the Distribution Agreement and has also agreed to reimburse Canaccord for certain expenses. The Company may also sell common stock to Canaccord as principal for Canaccord's own account at a price agreed upon at the time of sale. Any sale of common stock to Canaccord as principal would be pursuant to the terms of a separate terms agreement between the Company and Canaccord.

During the year ended December 31, 2024, the Company issued 111,200 shares of common stock for gross proceeds of $2,392,502 under the Distribution Agreement, and charged offering costs of $583,713 to additional paid in capital on the consolidated balance sheet. As of December 31, 2024 and 2023, there were deferred offering costs related to the Distribution Agreement of $0 and $171,944, respectively. The Company does not anticipate issuing further securities pursuant to the Distribution Agreement.

***Lincoln Park Equity Line***

On November 3, 2023, the Company entered into a Purchase Agreement (the "Lincoln Park Purchase Agreement") and a registration rights agreement (the "Registration Rights Agreement"), with Lincoln Park Capital Fund, LLC ("Lincoln Park"), pursuant to which Lincoln Park has committed to purchase up to $10.0 million of the Company's common stock subject to certain limitations and satisfaction of the conditions set forth in the Lincoln Park Purchase Agreement.

Under the terms and subject to the conditions of the Lincoln Park Purchase Agreement, the Company has the right, but not the obligation, to sell to Lincoln Park, and Lincoln Park is obligated to purchase up to $10.0 million of the Company's Common Stock (the "Purchase Shares"). However, such sales of Common Stock by the Company, if any, will be subject to important limitations set forth in the Lincoln Park Purchase Agreement, including limitations on number of shares that may be sold. Sales may occur from time to time, at the Company's sole discretion, over the 24-month period commencing on the date that the conditions to Lincoln Park's purchase obligation set forth in the Lincoln Park Purchase Agreement are satisfied, including that a registration statement on Form S-1 covering the resale of the shares of the Company's Common Stock that have been and may be issued to Lincoln Park under the Lincoln Park Purchase Agreement, which the Company has filed with the SEC pursuant to the Registration Rights Agreement, is declared effective by the SEC and a final prospectus relating thereto is filed with the SEC. As required under the Lincoln Park Purchase Agreement, the Company registered a resale of 76,032 shares of our common stock, plus the 9,294 commitment shares, by Lincoln Park on a registration statement on Form S-1 dated November 8, 2023, which was declared effective by the SEC on December 5, 2023. As of July 30, 2024, there were no remaining shares available to be issued in connection with this registration statement. On September 4, 2024, the Company filed a new registration statement on Form S-1, which was declared effective by the SEC on September 11, 2024. The new Form S-1 registered an additional 326,667 shares of common stock that are available to be issued to Lincoln Park in connection with the Lincoln Park Purchase Agreement. During the year ended December 31, 2024, the Company had issued 159,366 shares of common stock, through the Lincoln Park Purchase Agreement for gross cash proceeds of $1,083,709. As of December 31, 2024 there were 243,334 remaining shares available to be issued in connection with this amended registration statement. The Company engaged in a best efforts public offering in the first quarter of 2025 (described below), which restricts the use of the Lincoln Park Equity Line for a period of one year from February 3, 2025.

Because the purchase price per share to be paid by Lincoln Park for the shares of Common Stock that the Company may elect to sell to Lincoln Park under the Lincoln Park Purchase Agreement, if any, will fluctuate based on the market prices of the Company's Common Stock at the time the Company elects to sell shares to Lincoln Park pursuant to the Lincoln Park Purchase Agreement, if any, it is not possible for us to predict the number of shares of Common Stock that the Company will sell to Lincoln Park the purchase price per share that Lincoln Park will pay for shares purchased from us or the aggregate gross proceeds that the Company will receive from those purchases by Lincoln Park.

***Registered Direct Offerings***

Between March and May 2024, the Company entered into a series of common stock purchase agreements (the "Purchase Agreements") for the issuance in a registered direct offering of an aggregate of 45,780 shares of the Company's common stock to certain institutional investors. The issuance was made in exchange for the permanent and irrevocable waiver of the variable rate transaction limitation contained in certain inducement offer letters, dated December 28, 2023, between the Company and the institutional investors with respect to any existing or future agreement by the Company to effect any issuance of shares. The Company did not receive any net proceeds in connection with the offering. The offering was made to obtain a waiver of the variable rate transaction limitation as described above and further described in the Purchase Agreements so the Company could utilize its equity line of credit with Lincoln Park, and enter into any future agreements that involve a variable rate transaction and issue such shares thereunder. The fair value of the shares issued for consideration of waiving the variable rate transaction limitation was $322,453 and was charged to additional paid in capital, as it is direct and incremental to the Distribution Agreement, on the unaudited condensed consolidated balance sheet as an offering cost related to the Distribution Agreement. The fair value of the shares issued for consideration of waiving the variable rate transaction limitation was $448,840 and was recorded as deferred offering costs, as direct and incremental to the Purchase Agreement, within prepaid expenses and other current assets on the unaudited condensed consolidated balance sheet related to the Purchase Agreement.

***January 2025 Offering***

On January 30, 2025, the Company commenced a best efforts public offering (the "Offering") of an aggregate of (i) 1,229,330 shares (the "Shares") of common stock of the Company, (ii) 437,336 pre-funded warrants (the "Pre-Funded Warrants") to purchase 437,336 shares of common stock (the "Pre-Funded Warrant Shares"), (iii) 1,666,666 Series A warrants (the "Series A Warrants") to purchase 1,666,666 shares of common stock (the "Series A Warrant Shares"), and (iv) 1,666,666 Series B warrants (the "Series B Warrants," and together with the Series A Warrants, the "Warrants") to purchase 1,666,666 shares of common stock (the "Series B Warrant Shares"). Each Share or Pre-Funded Warrant was sold together with one Series A Warrant to purchase one share of common stock and one Series B Warrant to purchase one share of common stock. The offering price for each Share and accompanying Warrants was $3.00, and the offering price for each Pre-Funded Warrant and accompanying Warrants was $2.9999. The Pre-Funded Warrants have an exercise price of $0.0001 per share, are exercisable immediately and will expire when exercised in full. Each Warrant has an exercise price of $3.00 per share and will be exercisable immediately upon issuance ("Initial Exercise Date"). The Series A Warrants expire on the five-year anniversary of the Initial Exercise Date. The Series B Warrants expire on the 18-month anniversary of the Initial Exercise Date.

The Offering closed on February 3, 2025. The net proceeds of the Offering, after deducting the fees and expenses of the Placement Agent (as defined below) and other offering expenses payable by the Company, but excluding the net proceeds, if any, from the exercise of the Warrants, is approximately $4.2 million. The Company intends to use the net proceeds from the Offering for working capital, EB-003 development, and general corporate purposes.

**Financial Overview**

We are a pre-revenue biotech company that has to date, not generated any revenues. During the year ended December 31, 2024, we raised approximately $8.0 million from the sales of Common Stock and warrants. These amounts were the primary source of funds upon which our operations were financed during the year ended December 31, 2024.

**Research and Development Expenses**

Research and development expenses consist primarily of costs incurred for the research and development of our preclinical product candidates, and include, without limitation:

- employee-related expenses, including salaries, benefits and share-based compensation expense;
- expenses incurred under agreements with contract research organizations, contract manufacturing organizations, and consultants and other entities engaged to support our product research and development activities;
- the cost of acquiring, developing and manufacturing materials and lab supplies used in research and development activities;
- facility, equipment, depreciation and other expenses, which include, without limitation direct and allocated expenses for rent, maintenance of our facilities and equipment, insurance and other supplies;
- costs associated with preclinical activities and regulatory operations, including, without limitation, patent related costs;
- consulting and professional fees associated with research and development activities.

We expense research and development costs to operations as incurred. Research and development activities are central to our business model. We utilize a combination of internal and external efforts to advance product development from early-stage work to future clinical trial manufacturing and clinical trial support. External efforts include work with consultants and increasingly substantial work at CROs and CMOs. We support an internal research and development team in Calgary, Alberta, Canada. To move these programs forward along our development timelines, a large portion (approximately 75%) of our staff are research and development employees. In January 2024, the Company reduced its discovery team in Calgary and was primarily focused on the development of EB-002 and EB-003 pipeline assets (until we out-licensed EB-002 to MycoMedica Lifesciences in November of 2024). Because of the numerous risks and uncertainties associated with product development, however, we cannot determine with certainty the duration and completion costs of these or other current or future preclinical studies and clinical trials. The duration, costs and timing of clinical trials and development of our product candidates will depend on a variety of factors, including the uncertainties of future clinical and preclinical studies, uncertainties in clinical trial enrollment rates and significant and changing government regulation. In addition, the probability of success for each product candidate will depend on numerous factors, including competition, manufacturing capability and commercial viability.

***General and Administrative Expenses***

General and administrative expenses consist principally of salaries, benefits and related costs such as stock-based compensation for personnel and consultants in executive, finance, business development, corporate communications and human resource functions, facility costs not otherwise included in research and development expenses, accounting and audit costs, tax compliance costs, SEC compliance costs, investor relation costs, training and conference costs, insurance costs and legal fees.

***Stock-Based Compensation***

A significant portion of our operating expenses is related to stock-based compensation costs. Stock-based compensation costs were approximately $1.6 million and $2.2 million for the years ended December 31, 2024 and 2023, respectively.

Stock-based compensation consists of restricted stock units (“RSU”), restricted stock awards (“RSA”) and options to purchase shares of the Company’s common stock. The Company follows Accounting Standards Codification (“ASC”) 718, Compensation - Stock Compensation, which addresses the accounting for stock-based payment transactions, requiring such transactions to be accounted for using the fair value method. The fair value of RSU or RSA awards is determined by the closing price per share of the Company’s common stock on the date of the award. The Company uses the Black-Scholes option pricing model to determine the grant date fair value of options issued.

RSA's and RSU's may contain vesting conditions that include, without limitation, any or all of the following: immediate vesting, vesting over a defined time period, vesting based on specific volume weighted average price levels being achieved by the Company's common stock as publicly traded within specified measurement periods, and vesting based on the achievement of specific performance milestones. Options contain vesting conditions that provide for vesting over a defined time period.

The fair value of RSA's and RSU's and options, is charged to expense, on a straight line basis over the vesting periods defined in the award agreements, except for the fair value which is attributable to achievement of a specific performance milestones, which are charged to expense upon achievement of such milestones.

**Results of Operations**

The following table sets forth information comparing the components of net loss for the years ended December 31, 2024 and 2023:

| | For the Years Ended December 31, | |
|---|---|---|
| | **2024** | **2023** |
| **Operating expenses** | | |
| General and administrative | $ 6,453,505 | $ 8,852,021 |
| Research and development | 2,841,272 | 7,252,437 |
| Depreciation and amortization | 337,489 | 343,982 |
| **Total operating expenses** | **9,632,266** | **16,448,440** |
| **Loss from operations** | **(9,632,266)** | **(16,448,440)** |
| **Other income (expense)** | | |
| Inducement expense, net | — | (1,848,235) |
| Change in fair value of warrant liabilities | 24,370 | 94,396 |
| Change in fair value of investment option liability | 21,620 | 208,752 |
| Change in fair value of derivative liability | — | 727,000 |
| Other income | 20,000 | — |
| Interest income, net | 219 | 3,708 |
| **Total other income (expense)** | **66,209** | **(814,379)** |
| **Net loss before income taxes** | $ (9,566,057) | $ (17,262,819) |
| Income tax expense | (8,930) | (28,913) |
| **Net loss** | $ (9,574,987) | $ (17,291,732) |

***General and Administrative Expenses***

Our general and administrative expenses decreased to $6,453,505 for the year ended December 31, 2024 from $8,852,021 for the year ended December 31, 2023, a decrease of $2,398,516, or 27%. This change was primarily driven by decreases in consulting expenses of $1,067,245, salaries and wages of $623,101, stock compensation expense of $508,785, accounting fees of $345,488, insurance expenses of $193,932, and software expenses of $183,681. This is offset by an increase in director fees of $223,700, public company fees of $182,643, and Delaware Franchise Tax expenses of $81,421.

The decrease in consulting fees was due to decreased outsourcing to contractors. The decrease in salaries and wages was due to the reduction in force. The decrease in stock compensation expense was primarily to a reduction in expense related to restricted stock units as a result of forfeitures and decreased value of new grants as a result of lower stock prices. The decrease in accounting fees was due to a reduction in technical accounting services. The decrease in insurance expense was due to lower premiums as a result of lower payroll costs. The decrease in software expenses was due to the down-size in operations of Enveric Canada. The increase in director fees was due to the addition of a director to the Board during 2024 and cash payments made to each director during the year. The increase in public company fees was due to an increase in broker fees and other public company filing fees.

***Research and Development Expenses***

Our research and development expense for the year ended December 31, 2024 was $2,841,272 as compared to $7,252,437 for the year ended December 31, 2023 with a decrease of $4,411,165, or approximately 61%. This decrease was primarily driven by decreased salaries and wages of $1,560,017, research costs of $1,346,647, CRO costs of $1,247,284, lab expenses of $158,514, tax incentive of $149,262, and rent of $86,098. The decrease in salaries and wages was due to the reduction in force as a result of the Company's cost reduction plan. The decrease in research costs and CRO costs was due to the completion of the Australia research and development project during the second quarter of 2024. The decrease in lab expenses was due to a reduction in research and development during 2024. The decrease in tax incentives was due to a tax credit received during 2024. The decrease in rent was due to the expiration of the Company's Canadian lease during 2024. These decreases were slightly offset by an increase in consulting fees of $366,060. The increase in consulting fees was due to certain employees that were hired on a part-time consultant basis to perform certain research and development activities.

***Depreciation and Amortization Expense***

Depreciation and amortization expense for the year ended December 31, 2024 was $337,489 as compared to $343,982 for the year ended December 31, 2023, with a decrease of $6,493, or approximately 2%.

***Change in Fair Value of Warrant Liabilities***

Change in fair value of warrant liabilities for the year ended December 31, 2024 resulted in income of $24,370 as compared to $94,396 for the year ended December 31, 2023. The change in fair value of warrant liabilities is significantly influenced by the change in the closing price of Common Stock at the end of each period, as compared to the closing price of Common Stock at the beginning of each period with a strong inverse relationship between changes in fair value of warrant liabilities and the trading price of Common Stock. The significant decrease in the Company's stock price during the year ended December 31, 2024 compared to the year ended December 31, 2023, resulted in the significant decrease to the change in fair value of warrant liabilities.

***Change in Fair Value of Investment Option Liability***

Change in fair value of investment option liability for the year ended December 31, 2024 resulted in income of $21,620 as compared to $208,752 for the year ended December 31, 2023. The change in fair value of investment option liability is significantly influenced by the change in the closing price of Common Stock at the end of each period, as compared to the closing price of Common Stock at the beginning of each period with a strong inverse relationship between changes in fair value of warrant liabilities and the trading price of Common Stock. The significant decrease in the Company's stock price during the year ended December 31, 2024 compared to the year ended December 31, 2023, resulted in the significant decrease to the change in fair value of warrant liabilities.

***Inducement Expense***

There was no inducement expense for the year ended December 31, 2024 as compared to $1,848,235 for the year ended December 31, 2023. The expenses recorded were related to inducement incurred related to the conversion of warrants and investment options that occurred in December 2023.

***Change in Fair Value of Derivative Liability***

The Company's change in fair value of derivative liability is due to the May 2023 redemption which ceased the probability of occurrence of the Akos spin-off and Akos Series A Preferred Stock redemption.

***Other Income***

The Company's other income during the year ended December 31, 2024 relates to licensing income from the contract with MycoMedica Life Sciences.

**Going Concern, Liquidity and Capital Resources**

The Company has incurred a loss since inception resulting in an accumulated deficit of $106,074,505 as of December 31, 2024 and further losses are anticipated in the development of its business. Further, the Company had operating cash outflows of $7,726,139 for the year ended December 31, 2024. For the year ended December 31, 2024, the Company had a loss from operations of $9,632,266. Since inception, being a research and development company, the Company has not yet generated revenue and the Company has incurred continuing losses from its operations. The Company's operations have been funded principally through the issuance of debt and equity. These factors raise substantial doubt about the Company's ability to continue as a going concern for a period of one year from the issuance of these financial statements.

In assessing the Company's ability to continue as a going concern, the Company monitors and analyzes its cash and its ability to generate sufficient cash flow in the future to support its operating and capital expenditure commitments. At December 31, 2024, the Company had cash of $2,241,026 and working capital of $1,244,848. The Company's current cash on hand is insufficient to satisfy its operating cash needs for the 12 months following the filing of this Annual Report on Form 10-K. These conditions raise substantial doubt regarding the Company's ability to continue as a going concern for a period of one year after the date the financial statements are issued. Management's plan to alleviate the conditions that raise substantial doubt include raising additional working capital through public or private equity or debt financings or other sources, and may include additional collaborations with third parties as well as disciplined cash spending. Adequate additional financing may not be available to us on acceptable terms, or at all. Should the Company be unable to raise sufficient additional capital, the Company may be required to undertake cost-cutting measures including delaying or discontinuing certain operating activities.

As a result of these factors, management has concluded that there is substantial doubt about the Company's ability to continue as a going concern for a period of one year after the date of the financial statements. The Company's consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

**Cash Flows**

Since inception, we have primarily used our available cash to fund our product development and operations expenditures.

***Cash Flows for the Years Ended December 31, 2024 and 2023***

The following table sets forth a summary of cash flows for the years presented:

| | For the Years Ended December 31, | |
|---|---|---|
| | **2024** | **2023** |
| Net cash used in operating activities | $ (7,726,139) | $ (14,094,411) |
| Net cash provided by investing activities | — | 11,667 |
| Net cash provided by (used in) financing activities | 7,673,834 | (1,343,141) |
| Effect of foreign exchange rate on changes on cash | 5,354 | (10,022) |
| Net decrease in cash | $ (46,951) | $ (15,435,907) |

*Operating Activities*

Net cash used in operating activities was $7,726,139 during the year ended December 31, 2024, which consisted primarily of a net loss adjusted for non-cash items of $7,302,896, a decrease in prepaid expenses of $178,496, an increase in due to related parties of $232,891 and a decrease in accounts payable and accrued liabilities of $834,630.

Net cash used in operating activities was $14,094,411 during the year ended December 31, 2023, which consisted primarily of a net loss adjusted for non-cash items of $13,919,661, an increase in prepaid expenses and other current assets of $6,857, a decrease in accounts payable and accrued liabilities of $103,848, and a decrease in right-of-use operating lease asset and obligation of $64,045.

*Investing Activities*

Net cash provided by investing activities was $0 during the year ended December 31, 2024.

Net cash used in investing activities was $11,667 during the year ended December 31, 2023, which consisted of the purchase of property and equipment, offset by proceeds from sale of property and equipment.

*Financing Activities*

Net cash provided by financing activities was $7,673,834 during the year ended December 31, 2024, which consisted of $1,804,819 in proceeds from the subscription receivable related to issuance of Inducement Warrants and the exercise of warrants and preferred investment options, $2,676,980 in proceeds from the exercise of Inducement Warrants, $2,290,186 in proceeds from commons stock sold under the Distribution Agreement, net of offering costs, $1,083,706 in proceeds from common stock sold under the Purchase Agreement, net of offering costs, offset by the payment of offering costs previously accrued of $181,857.

Net cash used in financing activities was $1,343,141 during the year ended December 31, 2023, which consisted of $1,052,057 for the redemption of Series A Preferred Stock and the payment of offering costs previously accrued of $291,084.

**Critical Accounting Estimates**

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP"). The preparation of our consolidated financial statements and related disclosures requires us to make estimates, assumptions and judgments that affect the reported amount of assets, liabilities, costs and expenses and related disclosures. Our critical accounting estimates are those estimates that involve a significant level of uncertainty at the time the estimate was made, and changes in them have had or are reasonably likely to have a material effect on our financial condition or results of operations. Accordingly, actual results could differ materially from our estimates. We base our estimates on past experience and other assumptions that we believe are reasonable under the circumstances, and we evaluate these estimates on an ongoing basis. Significant areas requiring management's estimates and assumptions include determining the fair value of transactions involving common stock, the valuation of warrants and preferred investment options, the valuation of stock-based compensation and accruals associated with third party providers supporting research and development efforts. Actual results could differ from those estimates.

**Item 7A. Quantitative and Qualitative Disclosures About Market Risk**

Our primary market risk exposure is foreign currency exchange rate risk. From inception through December 31, 2024, the Company's reporting currency is the United States dollar while the functional currency of certain of the Company's subsidiaries were the Canadian dollar and Australian dollar. For the reporting periods ended December 31, 2024 and December 31, 2023, the Company engaged in a number of transactions denominated in Canadian dollars and Australian dollars. As a result, the Company is subject to exposure from changes in the exchange rates of the Canadian dollar and Australian dollar against the U.S. dollar.

The Company has not entered into any financial derivative instruments that expose it to material market risk, including any instruments designed to hedge the impact of foreign currency exposures. The Company may, however, hedge such exposure to foreign currency exchange fluctuations in the future.

**Item 8. Financial Statements and Supplementary Data**

The information required by this Item 8 is incorporated by reference to the Annual Report on Form 10-K beginning on page F-1.

**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***

We maintain disclosure controls and procedures designed to ensure that the information we are required to disclose in reports we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified under the rules and forms of the SEC. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that such information is accumulated and communicated to our management, including our Chief Executive Officer and our Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosures. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

As required by paragraph (b) of Rules 13a-15 and 15d-15 under the Exchange Act, our Chief Executive Officer (our principal executive) and Chief Financial Officer (our principal financial officer and principal accounting officer) carried out an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as of December 31, 2024. Based on this evaluation, and in light of the material weaknesses found in our internal controls over financial reporting, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures (as defined in paragraph (e) of Rules 13a-15 and 15d-15 under the Exchange Act) were not effective as of December 31, 2024.

***Limitations on Internal Control over Financial Reporting***

An internal control system over financial reporting has inherent limitations and may not prevent or detect misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. However, these inherent limitations are known features of the financial reporting process. Therefore, it is possible to design into the process safeguards to reduce, though not eliminate, this risk.

***Management's Annual Report on Internal Control over Financial Reporting***

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Exchange Act Rule 13a-15(f) and 15d-15(f). Internal control over financial reporting is a process used to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of our financial statements for external purposes in accordance with generally accepted accounting principles in the United States. Internal control over financial reporting includes policies and procedures that pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets; provide reasonable assurance that transactions are recorded as necessary to permit preparation of our financial statements in accordance with generally accepted accounting principles in the United States, and that our receipts and expenditures are being made only in accordance with the authorization of our board of directors and management; and provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on our financial statements.

Under the supervision and with the participation of our management, including our Chief Executive Officer (our principal executive officer) and Chief Financial Officer (our principal financial officer and principal accounting officer), we performed an assessment of the Company's significant processes and key controls. Based on this assessment, management concluded that our internal control over financial reporting was not effective as of December 31, 2024 due to the material weaknesses described below.

A material weakness in internal control over financial reporting is a deficiency or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis. We determined that our internal control over financial reporting had the following material weaknesses:

- We were unable to document, formalize, implement and revise where necessary controls, policies and procedure documentation to evidence a system of controls, inclusive of IT controls, including testing of such controls that is consistent with our current personnel and available resources;
- We failed to document, maintain and test effective control activities over our control environment, risk assessment, information technology and monitoring components;
- We had insufficient segregation of duties, oversight of work performed and lack of compensating controls in our finance and accounting functions, including, without limitation, the processing, review and authorization of all routine and non-routine transactions, due to limited personnel and resources.

The Company is evaluating these weaknesses to determine the appropriate remedy. Because disclosure controls and procedures include those components of internal control over financial reporting that provide reasonable assurances that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, management also determined that its disclosure controls and procedures were not effective as a result of the foregoing material weaknesses in its internal control over financial reporting.

***Changes in Internal Control over Financial Reporting***

As of December 31, 2024, the Company is in process of remediating its material weaknesses and designing an effective internal control environment, however it has not yet remediated its material weaknesses.

***Remediation efforts to address material weaknesses in internal controls***

- We engaged information technology experts who designed and implemented a secure, cloud based, server and IT environment with controlled access, monitoring, help desk and a user training protocol;
- We installed and implemented third party software that provides improved control, approvals and segregation of duties over the purchase to pay operation cycle;
- We engaged third party subject matter experts who are providing independent supervision of accounting staff, transaction processing, reconciliations and financial statement preparation, resulting in improved segregation of duties;
- We engaged third party subject matter experts who are assisting in the financial reporting function, with such activities, including, without limitation, preparation, review and reconciliation of financial reports, research of technical accounting issues/transactions, performing various checklists to ensure compliance with GAAP and SEC requirements, with all such activities resulting in improved segregation of duties.
- Previously, we engaged third party subject matter experts to assist in the design and documentation of an internal control environment meeting those requirements and criteria established in the COSO 2013 Internal Control Integrated Framework, but as of December 31, 2024 we did not have any third party subject matter experts engaged.

**Item 9B. Other Information**

None.

**Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections**

None.

## PART III

### Item 10. Directors, Executive Officers and Corporate Governance

We incorporate by reference the information responsive to this Item appearing in our definitive Proxy Statement on Schedule 14A for our 2025 Annual Meeting of Stockholders ("Proxy Statement"), which will be filed no later than 120 days after December 31, 2024.

### Item 11. Executive Compensation

We incorporate by reference the information responsive to this Item appearing in our Proxy Statement, which will be filed no later than 120 days after December 31, 2024.

### Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

We incorporate by reference the information responsive to this Item appearing in our Proxy Statement, which will be filed no later than 120 days after December 31, 2024.

### Item 13. Certain Relationships and Related Transactions and Director Independence

We incorporate by reference the information responsive to this Item appearing in our Proxy Statement, which will be filed no later than 120 days after December 31, 2024.

### Item 14. Principal Accountant Fees and Services

We incorporate by reference the information responsive to this Item appearing in our Proxy Statement, which will be filed no later than 120 days after December 31, 2024.

## PART IV

### Item 15. Exhibits and Financial Statement Schedules

The following documents are filed as part of this Annual Report on Form 10-K:

(1) Financial Statements:



(2) Financial Statement Schedules:

None. Financial statement schedules have not been included because they are not applicable, or the information is included in the consolidated financial statements or notes thereto.

(3) Exhibits:

See "Index to Exhibits" for a description of our exhibits.

### Item 16. Form 10–K Summary

Not applicable.

**INDEX TO EXHIBITS**

| Exhibit No. | Description |
|---|---|
| 2.1 | Share Purchase Agreement, dated January 10, 2020, by and between AMERI Holdings, Inc. and Ameri100, Inc. (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K, filed with the Commission on January 13, 2020) |
| 2.2 | Tender Offer Support Agreement and Termination of Amalgamation Agreement, dated August 12, 2020, by and among AMERI Holdings, Inc., Jay Pharma Merger Sub, Inc., Jay Pharma Inc., 1236567 B.C. Unlimited Liability Company and Barry Kostiner, as the Ameri representative (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the Commission on August 12, 2020) |
| 2.3 | Amendment No. 1 To Tender Offer Support Agreement and Termination of Amalgamation Agreement, dated December 18, 2020, by and among Ameri, Jay Pharma Merger Sub, Inc., Jay Pharma Inc., 1236567 B.C. Unlimited Liability Company and Barry Kostiner, as the Ameri representative (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the Commission on December 18, 2020) |
| 2.4 | Amalgamation Agreement, dated May 24, 2021, by and among Enveric Biosciences, Inc., 1306432 B.C. LTD., 1306436 B.C. LTD., and MagicMed Industries, Inc. (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K, filed with the Commission on May 24, 2021) |
| 3.1 | Amended and Restated Certificate of Incorporation of Enveric Biosciences, Inc. (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, filed with the Commission on January 6, 2021) |
| 3.2 | Certificate of Amendment to Amended and Restated Certificate of Incorporation of Enveric Biosciences, Inc. (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K, filed with the Commission on January 6, 2021) |
| 3.3 | Certificate of Amendment of Amended and Restated Certificate of Incorporation of Enveric Biosciences, Inc. (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, filed with the Commission on July 14, 2022) |
| 3.4 | Certificate of Amendment of Amended and Restated Certificate of Incorporation of Enveric Biosciences, Inc. (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, filed with the Commission on January 21, 2025) |
| 3.5 | Amended and Restated Bylaws of Enveric Biosciences, Inc. (incorporated by reference to Exhibit 3.4 to the Company's Current Report on Form 8-K, filed with the Commission on January 6, 2021) |
| 3.6 | Amendment to the Amended and Restated Bylaws of Enveric Biosciences, Inc. (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, filed with the Commission on November 18, 2021) |
| 3.7 | Certificate of Designations of Series B Preferred Stock of Enveric Biosciences, Inc. (incorporated by reference to Exhibit 3.3 to the Company's Current Report on Form 8-K, filed with the Commission on January 6, 2021) |
| 3.8 | Certificate of Designation of the Series C Preferred Stock of the Company, dated May 4, 2022 (incorporated by reference to Exhibit 3.1 to the Company's Registration Statement on Form 8-A, filed with the Securities and Exchange Commission on May 4, 2022, File No. 000-26460) |
| 3.9 | Certificate of Amendment of Certificate of Designation of the Series C Preferred Stock of the Company, dated May 17, 2022 (incorporated by reference to Exhibit 3.2 to the Company's Registration Statement on Form 8-A/A, filed with the Securities and Exchange Commission on May 17, 2022, File No. 000 26460) |
| 4.1 | Description of Securities (incorporated by reference to Exhibit 4.1 of the Company's Annual Report on Form 10-K, filed with the Securities and Exchange Commission on March 31, 2023) |
| 4.2 | Form of Pre-Funded Warrant (issued in connection with January 2021 Registered Direct Offering) (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, filed with the Commission on January 12, 2021) |
| 4.3 | Form of Warrant (issued in connection with January 2021 Registered Direct Offering) (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K, filed with the Commission on January 12, 2021) |
| 4.4 | Form of Warrant (issued in connection with February 2021 Registered Direct Offering) (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, filed with the Commission on February 11, 2021) |
| 4.5 | Form of Series B Warrant (incorporated by reference to Exhibit 4.5 to the Company's Annual Report on Form 10-K filed with the Commission on April 1, 2021) |
| 4.6 | Form of MagicMed Warrant Certificate (incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on September 17, 2021) |

| Exhibit No. | Description |
|---|---|
| 4.7 | Form of Common Stock Purchase Warrant (in connection with February 2022 Offering) (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, filed with the Commission on February 15, 2022) |
| 4.8 | Form of RD Pre-Funded Warrant (in connection with July 2022 Offering) (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, filed with the Commission on July 26, 2022) |
| 4.9 | Form of PIPE Pre-Funded Warrant (in connection with July 2022 Offering) (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K, filed with the Commission on July 26, 2022) |
| 4.1 | Form of RD Preferred Investment Option (in connection with July 2022 Offering) (incorporated by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K, filed with the Commission on July 26, 2022) |
| 4.11 | Form of PIPE Preferred Investment Option (in connection with July 2022 Offering) (incorporated by reference to Exhibit 4.4 to the Company's Current Report on Form 8-K, filed with the Commission on July 26, 2022) |
| 4.12 | Form of Wainwright Warrant (in connection with July 2022 Offering) (incorporated by reference to Exhibit 4.5 to the Company's Current Report on Form 8-K, filed with the Commission on July 26, 2022) |
| 4.13 | Form of Inducement Warrant (in connection with December 2023 Offering) (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, filed with the Commission on December 29, 2023) |
| 4.14 | Form of Pre-Funded Warrant (in connection with January 2025 Offering) (incorporated by reference to Exhibit 4.14 to the Company's Registration Statement on Form S-1/A, filed with the Commission on January 30, 2025) |
| 4.15 | Form of Series A Warrant (in connection with January 2025 Offering) (incorporated by reference to Exhibit 4.15 to the Company's Registration Statement on Form S-1/A, filed with the Commission on January 30, 2025) |
| 4.16 | Form of Series B Warrant (in connection with January 2025 Offering) (incorporated by reference to Exhibit 4.16 to the Company's Registration Statement on Form S-1/A, filed with the Commission on January 30, 2025) |
| 4.17 | Form of Placement Agent Warrant (in connection with January 2025 Offering) (incorporated by reference to Exhibit 4.17 to the Company's Registration Statement on Form S-1/A, filed with the Commission on January 30, 2025) |
| 10.1# | Employment Agreement between Kevin Coveney and the Company, effective March 13, 2023 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the Commission on February 28, 2023) |
| 10.2 | Form of Securities Purchase Agreement (entered into in connection with the May 5, 2022 Private Placement) (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the Commission on May 11, 2022) |
| 10.3 | Certificate of the Designations, Preferences and Rights of Akos Series A Convertible Preferred Stock (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, filed with the Commission on May 11, 2022) |
| 10.4 | Form of Registration Rights Agreement (entered into in connection with the May 5, 2022 Private Placement) (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K, filed with the Commission on May 11, 2022) |
| 10.5 | Form of Warrant (entered into in connection with the May 5, 2022 Private Placement) (incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K, filed with the Commission on May 11, 2022) |
| 10.6 | Form of Warrant Amendment (in connection with the July 2022 Offerings) (incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K, filed with the Commission on July 26, 2022) |
| 10.7# | First Amendment to the Enveric Biosciences, Inc. 2020 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the Commission on July 14, 2022) |
| 10.8 | Form of Warrant Amendment (in connection with July 2022 Offering) (incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K, filed with the Commission on July 26, 2022) |
| 10.9 | Form of Securities Purchase Agreement (in connection with July 2022 Offering) (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the Commission on July 26, 2022) |
| 10.10 | Form of Securities Purchase Agreement (in connection with July 2022 Offering) (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, filed with the Commission on July 26, 2022) |
| 10.11 | Form of Registration Rights Agreement (in connection with July 2022 Offering) (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K, filed with the Commission on July 26, 2022) |
| 10.12# | Enveric Biosciences, Inc. 2020 Long-Term Equity Incentive Plan (incorporated by reference to Exhibit 10.5 to the Company's Current Report on Form 8-K, filed with the Commission on January 6, 2021) |
| 10.13# | Form of RSU Award Agreement (incorporated by reference to Exhibit 10.6 to the Company's Current Report on Form 8-K, filed with the Commission on January 6, 2021) |
| 10.14# | Form of RSA Award Agreement* |

| Exhibit No. | Description |
|---|---|
| 10.15 | Form of Securities Purchase Agreement, dated January 11, 2021, by and among the Company and the purchasers thereto (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the Commission on January 12, 2021) |
| 10.16 | Form of Registration Rights Agreement, dated January 11, 2021, by and among the Company and the purchasers thereto (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, filed with the Commission on January 12, 2021) |
| 10.17 | Letter Agreement, dated January 11, 2021, by and between the Company and Alpha Capital Anstalt (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K, filed with the Commission on January 12, 2021) |
| 10.18 | Form of Securities Purchase Agreement, dated February 9, 2021, by and among the Company and the purchasers thereto (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the Commission on February 11, 2021) |
| 10.19 | Form of Registration Rights Agreement, dated February 9, 2021, by and among the Company and the purchasers thereto (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, filed with the Commission on February 11, 2021) |
| 10.20 | Exclusive License Agreement, between the Company and Diverse Biotech, Inc., dated March 5, 2021 (incorporated by reference to Exhibit 10.6 the Company's Quarterly Report on Form 10-Q, filed with the Commission on May 17, 2021) |
| 10.21 | Form of Voting and Support Agreement, dated as of May 24, 2021, by and among Enveric Biosciences, Inc. and certain shareholders of MagicMed Industries Inc. named therein (incorporated by reference to Annex B-1 to the Company's Proxy Statement/Prospectus, filed with the Commission on August 6, 2021) |
| 10.22 | Form of Voting Agreement, dated as of May 24, 2021, by and among MagicMed Industries Inc. and certain shareholders of Enveric Biosciences, Inc. named therein (incorporated by reference to Annex B-2 to the Company's Proxy Statement/Prospectus, filed with the Commission on August 6, 2021) |
| 10.23 | Form of Lock-Up Agreement, dated as of May 24, 2021, by and among Enveric Biosciences, Inc. and certain shareholders of MagicMed Industries Inc. named therein (incorporated by reference to Annex C-1 to the Company's Proxy Statement/Prospectus, filed with the Commission on August 6, 2021) |
| 10.24 | Form of Lock-Up/Leak-Out Agreement, dated as of May 24, 2021, by and among Enveric Biosciences, Inc. and certain shareholders of MagicMed Industries Inc. named therein (incorporated by reference to Annex C-2 to the Company's Proxy Statement/Prospectus, filed with the Commission on August 3, 2021) |
| 10.25# | Employment Agreement between Joseph Tucker and Enveric Biosciences, Inc. (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on May 24, 2021) |
| 10.26# | Employment Agreement between Peter Facchini and Enveric Biosciences, Inc. (incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on May 24, 2021) |
| 10.27# | MagicMed Stock Option Plan, as amended September 10, 2021 (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on September 17, 2021) |
| 10.28*** | Form of Termination of Prior Agreements and Mutual Release (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q, filed with the Commission on May 15, 2023) |
| 10.29 | Equity Distribution Agreement, dated September 1, 20123, by and among the Company and Canaccord Genuity, LLC (incorporated by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K, filed with the Commission on September 1, 2023) |
| 10.30 | Purchase Agreement, dated November 3, 2023, by and among the Company and Lincoln Park Capital Fund, LLC (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, filed with the Commission on November 6, 2023) |
| 10.31 | Registration Rights Agreement, dated November 3, 2023, by and among the Company and Lincoln Park Capital Fund, LLC (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K, filed with the Commission on November 6, 2023) |
| 10.32 | Form of Inducement Warrant, dated December 28, 2023, by and among the investors thereto (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the Commission on December 29, 2023) |
| 10.33 | Form of Common Stock Purchase Agreement, dated March 8, 2024, between Enveric Biosciences, Inc. and the investors set forth therein (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on March 11, 2024) |

| Exhibit No. | Description |
|---|---|
| 10.34 | Form of Common Stock Purchase Agreement, dated May 3, 2024, between Enveric Biosciences, Inc. and the investors set forth therein (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, filed with the Commission on May 3, 2024) |
| 10.35 | Form of Securities Purchase Agreement (incorporated by reference to Exhibit 10.33 to the Company's Registration Statement on Form S-1/A, filed with the Commission on January 30, 2025) |
| 10.36*** | Exclusive License Agreement, dated July 10, 2024, between Akos Biosciences, Inc. and Aries Science and Technology, LLC (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q, filed with the Commission on November 14, 2024) |
| 10.37*** | Exclusive License Agreement, dated November 7, 2024, between Enveric Biosciences, Inc. and MycoMedica Life Sciences, PBC* |
| 14 | Code of Ethics (incorporated by reference to Exhibit 14 to the Company's Annual Report on Form 10-K, filed with the Commission on March 26, 2024) |
| 19 | Policy on Insider Trading (incorporated by reference to Exhibit 19 to the Company's Annual Report on Form 10-K, filed with the Commission on March 26, 2024) |
| 21 | Subsidiaries* |
| 23.1 | Consent of independent registered public accountant – Marcum LLP* |
| 31.1 | Certification pursuant to Section 302 of the Sarbanes–Oxley Act of 2002 of Principal Executive Officer* |
| 31.2 | Certification pursuant to Section 302 of the Sarbanes–Oxley Act of 2002 of Principal Financial and Accounting Officer* |
| 32 | Certification pursuant to Section 906 of the Sarbanes–Oxley Act of 2002 of Principal Executive Officer, Principal Financial and Accounting Officer** |
| 97 | Clawback Policy (incorporated by reference to Exhibit 97 to the Company's Annual Report on Form 10-K, filed with the Commission on March 26, 2024) |
| 101.INS | Inline XBRL Instance Document* |
| 101.SCH | Inline XBRL Taxonomy Extension Schema* |
| 101.CAL | Inline XBRL Taxonomy Extension Calculation Linkbase Document* |
| 101.DEF | Inline XBRL Taxonomy Extension Definition Linkbase Document* |
| 101.LAB | Inline XBRL Taxonomy Extension Labels Linkbase Document* |
| 101.PRE | Inline XBRL Taxonomy Extension Presentation Linkbase Document* |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document) |

* Filed herewith.

** Furnished herewith.

*** Certain confidential portions of this Exhibit were omitted by means of marking such portions with brackets ("[***]") because the identified confidential portions (i) are not material and (ii) would be competitively harmful if publicly disclosed.

# Management contract or compensatory plan or arrangement.

## SIGNATURES

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

**ENVERIC BIOSCIENCES, INC.**

March 28, 2025 By: */s/ Joseph Tucker*
Joseph Tucker, Ph.D.
Chief Executive Officer
(Principal Executive Officer)

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

March 28, 2025 By: */s/ Joseph Tucker*
Joseph Tucker, Ph.D.
Chief Executive Officer
(Principal Executive Officer)

March 28, 2025 By: */s/ Kevin Coveney*
Kevin Coveney
Chief Financial Officer
(Principal Financial and Accounting Officer)

March 28, 2025 By: */s/ Michael Webb*
Michael Webb
Director

March 28, 2025 By: */s/ George Kegler*
George Kegler
Director

March 28, 2025 By: */s/ Marcus Schabacker*
Marcus Schabacker, Ph.D., M.D.
Director

March 28, 2025 By: */s/ Frank Pasqualone*
Frank Pasqualone
Director

March 28, 2025 By: */s/ Sheila DeWitt*
Sheila DeWitt, Ph.D.
Director

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors of
Enveric Biosciences, Inc.

***Opinion on the Financial Statements***

We have audited the accompanying consolidated balance sheets of Enveric Biosciences, Inc. (the "Company") as of December 31, 2024 and 2023, the related consolidated statements of operations and comprehensive loss, changes in mezzanine equity and shareholders' equity and cash flows for the years ended December 31, 2024 and 2023, 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 the years ended December 31, 2024 and 2023, 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 1, the Company has incurred significant losses and needs to raise additional funds to meet its obligations and sustain its operations. 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 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

***Basis for Opinion***

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the 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 Matters*

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

/s/ Marcum LLP

We have served as the Company's auditor since 2021.

Morristown, New Jersey March 28, 2025

**ENVERIC BIOSCIENCES, INC. AND SUBSIDIARIES**
**CONSOLIDATED BALANCE SHEETS**

| | As of December 31, | |
|---|---|---|
| | **2024** | **2023** |
| **ASSETS** | | |
| **Current assets:** | | |
| Cash | $ 2,241,026 | $ 2,287,977 |
| Prepaid expenses and other current assets | 493,558 | 1,293,554 |
| **Total current assets** | **2,734,584** | **3,581,531** |
| **Other assets:** | | |
| Property and equipment, net | 305,777 | 507,377 |
| Intangible assets, net | 42,182 | 210,932 |
| **Total other assets** | **347,959** | **718,309** |
| **Total assets** | **$ 3,082,543** | **$ 4,299,840** |
| **LIABILITIES, MEZZANINE EQUITY, AND SHAREHOLDERS' EQUITY** | | |
| **Current liabilities:** | | |
| Accounts payable | $ 521,747 | $ 1,218,783 |
| Due to related parties | 232,891 | — |
| Accrued liabilities | 732,010 | 1,075,643 |
| Investment option liability | 1,988 | 23,608 |
| Warrant liability | 1,100 | 25,470 |
| **Total current liabilities** | **1,489,736** | **2,343,504** |
| **Commitments and contingencies (Note 12)** | | |
| **Mezzanine equity** | | |
| Series C redeemable preferred stock, $0.01 par value, 100,000 shares authorized, and 0 shares issued and outstanding as of December 31, 2024 and 2023, respectively | — | — |
| Redeemable non-controlling interest | — | — |
| **Total mezzanine equity** | — | — |
| **Shareholders' equity** | | |
| Preferred stock, $0.01 par value, 20,000,000 shares authorized; Series B preferred stock, $0.01 par value, 3,600,000 shares authorized, 0 shares issued and outstanding as of December 31, 2024 and 2023, respectively | — | — |
| Common stock, $0.01 par value, 100,000,000 shares authorized, 678,002 and 182,625 shares issued and outstanding as of December 31, 2024 and 2023, respectively | 6,780 | 1,827 |
| Additional paid-in capital | 108,255,049 | 100,841,416 |
| Stock subscription receivable | — | (1,817,640) |
| Accumulated deficit | (106,074,505) | (96,499,518) |
| Accumulated other comprehensive loss | (594,517) | (569,749) |
| **Total shareholders' equity** | **1,592,807** | **1,956,336** |
| **Total liabilities, mezzanine equity, and shareholders' equity** | **$ 3,082,543** | **$ 4,299,840** |

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

**ENVERIC BIOSCIENCES, INC. AND SUBSIDIARIES**
**CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS**

| | For the Years Ended December 31, | |
|---|---|---|
| | **2024** | **2023** |
| **Operating expenses** | | |
| General and administrative | $ 6,453,505 | $ 8,852,021 |
| Research and development | 2,841,272 | 7,252,437 |
| Depreciation and amortization | 337,489 | 343,982 |
| **Total operating expenses** | 9,632,266 | 16,448,440 |
| **Loss from operations** | (9,632,266) | (16,448,440) |
| **Other income (expense)** | | |
| Inducement expense, net | — | (1,848,235) |
| Change in fair value of warrant liabilities | 24,370 | 94,396 |
| Change in fair value of investment option liability | 21,620 | 208,752 |
| Change in fair value of derivative liability | — | 727,000 |
| Other income | 20,000 | — |
| Interest income, net | 219 | 3,708 |
| **Total other income (expense)** | 66,209 | (814,379) |
| **Net loss before income taxes** | (9,566,057) | (17,262,819) |
| Income tax expense | (8,930) | (28,913) |
| **Net loss** | (9,574,987) | (17,291,732) |
| Less preferred dividends attributable to non-controlling interest | — | 19,041 |
| Less deemed dividends attributable to accretion of embedded derivative at redemption value | — | 147,988 |
| **Net loss attributable to shareholders** | (9,574,987) | (17,458,761) |
| **Other comprehensive loss** | | |
| Foreign currency translation | (24,768) | (33,015) |
| **Comprehensive loss** | $ (9,599,755) | $ (17,491,776) |
| Net loss per share - basic and diluted | $ (19.04) | $ (121.29) |
| Weighted average shares outstanding, basic and diluted | 502,900 | 143,938 |

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

**ENVERIC BIOSCIENCES, INC. AND SUBSIDIARIES**
**CONSOLIDATED STATEMENTS OF CHANGES IN MEZZANINE EQUITY AND SHAREHOLDERS' EQUITY**

| | FOR THE YEAR ENDED DECEMBER 31, 2024 | | | | | | |
|---|---|---|---|---|---|---|---|
| | Common Stock | | Additional Paid-In | Subscription | Accumulated | Accumulated Other Comprehensive | Total Shareholders' |
| | Shares | Amount | Capital | Receivable | Deficit | Loss | Equity |
| **Balance at January 1, 2024** | 182,625 | $ 1,827 | $100,841,416 | $ (1,817,640) | $ (96,499,518) | $ (569,749) | $ 1,956,336 |
| Common stock sold under the Equity Distribution Agreement, net of offering costs of $583,713 | 111,200 | 1,112 | 1,807,677 | — | — | — | 1,808,789 |
| Issuance of direct offering shares (see Note 8) | 45,780 | 458 | 770,835 | — | — | — | 771,293 |
| Exercise of Inducement Warrants for common stock | 130,267 | 1,303 | 2,675,677 | — | — | — | 2,676,980 |
| Stock-based compensation | — | — | 1,562,392 | — | — | — | 1,562,392 |
| Issuance of common shares for vested RSU | 1,830 | 18 | (18) | — | — | — | — |
| Proceeds from the subscription receivable related to the issuance of Inducement Warrants, net of offering costs of $12,821 | — | — | (12,821) | 280,500 | — | — | 267,679 |
| Proceeds from the subscription receivable related to the exercise of warrants and preferred investment options and issuance of common stock in abeyance | 46,934 | 469 | (469) | 1,537,140 | — | — | 1,537,140 |
| Common stock sold under the Purchase Agreement, net of offering costs of $471,756 | 159,366 | 1,593 | 610,360 | — | — | — | 611,953 |
| Foreign exchange translation loss | — | — | — | — | — | (24,768) | (24,768) |
| Net loss | — | — | — | — | (9,574,987) | — | (9,574,987) |
| **Balance at December 31, 2024** | 678,002 | $ 6,780 | $108,255,049 | $ — | $(106,074,505) | $ (594,517) | $ 1,592,807 |

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

**ENVERIC BIOSCIENCES, INC. AND SUBSIDIARIES**
**CONSOLIDATED STATEMENTS OF CHANGES IN MEZZANINE EQUITY AND SHAREHOLDERS' EQUITY**

| | FOR THE YEAR ENDED DECEMBER 31, 2023 | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Redeemable Non-controlling Interest | | Total Mezzanine Equity | Common Stock | | Additional Paid-In Capital | Subscription Receivable | Accumulated Deficit | Accumulated Other Comprehensive Loss | Total Shareholders' Equity |
| | Shares | Amount | | Shares | Amount | | | | | |
| **Balance at January 1, 2023** | 1,000 | $ 885,028 | $ 885,028 | 138,554 | $ 1,386 | $ 94,415,058 | $ — | $ (79,207,786) | $ (536,734) | $ 14,671,924 |
| Preferred dividends attributable to redeemable non-controlling interest | — | 19,041 | 19,041 | — | — | (19,041) | — | — | — | (19,041) |
| Accretion of embedded derivative to redemption value | — | 147,988 | 147,988 | — | — | (147,988) | — | — | — | (147,988) |
| Redemption of Series A preferred stock | (1,000) | (1,052,057) | (1,052,057) | — | — | — | — | — | — | — |
| Stock-based compensation | — | — | — | — | — | 2,150,160 | — | — | — | 2,150,160 |
| Issuance of common shares for vested RSU | — | — | — | 6,910 | 69 | (69) | — | — | — | — |
| Issuance of common shares for deferred offering costs | — | — | — | 9,294 | 93 | 255,014 | — | — | — | 255,107 |
| Issuance of Inducement Warrants, net of offering costs of $239,302 | — | — | — | — | — | 1,967,424 | (280,500) | — | — | 1,686,924 |
| Induced conversion of warrants and preferred investment options | — | — | — | — | — | 683,997 | — | — | — | 683,997 |
| Exercise of warrants and preferred investment options | — | — | — | 27,867 | 279 | 1,536,861 | (1,537,140) | — | — | — |
| Foreign exchange translation loss | — | — | — | — | — | — | — | — | (33,015) | (33,015) |
| Net loss | — | — | — | — | — | — | — | (17,291,732) | — | (17,291,732) |
| **Balance at December 31, 2023** | — | $ — | $ — | 182,625 | $ 1,827 | $100,841,416 | $ (1,817,640) | $ (96,499,518) | $ (569,749) | $ 1,956,336 |

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

**ENVERIC BIOSCIENCES, INC. AND SUBSIDIARIES**
**CONSOLIDATED STATEMENTS OF CASH FLOWS**

| | For the Years Ended December 31, | |
|---|---|---|
| | **2024** | **2023** |
| **Cash Flows From Operating Activities:** | | |
| Net loss | $ (9,574,987) | $ (17,291,732) |
| Adjustments to reconcile net loss to cash used in operating activities | | |
| Change in fair value of warrant liability | (24,370) | (94,396) |
| Change in fair value of investment option liability | (21,620) | (208,752) |
| Change in fair value of derivative liability | — | (727,000) |
| Stock-based compensation | 1,562,392 | 2,150,160 |
| Inducement expense | — | 1,848,235 |
| Deferred offering costs expensed | 418,200 | — |
| Amortization of right of use asset | — | 64,048 |
| Amortization of intangibles | 168,750 | 168,754 |
| Depreciation expense | 168,739 | 175,228 |
| Gain on disposal of property and equipment | — | (4,206) |
| **Change in operating assets and liabilities:** | | |
| Prepaid expenses and other current assets | 178,496 | (6,857) |
| Accounts payable and accrued liabilities | (834,630) | (103,848) |
| Due to related parties | 232,891 | — |
| Right-of-use operating lease asset and obligation | — | (64,045) |
| Net cash used in operating activities | (7,726,139) | (14,094,411) |
| **Cash Flows From Investing Activities:** | | |
| Purchases of property and equipment | — | (5,180) |
| Proceeds from disposal of property and equipment | — | 16,847 |
| Net cash provided by investing activities | — | 11,667 |
| **Cash Flows From Financing Activities:** | | |
| Proceeds from the subscription receivable related to the issuance of Inducement Warrants and the exercise of warrants and preferred investment options | 1,804,819 | — |
| Proceeds from exercise of Inducement Warrants | 2,676,980 | — |
| Proceeds from common stock sold under the Equity Distribution Agreement, net of offering costs | 2,290,186 | — |
| Proceeds from common stock sold under the Purchase Agreement, net of offering costs | 1,083,706 | — |
| Payment for offering costs previously accrued | (181,857) | — |
| Payment for equity distribution offering costs | — | (291,084) |
| Redemption of Series A Preferred Stock | — | (1,052,057) |
| Net cash provided by (used in) financing activities | 7,673,834 | (1,343,141) |
| Effect of foreign exchange rate on changes on cash | 5,354 | (10,022) |
| Net decrease in cash | (46,951) | (15,435,907) |
| Cash at beginning of year | 2,287,977 | 17,723,884 |
| Cash at end of year | $ 2,241,026 | $ 2,287,977 |
| **Supplemental disclosure of cash flow transactions:** | | |
| Cash paid for interest | $ — | $ — |
| Income taxes paid | $ 5,000 | $ 9,507 |
| **Non-cash financing and investing activities:** | | |
| Stock subscription receivable | $ — | $ 1,817,640 |
| Offering costs accrued not paid | $ — | $ 182,724 |
| Warrants issued for offering costs | $ — | $ 77,991 |
| Issuance of common shares for offering costs | $ 771,293 | $ 255,107 |
| Deferred offering costs charged to offering costs | $ 612,000 | $ — |
| Induced conversion of warrants and preferred investment options | $ — | $ 683,997 |
| Preferred dividends attributable to redeemable non-controlling interest | $ — | $ 19,041 |
| Accretion of embedded derivative to redemption value | $ — | $ 147,988 |

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

## NOTE 1. BUSINESS AND LIQUIDITY AND OTHER UNCERTAINTIES

### *Nature of Operations*

Enveric Biosciences, Inc. ("Enveric" or the "Company") is a biotechnology company dedicated to the development of novel neuroplastogenic small-molecule therapeutics for the treatment of depression, anxiety, addiction, and other psychiatric disorders. The head office of the Company is located in Naples, Florida. The Company has the following wholly-owned subsidiaries: Jay Pharma Inc. ("Jay Pharma"), 1306432 B.C. Ltd., 1236567 B.C. Unlimited Liability Company, MagicMed Industries, Inc. ("MagicMed"), Enveric Biosciences Canada Inc., Akos Biosciences, Inc. ("Akos"), and Enveric Therapeutics, Pty. Ltd. ("Enveric Therapeutics").

Enveric's lead program, the EVM301 Series, and its lead drug candidate, EB-003, are intended to offer a first-in-class, new approach to the treatment of difficult-to-address mental health disorders, mediated by the promotion of neuroplasticity and without also inducing hallucinations in the patient. Previously, Enveric was developing the EVM201 Series, and its lead drug candidate EB-002 (formerly EB-373), for the treatment of neuropsychiatric disorders. The EVM201 series comprised next generation synthetic prodrugs of the active metabolite, psilocin. Recently, Enveric out-licensed the EVM201 Series program to MycoMedica Life Sciences, who will seek to develop, manufacture, and commercialize EB-002, in exchange for certain development and milestone payments to Enveric. Our primary focus is to develop our lead asset EB-003 in the EVM301 Series.

### *Reverse Stock Split*

The Company effected a 1-for-15 reverse stock split ("Reverse Stock Split") on January 27, 2025, which began trading on a split-adjusted basis on January 29, 2025, pursuant to which every 15 shares of the Company's issued and outstanding common stock were reclassified as one share of common stock. The Reverse Stock Split had no impact on the par value of the Company's common stock or the authorized number of shares of common stock. Unless otherwise indicated, all share and per share information in these consolidated financial statements are retroactively adjusted to reflect the Reverse Stock Split, prior to the rounding of any fractional shares. Any fractional share resulting from the Reverse Stock Split were rounded up to the next whole number of shares, upon which 87,131 roundup shares were issued in January 2025.

### *Going Concern, Liquidity and Other Uncertainties*

The Company has incurred losses since inception resulting in an accumulated deficit of $106,074,505 as of December 31, 2024 and further losses are anticipated in the development of its business. Further, the Company has operating cash outflows of $7,726,139 for the year ended December 31, 2024. For the year ended December 31, 2024, the Company had a loss from operations of $9,632,266. Since inception, being a research and development company, the Company has not yet generated revenue and the Company has incurred continuing losses from its operations. The Company's operations have been funded principally through the issuance of equity. These factors raise substantial doubt about the Company's ability to continue as a going concern for a period of one year from the issuance of these consolidated financial statements.

In assessing the Company's ability to continue as a going concern, the Company monitors and analyzes its cash and its ability to generate sufficient cash flow in the future to support its operating and capital expenditure commitments. At December 31, 2024, the Company had cash of $2,241,026 and working capital of $1,244,848. In January 2025, the Company raised net proceeds of approximately $4.2 million from a public stock offering. See Note 14. The Company's current cash on hand is not sufficient enough to satisfy its operating cash needs for the 12 months from the filing of this Annual Report on Form 10-K. These conditions raise substantial doubt regarding the Company's ability to continue as a going concern for a period of one year after the date the consolidated financial statements are issued. Management's plan to alleviate the conditions that raise substantial doubt include raising additional working capital through public or private equity or debt financings or other sources, and may include additional collaborations with third parties as well as disciplined cash spending. Adequate additional financing may not be available to the Company on acceptable terms, or at all. Should the Company be unable to raise sufficient additional capital, the Company may be required to undertake further cost-cutting measures including delaying or discontinuing certain operating activities.

As a result of these factors, management has concluded that there is substantial doubt about the Company's ability to continue as a going concern for a period of one year after the date of the consolidated financial statements are issued. The Company's consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

***Nasdaq Notice***

On May 16, 2024, the Company received a letter from Nasdaq notifying the Company that for the prior 30 consecutive business days the bid price for the Company's common stock had closed below the minimum $1.00 per share requirement for continued inclusion on Nasdaq pursuant to Nasdaq Listing Rule 5550(a)(2) (the "Bid Price Rule"). The deficiency letter did not result in the immediate delisting of the Company's common stock from Nasdaq. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), the Company was provided an initial period of 180 calendar days, until November 12, 2024, to regain compliance with the Bid Price Rule. On November 20, 2024, Nasdaq issued a delisting notice, indicating that the Company did not satisfy the Bid Price Rule by the compliance date and that unless the Company requested an appeal of this determination before Nasdaq's listing qualifications panel, the Company's common stock would be scheduled for delisting from Nasdaq and trading suspended. The Company appealed the determination before Nasdaq's listing qualifications panel and on December 30, 2024, the Company received an extension until May 19, 2025, to regain compliance with Bid Price Rule. The Company has applied for a second 180-day compliance period. The Company conducted the Reverse Stock Split on January 27, 2025, which became effective January 29, 2025, in order to regain compliance with the Minimum Bid Price Requirement. The Company has notified NASDAQ on February 11, 2025 that the Company has completed steps to cure the deficiency and regain compliance. On March 4, 2025, the Company received notice from the Nasdaq Office of General Counsel that the Company regained compliance with the Bid Price Rule.

## NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

***Basis of Presentation and Principal of Consolidation***

The accompanying consolidated financial statements have been prepared in accordance and in conformity with U.S. generally accepted accounting principles ("GAAP") and the applicable rules and regulations of the Securities and Exchange Commission (the "SEC") regarding consolidated financial information. All intercompany transactions have been eliminated in consolidation.

***Use of Estimates***

The preparation of the consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amount of assets and liabilities at the date of the financial statements and expenses during the periods reported. By their nature, these estimates are subject to measurement uncertainty and the effects on the financial statements of changes in such estimates in future periods could be significant. Significant areas requiring management's estimates and assumptions include determining the fair value of transactions involving common stock, the valuation of warrants and preferred investment options, the valuation of stock-based compensation and accruals associated with third party providers supporting research and development efforts. Actual results could differ from those estimates.

***Foreign Currency Translation***

From inception through December 31, 2024, the reporting currency of the Company was the United States dollar while the functional currency of certain of the Company's subsidiaries was the Canadian dollar or the Australian dollar. For the years ended December 31, 2024 and 2023, the Company engaged in a number of transactions denominated in Canadian dollars and Australian dollars. As a result, the Company is subject to exposure from changes in the exchange rates of the Canadian dollar and Australian dollar against the United States dollar.

The Company translates the assets and liabilities of its Canadian subsidiaries and Australian subsidiary into the United States dollar at the exchange rate in effect on the balance sheet date. Revenues and expenses are translated at the average exchange rate in effect during each monthly period. Unrealized translation gains and losses are recorded as foreign currency translation gain (loss), which is included in the consolidated statements of shareholders' equity as a component of accumulated other comprehensive loss.

The Company has not entered into any financial derivative instruments that expose it to material market risk, including any instruments designed to hedge the impact of foreign currency exposures. The Company may, however, hedge such exposure to foreign currency exchange fluctuations in the future.

Adjustments that arise from exchange rate changes on transactions denominated in a currency other than the local currency are included in other comprehensive loss in the consolidated statements of operations and comprehensive loss as incurred.

***Cash and Cash Equivalents***

The Company considers all highly liquid investments purchased with an original maturity of three months or less to be cash equivalents. The Company did not have any cash equivalents as of December 31, 2024 and 2023.

***Concentration of Credit Risk***

Financial instruments that potentially subject the Company to concentrations of credit risk consist of cash accounts in a financial institution, which at times, may exceed the federal depository insurance coverage of $250,000 in the United States, AUD$250,000 in Australia and C$100,000 in Canada. The Company has not experienced losses on these accounts, and management believes the Company is not exposed to significant risks on such accounts. As of December 31, 2024, the Company had greater than $250,000 at United States financial institutions, less than AUD$250,000 at Australian financial institutions, and less than C$100,000 at Canadian financial institutions. As of December 31, 2023, the Company had greater than $250,000 at United States financial institutions, less than AUD$250,000 at Australian financial institutions, and greater than C$100,000 at Canadian financial institutions.

***Comprehensive Loss***

Comprehensive loss consists of two components, net loss and other comprehensive loss. Other comprehensive loss refers to revenue, expenses, gains, and losses that under GAAP are recorded as an element of shareholders' equity but are excluded from net loss. Other comprehensive loss consists of foreign currency translation adjustments from those subsidiaries not using the U.S. dollar as their functional currency.

***Intangible Assets***

Intangible assets consist of a license agreement. The cost of license agreements is amortized over the economic life of the license. The Company assesses the carrying value of its intangible assets for impairment each year.

***Property & Equipment***

Property and equipment are recorded at cost. Major property additions, replacements, and betterments are capitalized, while maintenance and repairs that do not extend the useful lives of an asset or add new functionality are expensed as incurred. Depreciation and amortization are recorded using the straight-line method over the respective estimated useful lives of the Company's long-lived assets. The estimated useful lives are typically 3 to 5 years for office furniture and equipment and are depreciated on a straight-line basis.

***Deferred Offering Costs***

The Company allocates offering costs to the different components of the capital raise on a pro rata basis. Any offering costs allocated to common stock are charged directly to additional paid-in capital. Any offering costs allocated to warrant liabilities are charged to general and administrative expenses on the Company's consolidated statement of operations and comprehensive loss.

The Company complies with the requirements of ASC Topic 340, *Other Assets and Deferred Costs* ("ASC 340") and SAB 5A - *Expenses of Offering*. Offering costs, which consist mainly of legal, accounting and consulting fees directly attributable to the issuance of an equity contract to be classified in equity are recorded as a reduction in equity. For the year ended December 31, 2024, the Company incurred $494,292 in deferred offering costs in connection with the Equity Distribution Agreement (the "Distribution Agreement"), with Canaccord Genuity LLC ("Canaccord") and the Purchase Agreement (the "Purchase Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park"). These deferred offering costs were proportionately offset against the total proceeds from the issuance of common stock available under the agreements and the Company expensed any remaining balance of deferred offering costs when the agreements were terminated. As of December 31, 2024, the Company expensed the remaining balance of deferred offering costs related to Lincoln Park as the Company no longer intends to use this purchase agreement, reflected in general and administration expenses in the accompanying consolidated statement of operations. As of December 31, 2024, the balance of deferred offering costs is $0.

For the year ended December 31, 2023, the Company incurred $567,603 in deferred offering costs in connection with the Distribution Agreement, with Canaccord and the Purchase Agreement with Lincoln Park. These deferred offering costs will be proportionately offset against the total proceeds from the issuance of common stock available under the agreements and the Company will expense any remaining balance of deferred offering costs if the agreements are terminated. For the year ended December 31, 2023, there were no issuances of common stock under the agreements resulting in the deferral of offering costs.

***Warrant Liability and Investment Options***

The Company evaluates all of its financial instruments, including issued stock purchase warrants and investment options, to determine if such instruments are derivatives or contain features that qualify as embedded derivatives, pursuant to ASC 480 "Distinguishing Liabilities from Equity" ("ASC 480") and FASB ASC Topic 815, "Derivatives and Hedging" ("ASC 815"). The Company accounts for warrants and investment options for shares of the Company's common stock that are not indexed to its own stock as derivative liabilities at fair value on the consolidated balance sheets. The Company accounts for common stock warrants and investment options with put options as liabilities under ASC 480. Such warrants and investment options are subject to remeasurement at each consolidated balance sheet date and any change in fair value is recognized as a component of other expense on the consolidated statements of operations. The Company will continue to adjust the liability for changes in fair value until the earlier of the exercise or expiration of such common stock warrants and investment options. At that time, the portion of the warrant liability and investment options related to such common stock warrants will be reclassified to additional paid-in capital.

***Modification and Inducement of Warrants and Investment Options***

A change in any of the terms or conditions of warrants is accounted for as a modification. For a warrant modification accounted for under ASC 815, the effect of a modification shall be measured as the difference between the fair value of the modified warrant over the fair value of the original warrant immediately before its terms are modified, measured based on the fair value of the shares and other pertinent factors at the modification date. The accounting for incremental fair value of warrants is based on the specific facts and circumstances related to the modification. When a modification is directly attributable to equity offerings, the incremental change in fair value of the warrants are accounted for as equity issuance costs.

The Company accounts for the inducement to exercise warrants in accordance with ASC Subtopic 470-20-40 "Debt with Conversion and Other Options" ("ASC 470-20-40"). ASC 470-20-40 requires the recognition through earnings of an inducement charge equal to the fair value of the consideration delivered in excess of the consideration issuable under the original conversion terms. Therefore, the Company recognized a loss on the warrant inducement for the incremental change of the warrants related to the reduced exercise price and the issuance of new warrants as these components induced the holders to exercise the warrants.

***Derivative Liability***

The Company evaluates its financial instruments to determine if such instruments are derivatives or contain features that qualify as embedded derivatives in accordance with ASC 815. For derivative financial instruments that are accounted for as assets or liabilities, the derivative instrument is initially recorded at its fair value on the grant date and is then re-valued at each reporting date, with changes in the fair value reported in the consolidated statements of operations. The classification of derivative instruments, including whether such instruments should be recorded as assets or liabilities or as equity, is evaluated at the end of each reporting period. Derivative liabilities are classified in the consolidated balance sheets as current or non-current based on whether or not net-cash settlement or conversion of the instrument could be required within 12 months of the balance sheet date.

***Research and Development***

Research and development expenses are charged to operations as incurred. Research and development expenses include, among other things, internal and external costs associated with preclinical development, pre-commercialization manufacturing expenses, and clinical trials. The Company accrues for costs incurred as the services are being provided by monitoring the status of the trial or services provided and the invoices received from its external service providers. In the case of clinical trials, a portion of the estimated cost normally relates to the projected cost to treat a patient in the trials, and this cost is recognized based on the number of patients enrolled in the trial. As actual costs become known, the Company adjusts its accruals accordingly.

***Research and Development Tax Incentive Receivable***

The Company, through its wholly-owned subsidiary in Australia, participates in the Australian research and development tax incentive program, such that a percentage of the Company's qualifying research and development expenditures are reimbursed by the Australian government, and such incentives are reflected as a reduction of research and development expense. The Australian research and development tax incentive is recognized when there is reasonable assurance that the incentive will be received, the relevant expenditure has been incurred and the amount of the consideration can be reliably measured. At each period end, management estimates the reimbursement available to the Company based on available information at the time.

***Income Taxes***

The Company utilizes an asset and liability approach for financial accounting and reporting for income taxes. The provision for income taxes is based upon income or loss after adjustment for those permanent items that are not considered in the determination of taxable income. Deferred income taxes represent the tax effects of differences between the financial reporting and tax basis of the Company's assets and liabilities at the enacted tax rates in effect for the years in which the differences are expected to reverse.

The Company evaluates the recoverability of deferred tax assets and establishes a valuation allowance when it is more likely than not that some portion or all the deferred tax assets will not be realized. Management makes judgments as to the interpretation of the tax laws that might be challenged upon an audit and cause changes to previous estimates of tax liabilities. In management's opinion, adequate provisions for income taxes have been made. If actual taxable income by tax jurisdiction varies from estimates, additional allowances or reversals of reserves may be necessary.

Tax benefits are recognized only for tax positions that are more likely than not to be sustained upon examination by tax authorities. The amount recognized is measured as the largest amount of benefit that is greater than 50 percent likely to be realized upon settlement. A liability for "unrecognized tax benefits" is recorded for any tax benefits claimed in the Company's tax returns that do not meet these recognition and measurement standards. As of December 31, 2024 and 2023, no liability for unrecognized tax benefits was required to be recorded.

The Company's policy for recording interest and penalties associated with tax audits is to record such items as a component of operating expenses. There were no amounts accrued for penalties and interest for the years ended December 31, 2024 and 2023. The Company does not expect its uncertain tax positions to change during the next twelve months. Management is currently unaware of any issues under review that could result in significant payments, accruals or material deviations from its position.

The Company has identified its United States, Canadian and Australian federal tax returns, and its state and provincial tax returns in Florida, Massachusetts, New Jersey, Pennsylvania, and Ontario, CA as its "major" tax jurisdictions. The Company is in the process of filing its United States federal and state, Australian federal, and Canadian corporate tax returns for the year ended December 31, 2024. Net operating losses for these periods will not be available to reduce future taxable income until the returns are filed.

***Stock-Based Compensation***

The Company follows ASC 718, Compensation - Stock Compensation, which addresses the accounting for stock-based payment transactions, requiring such transactions to be accounted for using the fair value method. Awards of shares for property or services are recorded at the more readily measurable of the estimated fair value of the stock award and the estimated fair value of the service. The Company uses the Black-Scholes option-pricing model to determine the grant date fair value of certain stock-based awards under ASC 718. The assumptions used in calculating the fair value of stock-based awards represent management's reasonable estimates and involve inherent uncertainties and the application of management's judgment. Fair value of restricted stock units or restricted stock awards is determined by the closing price per share of the Company's common stock on the date of award grant.

The estimated fair value is amortized as a charge to earnings on a straight-line basis, for awards or portions of awards that do not require specified milestones or performance criteria as a vesting condition and also depending on the terms and conditions of the award, and the nature of the relationship of the recipient of the award to the Company. The Company records the grant date fair value in line with the period over which it was earned. For employees and consultants, this is typically considered to be the vesting period of the award. The Company accounts for forfeitures as they occur.

The estimated fair value of awards that require specified milestones or recipient performance are charged to expense when such milestones or performance criteria are probable to be met.

Restricted stock units, restricted stock awards, and stock options are granted at the discretion of the Compensation Committee of the Company's board of directors (the "Board of Directors"). These awards are restricted as to the transfer of ownership and generally vest over the requisite service periods, typically over a 12 to 48-month period. A significant portion of these awards may include vesting terms that include, without limitation, defined volume weighted average price levels being achieved by the Company's Common Stock, specific performance milestones, employment, or engagement by the Company, with no assurances of achievement of any such vesting conditions, if applicable.

The value of RSU's is equal to the product of the number of units awarded, multiplied by the closing price per share of the Company's Common Stock on the date of the award. The terms and conditions of each RSU is defined in the RSU agreement and includes vesting terms that consist of any or all of the following: immediate vesting, vesting over a defined period of time, vesting based on achievement of a defined volume weighted average price levels at specified times, vesting based on achievement of specific performance milestones within a specific time frame, change of control, termination of the employee without cause by the Company, resignation of the employee with good cause. The value assigned to each RSU is charged to expense based on the vesting terms, as follows: value of RSU's that vest immediately are charged to expense on the date awarded, value of RSU's that vest based upon time, or achievement of stock price levels over a period of time are charged to expense on a straight line basis over the time frame specified in the RSU and the value of RSU's that vest based upon achievement of specific performance milestones are charged to expense during the period that such milestone is achieved. Vested RSU's may be converted to shares of Common Stock of an equivalent number upon either the termination of the recipient's employment with the Company, or in the event of a change in control. If the recipient is not an employee, such person's engagement with the Company must either be terminated prior to such conversion of RSU's to shares of Common Stock, or in the event of a change in control. Furthermore, as required by Section 409A of the Internal Revenue Code, if the recipient is a "specified employee" (generally, certain officers and highly compensated employees of publicly traded companies), such recipient may only convert vested RSU's into shares of Common Stock no earlier than the first day of the seventh month following such recipients termination of employment with the Company, or the event of change in control.

The value of RSA's is equal to the product of the number of restricted shares awarded, multiplied by the closing price per share of the Company's Common Stock on the date of the award. The terms and conditions of each RSA is defined in the RSA agreement and includes vesting terms that consist of any or all of the following: immediate vesting, vesting over a defined period of time, or vesting based on achievement of a defined volume weighted average price levels at specified times. Upon vesting, the recipient may receive restricted stock which includes a legend prohibiting sale of the shares during a restriction period that is defined in the RSA agreement. Termination of employment by or engagement with the Company is not required for the recipient to receive restricted shares of Common Stock. The value assigned to each RSA is charged to expense based on the vesting terms, as follows: value of RSA's that vest immediately are charged to expense on the date awarded, value of RSA's that vest based upon time, or achievement of stock price levels over a period of time are charged to expense on a straight-line basis over the time frame specified in the RSA.

***Net Loss per Share***

Basic net loss per share is computed by dividing net loss by the weighted average number of shares of common stock outstanding during the period. Diluted loss per share is computed using the weighted average number of common shares and, if dilutive, potential common shares outstanding during the period. Potential common shares consist of the incremental common shares issuable upon the exercise of stock options and warrants (using the treasury stock method). The computation of basic net loss per share for the years ended December 31, 2024 and 2023 excludes potentially dilutive securities. The computations of net loss per share for each period presented is the same for both basic and fully diluted. In accordance with ASC 260 "Earnings per Share" ("ASC 260"), penny warrants were included in the calculation of weighted average shares outstanding for the purposes of calculating basic and diluted earnings per share. In accordance with ASC 260, 14,586 RSAs that were fully vested on December 31, 2024 were included in basic and dilutive earnings per share as there were no remaining contingencies for these shares to be issued as of December 31, 2024. The shares were issued during January 2025.

Potentially dilutive securities outlined in the table below have been excluded from the computation of diluted net loss per share the years ended December 31, 2024 and 2023 because the effect of their inclusion would have been anti-dilutive.

| | For the years ended December 31, | |
|---|---|---|
| | 2024 | 2023 |
| Warrants to purchase shares of common stock | 56,308 | 186,614 |
| Restricted stock units - vested and unissued | 1,369 | 1,390 |
| Restricted stock units - unvested | 48,017 | 9,366 |
| Common stock in abeyance | — | 46,934 |
| Investment options to purchase shares of common stock | 4,667 | 4,667 |
| Options to purchase shares of common stock | 1,538 | 2,022 |
| Total potentially dilutive securities | 111,899 | 250,993 |

***Fair Value of Financial Instruments***

The fair value of the Company's assets and liabilities, which qualify as financial instruments under ASC Topic 820, "Fair Value Measurements and Disclosures" ("ASC 820"), approximates the carrying amounts in the balance sheets, excluding the warrants and preferred investment option liabilities, primarily due to their short-term nature.

***Fair Value Measurements***

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. To increase the comparability of fair value measures, the following hierarchy prioritizes the inputs to valuation methodologies used to measure fair value:

Level 1 - Valuations based on quoted prices for identical assets and liabilities in active markets.

Level 2 - Valuations based on observable inputs other than quoted prices included in Level 1, such as quoted prices for similar assets and liabilities in active markets, quoted prices for identical or similar assets and liabilities in markets that are not active, or other inputs that are observable or can be corroborated by observable market data.

Level 3 - Valuations based on unobservable inputs reflecting the Company's own assumptions, consistent with reasonably available assumptions made by other market participants. These valuations require significant judgment.

For certain financial instruments, including cash and accounts payable, the carrying amounts approximate their fair values as of December 31, 2024 and 2023 because of their short-term nature.

***Leases***

Operating lease assets are included within right-of-use operating lease asset and operating lease liabilities are included in current portion of right-of-use operating lease obligation and non-current portion of right-of-use operating lease obligation on the consolidated balance sheets as of December 31, 2024 and 2023. The Company has elected not to present short-term leases as these leases have a lease term of 12 months or less at lease inception and do not contain purchase options or renewal terms that the Company is reasonably certain to exercise. Lease payments for short-term leases are recognized on a straight-line basis over the term of the lease. All other lease assets and lease liabilities are recognized based on the present value of lease payments over the lease term at commencement date. Because most of the Company's leases do not provide an implicit rate of return, the Company used an incremental borrowing rate based on the information available at adoption date in determining the present value of lease payments.

The Company assesses whether an arrangement is a lease or contains a lease at inception. For arrangements considered leases or that contain a lease that is accounted for separately, the Company determines the classification and initial measurement of the right-of-use asset and lease liability at the lease commencement date, which is the date that the underlying asset becomes available for use. The Company has elected to account for non-lease components associated with its leases and lease components as a single lease component.

The Company recognizes a right-of-use asset, which represents the Company's right to use the underlying asset for the lease term, and a lease liability, which represents the present value of the Company's obligation to make payments arising over the lease term. The present value of the lease payments is calculated using either the implicit interest rate in the lease or an incremental borrowing rate**.** The Company did not have any operating leases as of December 31, 2024 and 2023.

A lease qualifies as a finance lease if any of the following criteria are met at the inception of the lease: (i) there is a transfer of ownership of the leased asset to the Company by the end of the lease term, (ii) the Company holds an option to purchase the leased asset that it is reasonably certain to exercise, (iii) the lease term is for a major part of the remaining economic life of the leased asset, (iv) the present value of the sum of lease payments equals or exceeds substantially all of the fair value of the leased asset, or (v) the nature of the leased asset is specialized to the point that it is expected to provide the lessor no alternative use at the end of the lease term. All other leases are recorded as operating leases. Finance lease payments are bifurcated into (i) a portion that is recorded as interest expense and (ii) a portion that reduces the finance liability associated with the lease. The Company did not have any finance leases as of December 31, 2024 and 2023.

***Segment Reporting***

The Company determines its reporting units in accordance with FASB ASC 280, "Segment Reporting" ("ASC 280"). The Company evaluates a reporting unit by first identifying its operating segments under ASC 280. The Company then evaluates each operating segment to determine if it includes one or more components that constitute a business. If there are components within an operating segment that meet the definition of a business, the Company evaluates those components to determine if they must be aggregated into one or more reporting units. If applicable, when determining if it is appropriate to aggregate different operating segments, the Company determines if the segments are economically similar and, if so, the operating segments are aggregated.

The Company operates as one operating segment with a focus on developing novel neuroplastogenic small-molecule therapeutics for the treatment of depression, anxiety, and addiction disorders. The Company's Chief Executive Officer ("CEO") as the Chief Operating Decision Maker ("CODM"), manages and allocates resources to the operations of the Company on a consolidated basis. Consolidated loss from operations, which is reported in the accompanying consolidated statements of operations, is the measure of segment profit or loss that is regularly reviewed by the CODM. This enables the CEO to assess the overall level of available resources and determine how best to deploy these resources across research and development projects in line with the long-term company-wide strategic goals. Refer to the accompanying consolidated statements of operations for the presentation of consolidated loss from operations for the years ended December 31, 2024 and 2023. The measure of segment assets is reported in the accompanying consolidated balance sheets as "Total assets." There are no significant segment expenses as the expenses that are included in consolidated loss from operations are general and administrative and research and development.

***Recent Accounting Pronouncements***

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*. ASU 2023-07 updates reportable segment disclosure requirements primarily through enhanced disclosures about significant segment expenses. ASU 2023-07 is effective for all entities for fiscal years beginning after December 15, 2023, and for interim periods within fiscal years beginning after December 15, 2024. The amendments should be applied retrospectively to all prior periods presented in the financial statements. The Company has adopted ASU 2023-07, and this guidance did not have a material impact on the Company's consolidated financial statements.

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*, which amends the disclosure to address investor requests for more transparency about income tax information through improvements to income tax disclosures primarily related to the rate reconciliation and income taxes paid information and includes certain other amendments to improve the effectiveness of income tax disclosures. The ASU is effective on a prospective basis for annual periods beginning after December 15, 2024, and early adoption and retrospective application are permitted. The Company has adopted ASU 2023-09 effective January 1, 2025. The Company is in the process of evaluating the impact of ASU 2023-09 on the Company's consolidated financial statements which will be reflected in the December 31, 2025 financial statements.

In November 2024, the FASB issued ASU 2024-03, *Income Statement (Topic 220): Reporting Comprehensive Income - Expense Disaggregation Disclosures, Disaggregation of Income Statement Expenses*, that requires public companies to disclose, in interim and reporting periods, additional information about certain expenses in the financial statements. In January 2025, the FASB issued ASU No. 2025-01, *Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40): Clarifying the Effective.* ASU 2024-03, as clarified by ASU 2025-01, is effective for annual periods beginning after December 15, 2026 and interim reporting periods beginning after December 15, 2027. Early adoption is permitted and is effective on either a prospective basis or retrospective basis. The Company is currently assessing the potential impacts of ASU 2024-03.

## NOTE 3. PREPAID EXPENSES AND OTHER CURRENT ASSETS

As of December 31, 2024 and 2023, the prepaid expenses and other current assets of the Company consisted of the following:

| | December 31, 2024 | December 31, 2023 |
|---|---|---|
| Prepaid value-added taxes | $ 233,054 | $ 243,429 |
| Prepaid other | 152,894 | 62,036 |
| Prepaid insurance | 107,610 | 149,559 |
| Prepaid research and development | — | 46,320 |
| Deferred offering costs (see Note 8) | — | 567,603 |
| Franchise tax receivable | — | 79,258 |
| R&D tax incentive receivable | — | 145,349 |
| **Total prepaid expenses and other current assets** | $ 493,558 | $ 1,293,554 |

## NOTE 4. INTANGIBLE ASSETS

As of December 31, 2024 and 2023, the Company's intangible assets, which are located in the United States, consisted of:

| | |
|---|---|
| **Definite lived intangible assets** | |
| **Balance at January 1, 2023** | $ 379,686 |
| Amortization | (168,754) |
| **Balance at December 31, 2023** | $ 210,932 |
| Amortization | (168,750) |
| **Balance at December 31, 2024** | $ 42,182 |

For identified definite lived intangible assets, there was no impairment expense during the years ended December 31, 2024 and 2023. For identified definite lived intangible assets, amortization expense amounted to $168,750 and $168,754 during the years ended December 31, 2024 and 2023, respectively.

The Company amortizes definite lived intangible assets on a straight-line basis over their estimated useful lives. Amortization expense of identified intangible assets based on the carrying amount as of December 31, 2024 is as follows:

| Year ending December 31, | |
|---|---|
| 2025 | $ 42,182 |
| | $ 42,182 |

## NOTE 5. PROPERTY AND EQUIPMENT

Property and equipment consists of the following assets which are located in Calgary, Canada, with all amounts translated into U.S. dollars:

| | December 31, 2024 | December 31, 2023 |
|---|---|---|
| Lab equipment | $ 769,105 | $ 836,709 |
| Computer equipment and leasehold improvements | 26,073 | 28,379 |
| Less: Accumulated depreciation | (489,401) | (357,711) |
| **Property and equipment, net of accumulated depreciation** | **$ 305,777** | **$ 507,377** |

Depreciation expense was $168,739 and $175,228 for the years ended December 31, 2024 and 2023, respectively.

## NOTE 6. ACCRUED LIABILITIES

As of December 31, 2024 and December 31, 2023, the accrued liabilities of the Company consisted of the following:

| | December 31, 2024 | December 31, 2023 |
|---|---|---|
| Product development | $ 332,421 | $ 139,981 |
| Accrued salaries, wages, and bonuses | 1,327 | 8,889 |
| Professional fees | 103,968 | 584,810 |
| Accrued restructuring costs | — | 301,645 |
| Accrued franchise taxes | 261,100 | 22,318 |
| Patent costs | 18,000 | 18,000 |
| Other | 15,194 | — |
| **Total accrued expenses** | $ 732,010 | $ 1,075,643 |

## NOTE 7. RELATED PARTY TRANSACTIONS

As of December 31, 2024, there was $232,891 due to related parties. This balance is related to payments due to board members of the Company. Board member Sheila DeWitt has provided research and development services as an advisory consultant to the Company since May 2022. These services are provided as needed on an hourly basis. During the year ended December 31, 2024, the Company incurred $189,125 in service fees related to these services. Of these fees, $176,125 has been paid and $13,000 is included in due to related parties on the consolidated balance sheet as of December 31, 2024. There was no balance outstanding at December 31, 2023.

## NOTE 8. SHARE CAPITAL AND OTHER EQUITY INSTRUMENTS

### *Authorized Capital*

The holders of the Company's common stock are entitled to one vote per share. Holders of common stock are entitled to receive ratably such dividends, if any, as may be declared by the Board of Directors out of legally available funds. Upon the liquidation, dissolution, or winding up of the Company, holders of common stock are entitled to share ratably in all assets of the Company that are legally available for distribution. As of December 31, 2024 and December 31, 2023, 100,000,000 shares of common stock and 20,000,000 shares of Preferred Stock were authorized under the Company's articles of incorporation.

### *Equity Distribution Agreement*

On September 1, 2023, the Company entered into the Equity Distribution Agreement (the "Distribution Agreement"), with Canaccord, Genuity LLC ("Canaccord") pursuant to which the Company may offer and sell from time to time, through Canaccord as sales agent and/or principal, shares of common stock of the Company having an aggregate offering price of up to $10.0 million. Due to the offering limitations applicable to the Company and in accordance with the terms of the Distribution Agreement, the Company may offer Common Stock having an aggregate gross sales price of up to $2,392,514 pursuant to the prospectus supplement dated September 1, 2023 (the "Prospectus Supplement"). Subject to the terms and conditions of the Distribution Agreement, Canaccord may sell the Common Stock by any method permitted by law deemed to be an "at-the-market offering". The Company will pay Canaccord a commission equal to 3.0% of the gross sales price of the Common Stock sold through Canaccord under the Distribution Agreement and has also agreed to reimburse Canaccord for certain expenses. The Company may also sell Common Stock to Canaccord as principal for Canaccord's own account at a price agreed upon at the time of sale. Any sale of Common Stock to Canaccord as principal would be pursuant to the terms of a separate terms agreement between the Company and Canaccord.

On December 28, 2023, the Company entered into warrant exercise inducement offer letters (the "Inducement Letters") with certain holders (the "Holders") of the warrants that were modified in July 2022 (the "February 2022 Post-Modification Warrants") and registered direct ("RD") and the private investment in public equity ("PIPE") preferred investment options to purchase shares of the Company's common stock (the "Existing Warrants and Investment Options") pursuant to which the Holders agreed to exercise for cash their Existing Warrants and Investment Options to purchase 74,800 shares of the Company's common stock, in the aggregate, at a reduced exercised price of $20.55 per share (from an original exercise price of $116.70 per share), in exchange for the Company's agreement to issue new warrants (the "Inducement Warrants") to purchase up to 149,600 shares of the Company's common stock (the "Inducement Warrant Shares"), and the Holders to make a cash payment of $1.88 per Inducement Warrant share for total proceeds of $280,500. In January 2024, the Company received aggregate gross proceeds of $1,817,640 from the exercise of the Existing Warrants and Investment Options by the Holders and the sale of the Inducement Warrants. Because the Existing Warrants and Investment Options by the Holders and the sale of the Inducement Warrants that exercised on December 28, 2023 and unsettled until January 2024, the proceeds are included in the consolidated balance sheet as a subscription receivable as of December 31, 2023. As of December 31, 2023, 27,867 shares of the Existing Warrants and Investment Options exercised were considered issued as the Company had the enforceable right to obtain the cash proceeds, which were in-transit, and the Holders were no longer able to rescind the exercise election. Due to the beneficial ownership limitation provisions, 46,934 shares of the Existing Warrants and Investment Options exercised were initially unissued and held in abeyance for the benefit of the Holder until notice is received from the Holder that the shares may be issued in compliance with such limitation. During the year ended December 31, 2024, the Company issued all 46,934 shares of common stock of the 46,934 shares of Existing Warrants and Investment Options exercised that were held in abeyance due to the beneficial ownership limitation provisions.

On December 28, 2023, the Company entered into warrant exercise inducement offer letters (the "Inducement Letters") with certain holders of warrants and preferred investment options. The Inducement Letters prohibit the Company from entering into any variable rate transaction as defined in the Inducement Letters, including the issuance of (1) any variable priced debt or equity securities or (2) transactions whereby the Company may issue securities at a future determined price, such as through an at-the-market offering or an equity line of credit. The variable rate transaction restriction would have expired after six-months from the closing date of December 28, 2023 for the Inducement Letters for an issuance through an at-the-market offering, and one-year for the remaining variable rate transactions, however the restriction was waived for the at-the-market offering on March 8, 2024 and the equity line on May 3, 2024.

On March 8, 2024, the Company entered into a series of common stock purchase agreements for the issuance in a registered direct offering of 15,246 shares of the Company's common stock to the Holders of the Inducement Warrants. The issuance was made in exchange for the permanent and irrevocable waiver of the variable rate transaction limitation solely with respect to the entry into and/or issuance of shares of common stock in an at the market offering contained in the Inducement Letters. The fair value of the shares issued for consideration of waiving the variable rate transaction limitation was $322,453 and was charged to additional paid in capital, as it is direct and incremental to the Distribution Agreement, on the consolidated balance sheet as an offering cost related to the Distribution Agreement.

During the year ended December 31, 2024, the Company issued 111,200 shares of common stock for gross proceeds of $2,392,502 under the Distribution Agreement, and charged offering costs of $583,713 to additional paid in capital on the consolidated balance sheet. As of December 31, 2024 and December 31, 2023, there were deferred offering costs related to the Distribution Agreement of $0 and $171,944, respectively. As of December 31, 2024, there is $0 available under the Distribution Agreement.

***Lincoln Park Equity Line***

On November 3, 2023, the Company entered into a Purchase Agreement (the "Purchase Agreement") and a registration rights agreement (the "Registration Rights Agreement"), with Lincoln Park Capital Fund, LLC ("Lincoln Park"), pursuant to which Lincoln Park has committed to purchase up to $10.0 million of the Company's common stock, subject to certain limitations and satisfaction of the conditions set forth in the Purchase Agreement.

Under the terms and subject to the conditions of the Purchase Agreement, the Company has the right, but not the obligation, to sell to Lincoln Park, and Lincoln Park is obligated to purchase up to $10.0 million of the Company's Common Stock (the "Purchase Shares"). However, such sales of Common Stock by the Company, if any, will be subject to important limitations set forth in the Purchase Agreement, including limitations on number of shares that may be sold. Sales may occur from time to time, at the Company's sole discretion, over the 24-month period commencing on the date that the conditions to Lincoln Park's purchase obligation set forth in the Purchase Agreement are satisfied, including that a registration statement on Form S-1 covering the resale of the shares of the Company's Common Stock that have been and may be issued to Lincoln Park under the Purchase Agreement, which the Company has filed with the SEC pursuant to the Registration Rights Agreement, is declared effective by the SEC and a final prospectus relating thereto is filed with the SEC. As required under the Purchase Agreement, the Company registered a resale of 76,032 shares of the Company's common stock, plus the 9,294 commitment shares, by Lincoln Park on a registration statement on Form S-1 dated November 8, 2023, which was declared effective by the SEC on December 5, 2023. As of July 30, 2024, there were no remaining shares available to be issued in connection with this registration statement. On September 4, 2024, the Company filed an amended Form S-1, which was declared effective by the SEC on September 11, 2024. The amended Form S-1 registered an additional 326,667 shares of common stock that are available to be issued to Lincoln Park in connection with this agreement.

Because the purchase price per share to be paid by Lincoln Park for the shares of Common Stock that the Company may elect to sell to Lincoln Park under the Purchase Agreement, if any, will fluctuate based on the market prices of the Company's Common Stock at the time the Company elects to sell shares to Lincoln Park pursuant to the Purchase Agreement, if any, it is not possible for the Company to predict the number of shares of Common Stock that the Company will sell to Lincoln Park under the Purchase Agreement, the purchase price per share that Lincoln Park will pay for shares purchased from the Company under the Purchase Agreement, or the aggregate gross proceeds that the Company will receive from those purchases by Lincoln Park under the Purchase Agreement.

On May 3, 2024, the Company entered into a series of common stock purchase agreements for the issuance in a registered direct offering of an aggregate of 30,534 shares of the Company's common stock, to certain institutional investors. The issuance was made in exchange for the permanent and irrevocable waiver of the variable rate transaction limitation with respect to any existing or future agreement by the Company to effect any issuance of shares and issue such shares thereunder, as contained in those certain Inducement Offer Letters, dated December 28, 2023, between the Company and those certain institutional investors. The Company will not receive any net proceeds in connection with the offering. The fair value of the shares issued for consideration of waiving the variable rate transaction limitation was $448,840 and was recorded as deferred offering costs, as direct and incremental to the Purchase Agreement, within prepaid expenses and other current assets on the consolidated balance sheet related to the Purchase Agreement.

The common stock purchase agreements contain customary representations and warranties and certain indemnification obligations of the Company. The common stock purchase agreements also restrict the Company from issuing, entering into any agreement to issue, or announcing the issuance of the Company's common stock from the date of the common stock purchase agreements until the earlier of 30 days after entering into the agreements or at such time as one million (1,000,000) shares of the Company's common stock have traded in the open market. The closing of the issuance of the Shares pursuant to the common stock purchase agreements closed on May 3, 2024.

During the year ended December 31, 2024, the Company had issued 159,366 shares of common stock, through the Purchase Agreement for gross cash proceeds of $1,083,709. During the year ended December 31, 2024, the Company charged offering costs of $471,756 to additional paid in capital on the consolidated balance sheet. As of December 31, 2024 and 2023, the Company has capitalized deferred offering costs of $0 and $395,660, respectively. As of December 31, 2024, there were 243,334 shares available to be issued in connection with the Purchase Agreement. The Company engaged in a best efforts public offering in the first quarter of 2025 (described below), which restricts the use of the Lincoln Park Equity Line for a period of one year from February 3, 2025.

***Common Stock Activity***

During the year ended December 31, 2024 a total of 1,830 shares of common stock were issued pursuant to the vesting of restricted stock units. During the year ended December 31, 2023 a total of 6,910 shares of common stock were issued pursuant to the vesting of restricted stock units.

***Stock Options***

***Amendment to 2020 Long-Term Incentive Plan***

On May 3, 2022, the board of directors ("Board") adopted the First Amendment (the "Plan Amendment") to the Enveric Biosciences, Inc. 2020 Long-Term Incentive Plan (the "Incentive Plan") to (i) increase the aggregate number of shares available for the grant of awards by 9,739 shares to a total of 13,334 shares, and (ii) add an "evergreen" provision whereby the number of shares authorized for issuance pursuant to awards under the Incentive Plan will be automatically increased on the first trading date immediately following the date the Company issues any share of common stock (defined below) to any person or entity, to the extent necessary so that the number of shares of the Company's common stock authorized for issuance under the Incentive Plan will equal the greater of (x) 13,334 shares, and (y) 15% of the total number of shares of the Company's common stock outstanding as of such issuance date (the "Evergreen Provision"). The Plan Amendment was approved by the Company's shareholders at a special meeting of the Company's shareholders held on July 14, 2022.

On November 2, 2023, the stockholders approved the amendments to the 2020 Long-Term Incentive Plan, which was approved by the Board on August 8, 2023 (the "Amended Incentive Plan"). The Amended Incentive Plan (i) increased the number of authorized shares reserved for issuance under the Amended Incentive Plan to a maximum of 23,334, subject to equitable adjustment, and (ii) removed the Evergreen Provision implemented in the Plan Amendment. During the first quarter of 2024, the Board approved an equitable adjustment to increase the number of shares available under the Plan by 8,986 shares. Effective October 9, 2024, the Board approved an equitable adjustment to increase the number of shares available under the Incentive Plan by 64,402 shares, which increased the total number of authorized shares under the Incentive Plan to 96,721 shares. As of December 31, 2024, the total number of shares available for grant under the Incentive Plan was 25,659.

A summary of the stock option activity under the Company's incentive plan for the years ended December 31, 2024 and 2023 is presented below:

| | Number of Shares | Weighted Average Exercise Price | Weighted Average Grant Date Fair Value | Weighted Average Remaining Contractual Term (years) | Aggregate Intrinsic Value |
|---|---|---|---|---|---|
| Outstanding at January 1, 2023..... | 3,222 | $ 555.75 | $ 672.30 | 4.1 | $ — |
| Granted..... | — | — | — | | — |
| Forfeited ..... | (1,200) | 46.05 | 38.70 | | — |
| Outstanding at December 31, 2023 | 2,022 | 857.55 | 1,158.30 | 3.4 | — |
| Granted..... | — | — | — | | — |
| Forfeited ..... | (484) | 590.25 | 810.30 | | — |
| Outstanding at December 31, 2024 | 1,538 | $ 941.55 | $ 1,267.65 | 2.3 | $ — |
| Exercisable at December 31, 2024 | 1,487 | $ 972.42 | $ 1,310.20 | 2.0 | $ — |

The Company's stock based compensation expense, recorded within general and administrative expense in the consolidated statement of operations and comprehensive loss, related to stock options for the years ended December 31, 2024 and 2023 was $(5,441) and $156,075, respectively.

As of December 31, 2024, the Company had $1,932 in unamortized stock option expense, which will be recognized over a weighted average period of 1.15 years.

***Issuance of Restricted Stock Units***

The Company's activity in restricted stock units was as follows for the year ended December 31, 2024:

| | Number of shares | Weighted average fair value |
|---|---|---|
| Non-vested at January 1, 2023 | 4,271 | $ 1,388.55 |
| Granted | 12,167 | 40.95 |
| Forfeited | (2,896) | 385.80 |
| Vested | (4,176) | 297.00 |
| Non-vested at December 31, 2023 | 9,366 | 434.55 |
| Granted | 42,543 | 8.84 |
| Forfeited | (1,850) | 43.05 |
| Vested | (2,042) | 333.30 |
| Non-vested at December 31, 2024 | 48,017 | $ 24.08 |

For the years ended December 31, 2024 and 2023, the Company recorded $1,475,947 and $1,994,085, respectively, in stock-based compensation expense related to restricted stock units, which is a component of both general and administrative and research and development expenses in the consolidated statement of operations and comprehensive loss. As of December 31, 2024, the Company had unamortized stock-based compensation costs related to restricted stock units of $892,536 which will be recognized over a weighted average period of 1.91 years. As of December 31, 2024, 1,369 restricted stock units are vested without shares of common stock being issued, with all of these shares due as of December 31, 2024.

The following table summarizes the Company's recognition of stock-based compensation for restricted stock units for the following periods:

| | Year ended December 31, | |
|---|---|---|
| | 2024 | 2023 |
| Stock-based compensation expense for RSUs: | | |
| General and administrative | $ 646,636 | $ 1,085,791 |
| Research and development | 829,311 | 908,294 |
| Total | $ 1,475,947 | $ 1,994,085 |

***Restricted Stock Awards***

The Company's activity in restricted common stock was as follows for the years ended December 31, 2024:

| | Number of shares | Weighted average fair value |
|---|---|---|
| Non-vested at January 1, 2024 | — | — |
| Granted | 14,586 | $ 6.30 |
| Vested | (14,586) | $ 6.30 |
| Non-vested at December 31, 2024 | — | $ — |

For the years ended December 31, 2024 and 2023, the Company recorded $91,886 and $0, respectively, in stock-based compensation expense within general and administrative expense, related to restricted stock awards. As of December 31, 2024, there were no unamortized stock-based compensation costs related to restricted share awards. The balance of Common Shares related to the vested restricted stock awards as of December 31, 2024 will be issued during the 2025 calendar year. There are 14,586 vested and unissued shares of restricted stock awards as of December 31, 2024. These shares were issued during the first quarter of 2025.

***Warrants and Preferred Investment Options***

The following table summarizes information about shares issuable under warrants outstanding at December 31, 2024 and 2023:

| | Warrant shares outstanding | Weighted average exercise price | Weighted average remaining life | Intrinsic value |
|---|---|---|---|---|
| Outstanding at January 1, 2023 | 43,698 | $ 875.40 | 3.6 | $ 5,514 |
| Issued | 154,088 | 20.55 | — | — |
| Exercised | (8,134) | 20.55 | — | — |
| Forfeited | (3,038) | 1,672.50 | | — |
| Outstanding at December 31, 2023 | 186,614 | 176.85 | 4.6 | — |
| Issued | — | — | — | — |
| Expired | (39) | 2,400.00 | — | — |
| Exercised | (130,267) | 20.55 | — | — |
| Outstanding at December 31, 2024 | 56,308 | $ 536.70 | 2.7 | $ — |
| Exercisable at December 31, 2024 | 56,308 | $ 536.70 | 2.7 | $ — |

The following table summarizes information about investment options outstanding at December 31, 2024 and 2023:

| | Investment options outstanding | Weighted average exercise price | Weighted average remaining life | Intrinsic value |
|---|---|---|---|---|
| Outstanding at January 1, 2023 | 71,334 | $ 118.95 | 5.1 | $ — |
| Exercised | (66,667) | 20.55 | — | — |
| Outstanding at December 31, 2023 | 4,667 | 150.00 | 4.1 | $ — |
| Exercised | — | — | — | — |
| Outstanding at December 31, 2024 | 4,667 | $ 150.00 | 2.6 | $ — |
| Exercisable at December 31, 2024 | 4,667 | $ 150.00 | 2.6 | $ — |

On December 28, 2023, the Company entered into warrant exercise inducement offer letters (the "Inducement Letters") with certain holders (the "Holders") of the February 2022 Post-Modification Warrant and RD and PIPE preferred investment options to purchase shares of the Company's common stock (the "Existing Warrants and Investment Options") pursuant to which the Holders agreed to exercise for cash their Existing Warrants and Investment Options to purchase 74,800 shares of the Company's common stock, in the aggregate, at a reduced exercised price of $20.55 per share (from an original exercise price of $116.70 per share), in exchange for the Company's agreement to issue new warrants (the "Inducement Warrants") to purchase up to 149,600 shares of the Company's common stock (the "Inducement Warrant Shares"), and the Holders to make a cash payment of $1.88 per Inducement Warrant share for total proceeds of $280,500. In January 2024, the Company received aggregate gross proceeds of $1,817,640 from the exercise of the Existing Warrants and Investment Options by the Holders and the sale of the Inducement Warrants. Because the Existing Warrants and Investment Options by the Holders and the sale of the Inducement Warrants that exercised on December 28, 2023 and unsettled until January 2024, the proceeds are included in the consolidated balance sheet as a subscription receivable as of December 31, 2023. As of December 31, 2023, 27,867 shares of the Existing Warrants and Investment Options exercised were considered issued as the Company had the enforceable right to the obtain the cash proceeds, which were in-transit, and the Holders were no longer able to rescind the exercise election. Due to the beneficial ownership limitation provisions, 46,934 shares of the Existing Warrants and Investment Options exercised were initially unissued and held in abeyance for the benefit of the Holder until notice is received from the Holder that the shares may be issued in compliance with such limitation. The Company engaged Roth Capital Partners, LLC ("Roth") to act as its financial advisor in connection with the transactions summarized above and has paid Roth approximately $144,000 for its services, in addition to reimbursement for certain expenses. Roth was also issued warrants to purchase up to 4,488 shares of common stock. The Roth Warrants have the same terms as the Inducement Warrants. The grant date fair value of these Roth Warrants was estimated to be $77,991 on December 28, 2023 and were charged to additional paid in capital as issuance costs. The Company also incurred legal fees of $17,254 related to the transactions above that were charged to additional paid in capital as issuance costs.

The Company also agreed to file a registration statement on Form S-3 covering the resale of the Inducement Warrant Shares issued or issuable upon the exercise of the Inducement Warrants (the "Resale Registration Statement") by January 8, 2024 (filed January 11, 2024). In the Inducement Letters, the Company agreed not to issue any shares of common stock or common stock equivalents or to file any other registration statement with the SEC (in each case, subject to certain exceptions) for a period ending on February 26, 2024. The Company also agreed not to effect or agree to effect any variable rate transaction (as defined in the Inducement Letters) until December 28, 2024. See the *Equity Distribution Agreement* section of this Note.

In connection with this transaction, the Company determined the fair value of the Existing Warrants and Investment Options immediately prior to the Inducement Letters and the fair value of the amended warrants and investment options immediately after the Inducement Letters. The pre-modification measurement of fair value of the Existing Warrants and Investment Options were determined utilizing a Black-Scholes model considering all relevant assumptions current at the date of modification (i.e. for the Existing Warrants share price of $23.40, exercise price of $116.70, term of 3.6 years, volatility of 94%, risk-free rate of 3.96%, and expected dividend rate of 0%, resulting in a fair value per share of $8.10 and for the Investment Options share price of $23.40, exercise price of $116.70, term of 4.1 years, volatility of 95%, risk-free rate of 3.90%, and expected dividend rate of 0%, resulting in a fair value per share of $9.30). The total fair value of the 8,134 Existing Warrants and 66,667 Investment Options was $65,349 and $618,648, respectively. The post-modification fair value was determined using the intrinsic value of $2.85 due to the inducement and totaled $23,180 and $190,000 for the Existing Warrants and Investment Options, respectively. The change in fair value from the date of the modification prior to modification and the fair value on the date of the modification after the modification, but prior to exercise was $470,817, which was reflected as an inducement gain, within other expenses on the Company's consolidated statement of operations and comprehensive loss.

The grant date fair value of these Inducement Warrants was estimated to be $2,599,552 on December 28, 2023 and the proceeds of $280,500, which were received on January 2, 2024, for the issuance of the Inducement Warrants is reflected as inducement expense, within other expenses on the Company's consolidated statement of operations and comprehensive loss.

The Company established the initial fair value of its equity classified Inducement Warrants at the date of issuance on December 28, 2023. The Company used a Black Scholes valuation model in order to determine their value. The key inputs into the Black Scholes valuation model for the valuation of the warrants are below:

| | | **Roth and Inducement Warrants December 28, 2023** |
|---|---|---|
| Term (years) | | 5.0 |
| Stock price | $ | 23.40 |
| Exercise price | $ | 20.55 |
| Dividend yield | | —% |
| Expected volatility | | 92.0% |
| Risk free interest rate | | 3.80% |
| | | |
| Number of warrants | | 154,088 |
| Value (per share) | $ | 17.40 |

***Series C Preferred Shares***

On May 3, 2022, the Board of Directors (the "Board") declared a dividend of one one-thousandth of a share of the Company's Series C Preferred Stock ("Series C Preferred Stock") for each outstanding share of the Company's common stock held of record as of 5:00 p.m. Eastern Time on May 13, 2022 (the "Record Date"). This dividend was based on the number of outstanding shares of common stock prior to the Reverse Stock Split. The outstanding shares of Series C Preferred Stock were entitled to vote together with the outstanding shares of the Company's common stock, as a single class, exclusively with respect to a proposal giving the Board the authority, as it determines appropriate, to implement a reverse stock split within twelve months following the approval of such proposal by the Company's stockholders (the "Reverse Stock Split Proposal"), as well as any proposal to adjourn any meeting of stockholders called for the purpose of voting on the Reverse Stock Split Proposal (the "Adjournment Proposal").

The Company held a special meeting of stockholders on July 14, 2022 (the "Special Meeting") for the purpose of voting on, among other proposals, a Reverse Stock Split Proposal and an Adjournment Proposal. All shares of Series C Preferred Stock that were not present in person or by proxy at the Special Meeting were automatically redeemed by the Company immediately prior to the opening of the polls at Special Meeting (the "Initial Redemption"). All shares that were not redeemed pursuant to the Initial Redemption were redeemed automatically upon the approval by the Company's stockholders of the Reverse Stock Split Proposal at the Special Meeting (the "Subsequent Redemption" and, together with the Initial Redemption, the "Redemption"). Each share of Series C Preferred Stock was entitled to receive $0.10 in cash for each 10 whole shares of Series C Preferred Stock immediately prior to the Redemption. As of June 30, 2022, there were 52,684.548 shares of Series C Preferred Stock issued and outstanding. As of December 31, 2022, both the Initial Redemption and the Subsequent Redemption had occurred. As a result, no shares of Series C Preferred Stock remain outstanding. As of December 31, 2024 and 2023, there are 100,000 shares of Series C Preferred Stock authorized for future issuances.

## NOTE 9. REDEEMABLE NON-CONTROLLING INTEREST

### *Spin-Off and Related Private Placement*

In connection with the Spin-Off, on May 5, 2022, Akos and the Company entered into into a Securities Purchase Agreement (the "Akos Purchase Agreement") with an accredited investor (the "Akos Investor"), pursuant to which Akos agreed to sell up to an aggregate of 5,000 shares of Akos Series A Preferred Stock, at price of $1,000 per share, and warrants (the "Akos Warrants") to purchase shares of Akos' common stock, par value $0.01 per share (the "Akos Common Stock"), for an aggregate purchase price of up to $5,000,000 (the "Akos Private Placement"). The Akos Purchase Agreement was guaranteed by the Company. Pursuant to the Akos Purchase Agreement, Akos issued 1,000 shares of the Akos Series A Preferred Stock to the Akos Investor in exchange for $1,000,000 on May 5, 2022. The additional $4,000,000 was to be received on or immediately prior to the Spin-Off. The issuance of the Akos Series A Preferred Stock results in RNCI (see Note 2). Palladium Capital Advisors, LLC ("Palladium") acted as placement agent for the Akos Private Placement. Pursuant to the Akos Purchase Agreement, Akos had agreed to pay Palladium a fee equal to 9% of the aggregate gross proceeds raised from the sale of the shares of the Akos Series A Preferred Stock and a non-accountable expense allowance of 1% of the aggregate gross proceeds raised the sale of the Akos Series A Preferred Stock in the Akos Private Placement. The fee due in connection with the Akos Private Placement to be paid to Palladium in the form of convertible preferred stock and warrants was on similar terms to the securities issued in the Akos Private Placement. Palladium was also entitled to warrants to purchase Akos Common Stock in an amount up to 8% of the number of shares of Akos Common Stock underlying the shares issuable upon conversion of the Akos Series A Preferred Stock. As of December 31, 2023, no accruals are required to be recorded for the fees or warrants since the Akos Series A Preferred Stock has been redeemed.

### *Terms of Akos Series A Preferred Stock*

Under the Certificate of the Designations, Preferences, and Rights of Series A Convertible Preferred Stock of Akos (the "Akos Series A Preferred Certificate of Designations"), on or immediately prior to the completion of the spin-off of Akos into an independent, separately traded public company listed on the Nasdaq Stock Market, the outstanding Akos Series A Preferred Stock automatically converted into a number of shares of Akos Common Stock equal to 25% of the then issued and outstanding Akos Common Stock, subject to the Beneficial Ownership Limitation (as defined in the Akos Purchase Agreement). Cumulative dividends on each share of Akos Series A Preferred Stock accrue at the rate of 5% annually.

The Akos Series A Preferred Certificate of Designations provided that upon the earlier of (i) the one-year anniversary of May 5, 2022, and only in the event that the Spin-Off has not occurred; or (ii) such time that Akos and the Company have abandoned the Spin-Off or the Company is no longer pursuing the Spin-Off in good faith, the holders of the Akos Series A Preferred Stock shall have the right (the "Put Right"), but not the obligation, to cause Akos to purchase all or a portion of the Akos Series A Preferred Stock for a purchase price equal to $1,000 per share, subject to certain adjustments as set forth in the Akos Series A Preferred Certificate of Designations (the "Stated Value"), plus all the accrued but unpaid dividends per share. In addition, after the one-year anniversary of May 5, 2022, and only in the event that the Spin-Off has not occurred and Akos is not in material default of any of the transaction documents, Akos may, at its option, at any time and from time to time, redeem the outstanding shares of Akos Series A Preferred Stock, in whole or in part, for a purchase price equal to the aggregate Stated Value of the shares of Akos Series A Preferred Stock being redeemed and the accrued and unpaid dividends on such shares. Pursuant to the Akos Purchase Agreement, the Company has guaranteed the payment of the purchase price for the shares purchased under the Put Right.

The Akos Series A Preferred Certificate of Designations contains limitations that prevent the holder thereof from acquiring shares of Akos Common Stock upon conversion of the Akos Series A Preferred Stock that would result in the number of shares of Akos Common Stock beneficially owned by such holder and its affiliates exceeding 9.99% of the total number of shares of Akos Common Stock outstanding immediately after giving effect to the conversion (the "Beneficial Ownership Limitation"), except that upon notice from the holder to Akos, the holder may increase or decrease the limit of the amount of ownership of outstanding shares of Akos Common Stock after converting the holder's shares of Akos Series A Preferred Stock, provided that any change in the Beneficial Ownership Limitation shall not be effective until 61 days following notice to Akos.

***Redemption of Akos Series A Preferred Stock***

In May 2023, pursuant to the Akos Series A Preferred Certificate of Designations, the holders of the Akos Series A Preferred Stock exercised the Put Right requiring Akos to force redemption of all of the Akos Series A Preferred Stock for $1,000 per share, plus accrued but unpaid dividends of approximately $52,000 for a total of approximately $1,052,000. The Company had 20 days following the receipt of the Put Exercise Notice to make the payment and made payment on May 19, 2023. Upon redemption in May 2023, the Company revalued the derivative liability and the Company recognized a change in fair value of the derivative liability on the Company's consolidated statement of operations during the second quarter of 2023 of $714,000.

The Company, Akos, and the Akos Investor have terminated the Akos Purchase Agreement in connection with the planned Spin-Off and certain registration rights agreement in connection with the Akos Private Placement.

***Accounting for Akos Series A Preferred Stock***

Since the shares of Akos Series A Preferred Stock were redeemable at the option of the holder and the redemption is not solely in the control of the Company, the shares of Akos Series A Preferred Stock were accounted for as a redeemable non-controlling interest and classified within mezzanine equity in the Company's consolidated balance sheets. The redeemable non-controlling interest was initially measured at fair value. Dividends on the shares of Akos Series A Preferred Stock were recognized as preferred dividends attributable to redeemable non-controlling interest in the Company's consolidated statement of operations and comprehensive loss.

The table below presents the reconciliation of changes in redeemable non-controlling interest:

| | | |
|---|---|---|
| Balance at December 31, 2022 | $ | 885,028 |
| Preferred dividends attributable to redeemable non-controlling interest | | 19,041 |
| Accretion of embedded derivative and transaction costs associated with Akos Series A Preferred Stock to redemption value | | 147,988 |
| Redemption of Akos Series A Preferred Stock | | (1,052,057) |
| Balance at December 31, 2023 | $ | — |

In May 2023, the Akos Series A Preferred Stock was redeemed for a total of $1,052,057, and the balance of the redeemable non-controlling interest is $0 as of December 31, 2023.

## NOTE 10. LICENSING AGREEMENTS

On July 10, 2024, Akos entered into an Exclusive License Agreement (the "License Agreement") with Aries Science and Technology, LLC, an Ohio limited liability company ("Aries"), pursuant to which Akos granted Aries a license of Akos's patented radiation dermatitis topical product. The license allows Akos to use the patented formulation to develop pharmaceutical or non-pharmaceutical products for treating radiation dermatitis suitable for administration to humans or animals. The license is exclusive (subject to certain exceptions contained in the License Agreement), worldwide, royalty-bearing, and includes the right to sublicense. Akos is entitled to potential license payments, milestone payments and royalties based on net revenues of the Licensed Product on a licensed product-by-licensed product and country-by-country basis pursuant to the terms of the Agreement. Aries has the option during the license term, to purchase the rights to each licensed product (on a licensed product-by-licensed product basis) in the form of an exclusive (as to the applicable licensed product), fully paid, transferable right and license to the licensed product.

The Company has not earned any revenue related to this agreement as of December 31, 2024.

On November 7, 2024, the Company entered into an Out-Licensing Agreement (the "Agreement") with MycoMedica Life Sciences, PBC, a Delaware public benefit corporation ("MycoMedica"), pursuant to which the Company will out-license EB-002 and its EVM201 series to MycoMedica for further development and sales of the product in treatment of neuropsychiatric disorders. MycoMedica will receive an exclusive, global license to the formulations, drugs, method of use, and medical devices developed by Enveric to utilize the compound. As part of the Agreement, the Company will receive a $20,000 upfront payment, and if certain conditions are met, will receive development and sales milestone payments of up to $62 million and tiered single-digit royalties based on future sales. MycoMedica has the option during the license term to buyout its milestone and royalty payment obligations at a predetermined amount depending upon the stage of product development and commercialization at the time of the buyout. Further, MycoMedica has the right to purchase the licensed patents at a nominal amount upon a change of control of the Company, although doing so does not relieve MycoMedica of any of its payment obligations. During the year ended December 31, 2024, the Company received $20,000 from MycoMedica as a licensing fee, which is recorded as other income in the consolidated statements of operations.

## NOTE 11. FAIR VALUE

The following table provides the financial liabilities measured on a recurring basis and reported at fair value on the balance sheet as of December 31, 2024 and 2023, and indicates the fair value of the valuation inputs the Company utilized to determine such fair value of warrant liabilities and investment options:

| | Level | December 31, 2024 | December 31, 2023 |
|---|---|---|---|
| Warrant liabilities - January 2021 Warrants | 3 | $ — | $ 4 |
| Warrant liabilities - February 2021 Warrants | 3 | — | 4 |
| Warrant liabilities - February 2022 Warrants | 3 | 1,100 | 25,462 |
| Fair value of warrant liability | | $ 1,100 | $ 25,470 |

| | Level | December 31, 2024 | December 31, 2023 |
|---|---|---|---|
| Wainwright investment options | 3 | $ 1,988 | $ 23,608 |
| Fair value of investment option liability | | $ 1,988 | $ 23,608 |

The warrant liabilities and investment options are all classified as Level 3, for which there is no current market for these securities such as the determination of fair value requires significant judgment or estimation. Changes in fair value measurement categorized within Level 3 of the fair value hierarchy are analyzed each period based on changes in estimates or assumptions and recorded within other income (expense) on the consolidated statements of operations and comprehensive loss

***Subsequent measurement***

The following table presents the changes in fair value of the warrant liabilities, derivative liability, and investment options that are classified as Level 3:

| | Total Warrant Liabilities |
|---|---|
| Fair value as of December 31, 2022 | $ 185,215 |
| Exercise of warrants | (65,349) |
| Change in fair value | (94,396) |
| Fair value as of December 31, 2023 | $ 25,470 |
| Change in fair value | (24,370) |
| Fair value as of December 31, 2024 | $ 1,100 |

| | Total Derivative Liability |
|---|---|
| Fair value as of December 31, 2022 | $ 727,000 |
| Change in fair value arising from redemption of Akos Series A Preferred Stock - See Note 9 | (727,000) |
| Redemption of Series A Preferred Stock | — |
| Fair value as of December 31, 2023 | $ — |

There was no activity related to the derivative liability during the year ended December 31, 2024.

| | Total Investment Options |
|---|---|
| Fair value as of December 31, 2022 | $ 851,008 |
| Change in fair value | (208,752) |
| Exercise of investment options | (618,648) |
| Fair value of investment option liability as of December 31, 2023 | $ 23,608 |
| Change in fair value | (21,620) |
| Fair value of investment option liability as of December 31, 2024 | $ 1,988 |

The key inputs into the Black Scholes valuation model for the Level 3 valuations of the warrant liabilities as of December 31, 2024 are below:

| | January 2021 Warrants | February 2021 Warrants | February 2022 Warrants |
|---|---|---|---|
| Term (years) | 1.0 | 1.1 | 2.1 |
| Stock price | $ 5.38 | $ 5.38 | $ 5.38 |
| Exercise price | $ 3,712.50 | $ 3,675.00 | $ 412.50 |
| Dividend yield | —% | —% | —% |
| Expected volatility | 90.0% | 90.0% | 106.0% |
| Risk free interest rate | 4.20% | 4.20% | 4.30% |
| Number of warrants | 2,429 | 2,286 | 22,534 |
| Value (per share) | $ — | $ — | $ 0.003 |

The key inputs into the Black Scholes valuation model for the Level 3 valuations of the warrant liabilities as of December 31, 2023 are below:

| | January 2021 Warrants | February 2021 Warrants | February 2022 Warrants Unmodified |
|---|---|---|---|
| Term (years) | 2.0 | 2.1 | 3.1 |
| Stock price | $ 19.50 | $ 19.50 | $ 19.50 |
| Exercise price | $ 3,712.50 | $ 3,675.00 | $ 412.50 |
| Dividend yield | —% | —% | —% |
| Expected volatility | 89.0% | 88.0% | 87.0% |
| Risk free interest rate | 4.20% | 4.20% | 4.00% |
| Number of warrants | 2,429 | 2,286 | 22,534 |
| Value (per share) | $ 0.00 | $ 0.00 | $ 1.20 |

The key inputs into the Black Scholes valuation model for the Level 3 valuations of the investment options as of December 31, 2024 are below:

| | H.C. Wainwright & Co., LLC Options |
|---|---|
| Term (years) | 2.6 |
| Stock price | $ 5.38 |
| Exercise price | $ 150.00 |
| Dividend yield | —% |
| Expected volatility | 108.0% |
| Risk free interest rate | 4.30% |
| Number of investment options | 4,667 |
| Value (per share) | $ 0.03 |

The key inputs into the Black Scholes valuation model for the Level 3 valuations of the investment options as of December 31, 2023 are below:

| | H.C. Wainwright & Co., LLC Options |
|---|---|
| Term (years) | 3.6 |
| Stock price | $ 19.50 |
| Exercise price | $ 150.00 |
| Dividend yield | —% |
| Expected volatility | 94.0% |
| Risk free interest rate | 4.0% |
| Number of investment options | 4,667 |
| Value (per share) | $ 5.10 |

## NOTE 12. COMMITMENTS AND CONTINGENCIES

The Company is periodically involved in legal proceedings, legal actions and claims arising in the normal course of business. Management believes that the outcome of such legal proceedings, legal actions and claims will not have a significant adverse effect on the Company's financial position, results of operations or cash flows.

***Australian Subsidiary Research and Development***

On March 23, 2023, the Company issued a press release announcing the selection of Australian CRO, Avance Clinical, in preparation for Phase 1 Study of EB-373, the Company's lead candidate targeting the treatment of anxiety disorders. Under the agreement, Avance Clinical will manage the Phase 1 clinical trial of EB-373 in coordination with the Company's newly established Australian subsidiary, Enveric Therapeutics Pty, Ltd. The Phase 1 clinical trial is designed as a multi-cohort, dose-ascending study to measure the safety and tolerability of EB-373. EB-373, a next-generation proprietary psilocin prodrug, has been recognized as a New Chemical Entity (NCE) by Australia's Therapeutic Goods Administration (TGA) and is currently in preclinical development targeting the treatment of anxiety disorder. The total cost of the Avance Clinical contract is approximately 3,400,000 AUD, which translates to approximately $2,114,000 USD as of December 31, 2024. The Company has terminated the agreement as of December 31, 2024. Total project costs were 3,300,000 AUD and the Company will not incur any future costs associated with the agreement. Accordingly, the Company has $0 recorded as prepaid assets within prepaid and other current assets, accrued $0 recorded as accrued liabilities and $0 as accounts payable on the accompanying consolidated balance sheet. For the years ended December 31, 2024 and 2023, the Company has expensed $495,465 and $1,751,444, respectively, in research and development expenses within the accompanying consolidated statement of operations. As of December 31, 2024, the project is completed.

According to Australian tax law, the Company is allowed an R&D tax credit that reduces a company's tax bill in Australia for expenses incurred in R&D subject to certain requirements. The Company's Australian subsidiary submits R&D tax credit requests annually for research and development expenses incurred. At December 31, 2024 and 2023, the Company had a research and development tax credit receivable of $0 and $145,349, respectively, for R&D expenses incurred in Australia, included in prepaid and other current assets within the accompanying consolidated statement of operations. The Company received the amount due in relation to the research and development tax credit of $290,447 during the year ended December 31, 2024.

***Purchase agreement with Prof. Zvi Vogel and Dr. Ilana Nathan***

On December 26, 2017, Jay Pharma entered into a purchase agreement with Prof. Zvi Vogel and Dr. Ilana Nathan (the "Vogel-Nathan Purchase Agreement"), pursuant to which Jay Pharma was assigned ownership rights to certain patents, which were filed and unissued as of the date of the Vogel-Nathan Purchase Agreement. The patent portfolio acquired and developed under the Vogel-Nathan Purchase Agreement was sold to undisclosed buyers for an amount not material to these financials in the first quarter of 2024. No additional financial or other obligations exist regarding the Vogel-Nathan Purchase Agreement.

***Other Consulting and Vendor Agreements***

The Company has entered into a number of agreements and work orders for future consulting, clinical trial support, and testing services, with terms ranging between one and 12 months. These agreements, in aggregate, commit the Company to approximately $0.3 million in future cash payments.

***Reduction in Force/Restructuring***

In May 2023, the Company entered into a cost reduction plan, including a reduction in force ("RIF") of approximately 35% of its full-time employees to streamline its operations and conserve cash resources. Additionally, contracts with seven consultants that were focused on the Akos cannabinoid spin-out were terminated. The plan included a focus on progressing the Company's existing non-cannabinoid pipeline while reducing the rate of spend and managing cash flow. In June 2023, the Company completed the reduction in force, with such severance expenses recorded in general and administrative accounts.

In June 2023, the Company entered into a separation agreement with Avani Kanubaddi, the Company's President and Chief Operating Officer (the "Kanubaddi Separation Agreement"). In accordance with the Kanubaddi Separation Agreement, Mr. Kanubaddi received salary and benefits that is paid out in twelve monthly installments beginning in July 2023, was eligible for his 2023 performance bonus, which was not achieved, and any outstanding restricted stock units retained their vesting conditions.

The following table summarizes the Reduction in Force/Restructuring activity and ending balance at December 31, 2024 and 2023 for the remaining severance payments included in accrued expenses in the consolidated balance sheet:

| | Accrued Restructuring Costs |
|---|---|
| January 1, 2023 Beginning balance | $ — |
| Restructuring costs incurred | 1,004,033 |
| Restructuring costs paid | (572,628) |
| Restructuring costs reversed | (129,760) |
| December 31, 2023 ending balance | $ 301,645 |
| Restructuring costs paid | (301,645) |
| December 31, 2024 ending balance | $ — |

## NOTE 13. INCOME TAXES

The Company's U.S. and foreign loss before income taxes are set forth below:

| | December 31, | |
|---|---|---|
| | 2024 | 2023 |
| United States | $ (7,465,630) | $ (10,205,116) |
| Foreign | (2,100,427) | (7,057,703) |
| Total | $ (9,566,057) | $ (17,262,819) |

For the years ended December 31, 2024 and 2023, the Company recorded income tax expense of $8,930 and $28,913, respectively. The income tax expense is as follows:

| | December 31, | |
|---|---|---|
| Current: | 2024 | 2023 |
| Federal | $ — | $ — |
| State | (8,930) | (28,913) |
| Foreign | — | $ — |
| | $ (8,930) | $ (28,913) |
| Deferred: | | |
| Federal | $ — | $ — |
| State | — | — |
| Foreign | — | — |
| | $ — | $ — |
| Total income tax expense | $ (8,930) | $ (28,913) |

The Company's deferred tax assets and deferred tax liabilities consist of the following:

| | December 31, | |
|---|---|---|
| | 2024 | 2023 |
| Deferred tax assets: | | |
| Net operating loss carryforwards | $ 12,010,882 | $ 10,889,863 |
| Stock-based compensation | 938,457 | 1,185,399 |
| Research and development capitalized expenses | 563,389 | 611,245 |
| Intangible amortization | 111,471 | 80,518 |
| Other | 31,376 | 70,730 |
| Less valuation allowances | (13,655,575) | (12,837,755) |
| Net deferred tax assets | $ — | $ — |

The Company had the following potentially utilizable net operating loss tax carryforwards:

| | December 31, | |
|---|---|---|
| | 2024 | 2023 |
| Federal | $ 30,086,333 | $ 24,268,692 |
| State | $ 14,467,439 | $ 11,220,065 |
| Foreign | $ 17,543,639 | $ 17,672,420 |

The Tax Cuts and Jobs Act of 2017 (the "Act") limits the net operating loss deduction to 80% of taxable income for losses arising in tax years beginning after December 31, 2017. As of December 31, 2024, the Company had federal net operating loss carryforwards of $30,086,333 which can be carried forward indefinitely, state net operating losses carryforwards of $14,467,439, of which $6,407,050 can be carried forward indefinitely and remainder can be carried 20 years and Canadian net operating loss carryforwards of $17,543,639, of which $16,215,951 will begin to expire in 2040 and the remainder is carried forward indefinitely.

The Company's effective tax rate varied from the statutory rate as follows:

| | December 31, | |
|---|---|---|
| | 2024 | 2023 |
| Federal income tax at the statutory rate | (21.0)% | (21.0)% |
| State income tax rate (net of federal) | (2.1)% | (1.2)% |
| Foreign tax rate differential | 2.1% | (3.0)% |
| Non-deductible expenses | 1.0% | 1.4% |
| Deferred true-up | 11.6% | 13.2% |
| Change in valuation allowance | 8.5% | 10.8% |
| Effective income tax rate | 0.1% | 0.2% |

In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. The valuation allowance increased by $817,820 and $1,859,862 during the years ended December 31, 2024 and 2023, respectively.

The Company files U.S. federal and state returns. The Company's foreign subsidiary also files a local tax return in their local jurisdiction. From a U.S. federal, state and Canadian perspective the years that remain open to examination are consistent with each jurisdiction's statute of limitations.

***Section 382***

The utilization of the Company's net operating losses may be subject to a substantial limitation in the event of any significant future changes in its ownership structure under Section 382 of the Internal Revenue Code and similar state provisions. Such limitation may result in the expiration of the net operating loss carryforwards before their utilization. We have not conducted any studies to determine annual limitations, if any, that could result from such changes in ownership.

***Section 174***

Beginning in 2022, the Tax Cuts and Jobs Act of 2017 ("TCJA") eliminated the option to deduct research and development expenditures in the current year and requires taxpayers to amortize US expenses over five years and foreign expense over fifteen years pursuant to IRC Section 174. During the years ended December 31, 2024 and 2023, the Company has estimated and capitalized gross $202,147 and $463,696, respectively, of research and development expenditures that will be amortized primarily over five years. This did not have a material impact on the Company's tax liability for the years ended December 31, 2024 and 2023. The Company will continue to evaluate the impact of these tax law changes on the current and future periods.

## NOTE 14. SUBSEQUENT EVENTS

On January 30, 2025, the Company commenced a best efforts public offering (the "Offering") of an aggregate of (i) 1,229,330 shares (the "Shares") of Common Stock of the Company, (ii) 437,336 pre-funded warrants (the "Pre-Funded Warrants") to purchase 437,336 shares of Common Stock (the "Pre-Funded Warrant Shares"), (iii) 1,666,666 Series A warrants (the "Series A Warrants") to purchase 1,666,666 shares of Common Stock (the "Series A Warrant Shares"), and (iv) 1,666,666 Series B warrants (the "Series B Warrants," and together with the Series A Warrants, the "Warrants") to purchase 1,666,666 shares of Common Stock (the "Series B Warrant Shares"). Each Share or Pre-Funded Warrant was sold together with one Series A Warrant to purchase one share of Common Stock and one Series B Warrant to purchase one share of Common Stock. The offering price for each Share and accompanying Warrants was $3.00, and the offering price for each Pre-Funded Warrant and accompanying Warrants was $2.9999. The Pre-Funded Warrants have an exercise price of $0.0001 per share, are exercisable immediately and will expire when exercised in full. Each Warrant has an exercise price of $3.00 per share and will be exercisable immediately upon issuance ("Initial Exercise Date"). The Series A Warrants expire on the five-year anniversary of the Initial Exercise Date. The Series B Warrants expire on the 18-month anniversary of the Initial Exercise Date.

The Offering closed on February 3, 2025. The net proceeds of the Offering, after deducting the fees and expenses of the Placement Agent (as defined below), described in more detail below, and other offering expenses payable by the Company, but excluding the net proceeds, if any, from the exercise of the Warrants, is approximately $4.2 million. The Company intends to use the net proceeds from the Offering for working capital, EB-003 development, and general corporate purposes.

In connection with the Offering, the Company entered into a securities purchase agreement (the "Purchase Agreement") with a certain institutional investor. Pursuant to the Purchase Agreement, the Company agreed not to issue, enter into any agreement to issue or announce the issuance or proposed issuance of any shares of Common Stock or any securities convertible into or exercisable or exchangeable for shares of Common Stock or file any registration statement or prospectus, or any amendment or supplement thereto for 60 days after the closing date of the Offering, subject to certain exceptions. In addition, the Company has agreed not to effect or enter into an agreement to effect any issuance of Common Stock or any securities convertible into or exercisable or exchangeable for shares of Common Stock involving a variable rate transaction (as defined in the Purchase Agreement) until the one-year anniversary of the closing date of the Offering, subject to an exception.

A holder will not have the right to exercise any portion of the Warrants or Pre-Funded Warrants if the holder (together with its affiliates) would beneficially own in excess of 4.99% or 9.99%, as applicable, of the number of shares of Common Stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Warrants or the Pre-Funded Warrants, respectively.

Pursuant to an engagement agreement, as amended, (the "Engagement Agreement") with H.C. Wainwright & Co., LLC (the "Placement Agent"), the Company agreed to pay the Placement Agent in connection with the Offering (i) a cash fee equal to 7.0% of the aggregate gross proceeds received in the Offering, (ii) a management fee equal to 1.0% of the aggregate gross proceeds received in the Offering, (iii) a non-accountable expense allowance of $25,000, (iv) reimbursement of up to $100,000 for legal fees and expenses and other out of pocket expenses and (v) up to $15,950 for the clearing expenses.

Also pursuant to the Engagement Agreement, the Company, in connection with the Offering, agreed to issue to the Placement Agent or its designees warrants (the "Placement Agent Warrants") to purchase up to an aggregate of 116,666 shares of Common Stock (the "Placement Agent Warrant Shares") (which represents 7.0% of the Shares and Pre-Funded Warrants sold in the Offering). The Placement Agent Warrants have an exercise price of $3.75 per share (which represents 125% of the public offering price per Share and accompanying Warrants), expire on January 30, 2030, and are exercisable following the Initial Exercise Date.

During February 2025, a total of 437,336 shares of Common Stock have been issued due to exercises of the Pre-Funded Warrants and 25,000 shares of Common Stock have been issued due to exercises of Series B Warrants.

On February 3, 2025, Akos entered into two licensing agreements with Restoration Biologics LLC ("Restoration Biologics"), a biotechnology company focused on the treatment of joint disease. The companies have executed two licenses for Akos' cannabinoid-COX-2 conjugate compounds, for pharmaceutical and potential non-pharmaceutical applications.

**Exhibit 10.14**

**RESTRICTED STOCK AWARD AGREEMENT**

**ENVERIC BIOSCIENCES, INC.**
**2020 LONG-TERM INCENTIVE PLAN**

1. Grant of Award. Pursuant to the Enveric Biosciences, Inc. 2020 Long-Term Incentive Plan (the "***Plan***") for Employees, Contractors, and Outside Directors of Enveric Biosciences, Inc., a Delaware corporation (the "***Company***"), the Company grants to

(the "***Participant***")

an Award of Restricted Stock in accordance with Section 6.4 of the Plan. The number of shares of Common Stock awarded under this Restricted Stock Award Agreement (the "***Agreement***") is _____ shares (the "***Awarded Shares***"). The "***Date of Grant***" of this Award is **_____**.

2. Subject to Plan. This Agreement is subject to the terms and conditions of the Plan, and the terms of the Plan shall control to the extent not otherwise inconsistent with the provisions of this Agreement. The capitalized terms used herein that are defined in the Plan shall have the same meanings assigned to them in the Plan. This Agreement is subject to any rules promulgated pursuant to the Plan by the Board or the Committee and communicated to the Participant in writing.

3. Vesting. Except as specifically provided in this Agreement and subject to certain restrictions and conditions set forth in the Plan, the Awarded Shares shall vest on the first anniversary of the date on which the Participant first provided services to the Company as an Outside Director or Contractor, including, without limitation, services as a member of the Company's Scientific Advisory Board (the "***Vesting Commencement Date***"), provided the Participant is employed by (or, if the Participant is a Contractor or an Outside Director, is providing services to) the Company or a Subsidiary on that date.

4. Forfeiture of Awarded Shares. Awarded Shares that are not vested in accordance with Section 3 shall be forfeited on the date of the Participant's Termination of Service for any reason as follows:

a. If the Termination of Service occurs on or after the first quarterly anniversary of the Vesting Commencement Date, twenty-five percent (25%) of the Awarded Shares shall vest, and the remaining Awarded Shares shall be forfeited, on such date;

b. If the Termination of Service occurs on or after the second quarterly anniversary of the Vesting Commencement Date, fifty percent (50%) of the Awarded Shares shall vest, and the remaining Awarded Shares shall be forfeited, on such date; and

c. If the Termination of Service occurs on or after the third quarterly anniversary of the Vesting Commencement Date, seventy-five percent (75%) of the Awarded Shares shall vest, and the remaining Awarded Shares shall be forfeited, on such date.

Upon forfeiture, all of the Participant's rights with respect to the forfeited Awarded Shares shall cease and terminate, without any further obligations on the part of the Company.

5. Restrictions on Awarded Shares. Subject to the provisions of the Plan and the terms of this Agreement, from the Date of Grant until the date the Awarded Shares are vested in accordance with Section 3 and are no longer subject to forfeiture in accordance with Section 4 (the "***Restriction Period***"), the Participant shall not be permitted to sell, transfer, pledge, hypothecate, margin, assign, or otherwise encumber any of the Awarded Shares that have not vested. Except for these limitations, the Committee may, in its sole discretion, remove any or all of the restrictions on such Awarded Shares whenever it may determine that, by reason of changes in Applicable Laws or changes in circumstances after the date of this Agreement, such action is appropriate.

6. Legend. The following legend shall be placed on all certificates issued representing Awarded Shares:

On the face of the certificate:

> "Transfer of this stock is restricted in accordance with conditions printed on the reverse of this certificate."

On the reverse:

> "The shares of stock evidenced by this certificate are subject to and transferable only in accordance with that certain Enveric Biosciences, Inc. 2020 Long-Term Incentive Plan, a copy of which is on file at the principal office of the Company in Naples, Florida. No transfer or pledge of the shares evidenced hereby may be made except in accordance with and subject to the provisions of said Plan. By acceptance of this certificate, any holder, transferee or pledgee hereof agrees to be bound by all of the provisions of said Plan."

The following legend shall be inserted on a certificate evidencing Common Stock issued under the Plan if the shares were not issued in a transaction registered under the applicable federal and state securities laws:

> "Shares of stock represented by this certificate have been acquired by the holder for investment and not for resale, transfer or distribution, have been issued pursuant to exemptions from the registration requirements of applicable state and federal securities laws, and may not be offered for sale, sold or transferred other than pursuant to effective registration under such laws, or in transactions otherwise in compliance with such laws, and upon evidence satisfactory to the Company of compliance with such laws, as to which the Company may rely upon an opinion of counsel satisfactory to the Company."

All Awarded Shares owned by the Participant shall be subject to the terms of this Agreement and shall be represented by a certificate or certificates bearing the foregoing legend.

7. Delivery of Certificates; Registration of Shares. The Company shall deliver certificates for the Awarded Shares to the Participant or shall register the Awarded Shares in the Participant's name, free of restriction under this Agreement, promptly after, and only after, the Restriction Period has expired without forfeiture pursuant to Section 4. In connection with any issuance of a certificate for Restricted Stock, the Participant shall endorse such certificate in blank or execute a stock power in a form satisfactory to the Company in blank and deliver such certificate and executed stock power to the Company.

8. Rights of a Stockholder. Except as provided in Section 4 and Section 5 above, the Participant shall have, with respect to his or her Awarded Shares, all of the rights of a stockholder of the Company, including the right to vote the shares and the right to receive any dividends thereon.

9. Voting. The Participant, as record holder of the Awarded Shares, has the exclusive right to vote, or consent with respect to, such Awarded Shares until such time as the Awarded Shares are transferred in accordance with this Agreement; provided, however, that this Section 9 shall not create any voting right where the holders of such Awarded Shares otherwise have no such right.

10. Adjustment to Number of Awarded Shares. The number of Awarded Shares shall be subject to adjustment in accordance with Articles 11-13 of the Plan.

11. Specific Performance. The parties acknowledge that remedies at law will be inadequate remedies for a breach of this Agreement and consequently agree that this Agreement shall be enforceable by specific performance. The remedy of specific performance shall be cumulative of all of the rights and remedies at law or in equity of the parties under this Agreement.

12. Participant's Representations. Notwithstanding any of the provisions hereof, the Participant hereby agrees that he or she will not acquire any Awarded Shares, and that the Company will not be obligated to issue any Awarded Shares to the Participant hereunder, if the issuance of such shares shall constitute a violation by the Participant or the Company of any provision of any law or regulation of any governmental authority. Any determination in this connection by the Company shall be final, binding, and conclusive. The rights and obligations of the Company and the rights and obligations of the Participant are subject to all Applicable Laws, rules, and regulations.

13. Investment Representation. Unless the Awarded Shares are issued in a transaction registered under applicable federal and state securities laws, by his or her execution hereof, the Participant represents and warrants to the Company that all Common Stock which may be purchased and/or received hereunder will be acquired by the Participant for investment purposes for his or her own account and not with any intent for resale or distribution in violation of federal or state securities laws. Unless the Common Stock is issued to him or her in a transaction registered under the applicable federal and state securities laws, all certificates issued with respect to the Common Stock shall bear an appropriate restrictive investment legend and shall be held indefinitely, unless they are subsequently registered under the applicable federal and state securities laws or the Participant obtains an opinion of counsel, in form and substance satisfactory to the Company and its counsel, that such registration is not required.

14. Participant's Acknowledgments. The Participant acknowledges that a copy of the Plan has been made available for his or her review by the Company and represents that he or she is familiar with the terms and provisions thereof, and hereby accepts this Award subject to all the terms and provisions thereof. The Participant hereby agrees to accept as binding, conclusive, and final all decisions or interpretations of the Committee or the Board, as applicable, upon any questions arising under the Plan or this Agreement.

15. Law Governing. This Agreement shall be governed by, construed, and enforced in accordance with the laws of the State of Delaware (excluding any conflict of laws rule or principle of Delaware law that might refer the governance, construction, or interpretation of this Agreement to the laws of another state).

16. No Right to Continue Service or Employment. Nothing herein shall be construed to confer upon the Participant the right to continue in the employ or to provide services to the Company or any Subsidiary, whether as an Employee, Contractor, or Outside Director, or to interfere with or restrict in any way the right of the Company or any Subsidiary to discharge the Participant as an Employee, Contractor, or Outside Director at any time.

17. Legal Construction. In the event that any one or more of the terms, provisions, or agreements that are contained in this Agreement shall be held by a court of competent jurisdiction to be invalid, illegal, or unenforceable in any respect for any reason, the invalid, illegal, or unenforceable term, provision, or agreement shall not affect any other term, provision, or agreement that is contained in this Agreement, and this Agreement shall be construed in all respects as if the invalid, illegal, or unenforceable term, provision, or agreement had never been contained herein.

18. Covenants and Agreements as Independent Agreements. Each of the covenants and agreements that are set forth in this Agreement shall be construed as a covenant and agreement independent of any other provision of this Agreement. The existence of any claim or cause of action of the Participant against the Company, whether predicated on this Agreement or otherwise, shall not constitute a defense to the enforcement by the Company of the covenants and agreements that are set forth in this Agreement.

19. Entire Agreement. This Agreement together with the Plan supersede any and all other prior understandings and agreements, either oral or in writing, between the parties with respect to the subject matter hereof and constitute the sole and only agreements between the parties with respect to the said subject matter. All prior negotiations and agreements between the parties with respect to the subject matter hereof are merged into this Agreement. Each party to this Agreement acknowledges that no representations, inducements, promises, or agreements, orally or otherwise, have been made by any party or by anyone acting on behalf of any party, which are not embodied in this Agreement or the Plan and that any agreement, statement, or promise that is not contained in this Agreement or the Plan shall not be valid or binding or of any force or effect.

20. Parties Bound. The terms, provisions, and agreements that are contained in this Agreement shall apply to, be binding upon, and inure to the benefit of the parties and their respective heirs, executors, administrators, legal representatives, and permitted successors and assigns, subject to the limitation on assignment expressly set forth herein. No person shall be permitted to acquire any Awarded Shares without first executing and delivering an agreement in the form satisfactory to the Company making such person or entity subject to the restrictions on transfer contained herein.

21. Modification. No change or modification of this Agreement shall be valid or binding upon the parties unless the change or modification is in writing and signed by the parties hereto. Notwithstanding the preceding sentence, the Company may amend the Plan to the extent permitted by the Plan.

22. Headings. The headings that are used in this Agreement are used for reference and convenience purposes only and do not constitute substantive matters to be considered in construing the terms and provisions of this Agreement.

23. Gender and Number. Words of any gender used in this Agreement shall be held and construed to include any other gender, and words in the singular number shall be held to include the plural, and vice versa, unless the context requires otherwise.

24. Notice. Any notice required or permitted to be delivered hereunder shall be deemed to be delivered only when actually received by the Company or by the Participant, as the case may be, at the addresses set forth below, or at such other addresses as they have theretofore specified by written notice delivered in accordance herewith:

a. Notice to the Company shall be addressed and delivered as follows: Enveric Biosciences, Inc.

4851 Tamiami Trail, Suite 200
Naples, Florida 34103
Attn:
Email:
Facsimile:

b. Notice to the Participant shall be addressed and delivered as set forth on the signature page.

25. Tax Requirements. **The Participant is hereby advised to consult immediately with his or her own tax advisor regarding the tax consequences of this Agreement, the method and timing for filing an election to include this Agreement in income under Section 83(b) of the Code, and the tax consequences of such election. By execution of this Agreement, the Participant agrees that if the Participant makes such an election, the Participant shall provide the Company with written notice of such election in accordance with the regulations promulgated under Section 83(b) of the Code.** The Company or, if applicable, any Subsidiary (for purposes of this Section 25, the term "***Company***" shall be deemed to include any applicable Subsidiary), shall have the right to deduct from all amounts paid in cash or other form in connection with the Plan, any federal, state, local, or other taxes required by law to be withheld in connection with this Award. The Company may, in its sole discretion, also require the Participant receiving shares of Common Stock issued under the Plan to pay the Company the amount of any taxes that the Company is required to withhold in connection with the Participant's income arising with respect to this Award. Such payments shall be required to be made when requested by the Company and may be required to be made prior to the delivery of any certificate representing shares of Common Stock or the registration of such shares in the Participant's name. Such payment may be made by (a) the delivery of cash to the Company in an amount that equals or exceeds (to avoid the issuance of fractional shares) the required tax withholding obligations of the Company; (b) if the Company, in its sole discretion, so consents in writing, the actual delivery by the Participant to the Company of shares of Common Stock, other than Common Stock that the Participant has acquired from the Company within six (6) months prior thereto, which shares so delivered have an aggregate Fair Market Value that equals or exceeds (to avoid the issuance of fractional shares) the required tax withholding payment; or (c) any combination of (a) and (b). The Company may, in its sole discretion, withhold any such taxes from any other cash remuneration otherwise paid by the Company to the Participant.

[*Remainder of Page Intentionally Left Blank; Signature Page Follows.*]

IN WITNESS WHEREOF, the Company has caused this Agreement to be executed by its duly authorized officer, and the Participant, to evidence his or her consent and approval of all the terms hereof, has duly executed this Agreement, as of the date specified in Section 1 hereof.

**COMPANY:**

Enveric Biosciences, Inc.

By: _____

Name: _____

Title: _____

**PARTICIPANT:**

_____

Signature

Name:

Address: _____

**Exhibit 10.37**

**CERTAIN INFORMATION IDENTIFIED BY "[***]" HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH NOT MATERIAL AND IS THE TYPE OF INFORMATION THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL**

# EXCLUSIVE LICENSE AGREEMENT

This **EXCLUSIVE LICENSE AGREEMENT** (the "Agreement") is made and entered as of ***November 7, 2024*** (the "Effective Date"), by and between ***Enveric Biosciences, Inc.***, a Delaware corporation (hereinafter "Company") and ***MycoMedica Life Sciences, PBC,*** a Delaware public benefit corporation (hereinafter "Licensee"). Company and Licensee shall each be considered a "Party" and together the "Parties."

**WHEREAS** Company owns or controls certain Company Intellectual Property, as defined herein;

**WHEREAS** Licensee is in the business of developing (including obtaining applicable regulatory approvals), manufacturing, commercializing, distributing, marketing, and/or selling of certain pharmaceutical products;

**WHEREAS** Company intends to license to Licensee, and Licensee agrees to obtain a license from Company to, the Company Intellectual Property so that Licensee can Develop, Manufacture and Commercialize Licensed Product(s); and

**NOW, THEREFORE,** in consideration of the foregoing premises and the mutual promises and covenants contained herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

## 1 ARTICLE 1 – DEFINITIONS

The terms in this Agreement with initial letters capitalized, whether used in the singular or the plural, shall have the meaning set forth below or, if not listed below, the meaning designated in places throughout this Agreement.

**1.1** "Affiliate" means, with respect to a Party, any specified Person, any other Person which (directly or indirectly) is controlled by controls or is under common control with such specified Person.

**1.2** "Ancillary Agreements" means any other agreements entered into after the Effective Date between the Parties (or their respective Affiliates) with respect to the Development or Manufacture of the Licensed Product.

**1.3** "Claim" means any demand or any civil, criminal, administrative, or investigative claim, action, or proceeding (including arbitration) asserted, commenced, or threatened against a Person or a Party and related to this Agreement.

**1.4** "Clinical Trial" means a controlled study in humans of the safety or efficacy of a product, and includes, without limitation, such clinical trials as are designed to support expanded labeling or to satisfy the requirements of a Regulatory Authority in connection with any product approval and any other human study used in the research and development of a product. Clinical Trials include Phases of said Clinical Trials as are described in the appropriate subsections of *21 CFR 312.21*.

**1.5** "Confidential Information" means, with respect to a Party, all non-public information of such Party or its Affiliates that is disclosed to the other Party under this Agreement, whether disclosed in oral, written, graphic, or electronic form regardless of whether the information is marked as confidential.

**1.6** "Combination Product" means a combination product as defined in *21 C.F.R. § 3.2(e)* or any other product consisting of the Licensed Product with any other drug, biological product, or medical device whether they are formulated together, packaged together and sold for a single price, or administered to patients together according to a Product label or other specific instructions approved by a Regulatory Authority (whether or not packaged together).

**1.7** "Commercialize," "Commercialization," or "Commercializing" means, with respect to any pharmaceutical product, all activities (whether occurring before (to the extent permitted by applicable Law) or after the regulatory approval for a product) pertaining to the marketing, market development, or promotion of a product for commercial sale, the commercial sale of a product, including advertising, market research, offering to commercially sell, distributing, importing, exporting, or transporting a product for commercial sale, and regulatory activities in connection with or in support of the foregoing, but, for clarity, not Development or Manufacture.

**1.8** "Commercially Reasonable Efforts" means the active carrying out of obligations or tasks with a level of effort and resources consistent with the commercially reasonable practices used by a similarly situated pharmaceutical company at a similar stage of commercialization and of similar market potential, profit potential and strategic value, taking into consideration safety and efficacy, cost, the competitiveness of alternative products, the proprietary position, and all other relevant factors as measured by the facts and circumstances at the time such efforts are due.

**1.9** "Company Indemnified Parties" means Company and its respective equity holders, directors, officers, managers, employees, and agents.

**1.10** "Company Intellectual Property" means Company Patents and Company Technology, together with Improvements thereto to the extent owned or controlled by Company which relate to the Licensed Product, including any modifications, analogs, or derivatives thereof, wherein such modification, analog, or derivative, is covered by a Valid Claim(s) of the Company Patents as of the Effective Date.

**1.11** "Company Patents" means the Patents set forth in Schedule A, attached hereto, and any continuations, continuations-in-part, divisionals, utility models, extensions (including extensions under the USA Patent Term Restoration Act, extensions of patents under the Japanese Patent Law and Supplementary Protection Certificates), renewals, substitutions and additions thereof and all reissues, revalidations and re-examinations thereof, including any and all foreign counterparts thereof, as well as any other patent rights controlled by Company that contain at least one Valid Claim that would be infringed by the manufacture, import, use, offering for sale, or sale of Licensed Product(s) (if such activity were performed by a Third Party).

**1.12** "Company Technology" means, collectively, all Know-How Controlled by Company that is related to Licensed Products and which is necessary or useful to research, Develop, Manufacture, and/or Commercialize Licensed Product(s), including, but not limited to: rights in unpatented subject matter, data (excluding protected health information as defined in the Health Insurance Portability and Accountability Act of 1996, codified as 42 U.S.C. 1320d or other personal protected information), and tangible materials that are: (a) directly related to or disclosed in the Company Intellectual Property; or (b) within the Field.

**1.13** "Control" means, with respect to Company Intellectual Property, possession of the right, whether directly or indirectly, and whether by ownership, license or otherwise, to assign, or grant a license, sublicense or other right to or under, such Company Intellectual Property as provided for herein without violating the terms of any written agreement with any Third Party.

**1.14** "Develop," "Developed," "Developing," or "Development" means, with respect to any pharmaceutical product, all activities relating to the development of a product and in obtaining the applicable regulatory approval for that product, including activities related to formulation, preclinical and other non-clinical testing, toxicology testing, human and animal clinical studies, test method development and stability testing, process development, analytic development, statistical analysis and report writing, the preparation and submission of regulatory approval applications, regulatory affairs with respect to the foregoing (including communications with Regulatory Authorities), and all other activities necessary or reasonably useful or otherwise requested or required by a Regulatory Authority as a condition or in support of obtaining the applicable regulatory approval for that product, including development of packaging and labeling components for regulatory approval and manufacturing process development and associated quality assurance, quality control activities, scale-up and/or analytic process development. For clarity, Development activities do not include any Manufacturing or Commercialization activities.

**1.15** "Development Costs" means, with respect to a Licensed Product, the sum of (i) all costs and expenses incurred by Licensee from the Effective Date through the date of calculation that directly relate to the Development conducted by or on behalf of Licensee with respect to a Licensed Product, including direct costs attributed to FTEs, out-of-pocket expenses, and any amounts paid to a Third Party for the development of the subject Licensed Product; (ii) general overhead costs incurred by Licensee or its Affiliates related to the subject matter of this Agreement through the date of calculation that are allocable to a Licensed Product, where general overhead costs are allocated as incurred on a monthly basis to such Licensed Product; and (iii) all license fees, milestones, and such other non-royalty payments due a Third Party under any option, license or covenant not to sue with respect to Development, Manufacture or Commercialization of the Licensed Product, including without limitation, settlement of any IP Claim.

**1.16** "Dispute" means any Claim, dispute, or controversy arising out of, or relating to, this Agreement and/or an Ancillary Agreement, including any of the foregoing with respect to the interpretation and/or enforcement of, or any determinations under, any provision of this Agreement and/or an Ancillary Agreement and the performance of either Party of its obligations under this Agreement and/or an Ancillary Agreement.

**1.17** "FDA" means the United States Food and Drug Administration or any successor entity thereto. For purposes of this Agreement, references to FDA shall include, as may be applicable, any foreign governmental agency having the administrative authority to regulate the marketing of animal or human pharmaceutical products or biological therapeutic products, delivery systems and devices within an applicable jurisdiction.

**1.18** "Field" means all fields.

**1.19** "First Commercial Sale" means, with respect to a Licensed Product, the first sale to a Third Party of a Licensed Product in a country.

**1.20** "Governmental Authority" means any supra-national, federal, national, regional, state, provincial, local, or other governmental department, Regulatory Authority, judicial or administrative body, whether domestic or foreign, or international.

**1.21** "Improvements" means, all Patents and Know-How related to the Licensed Product that are conceived, discovered, developed, reduced to practice, or otherwise made after the Effective Date.

**1.22** "IND" means an investigational new drug application filed with the FDA for authorization to commence clinical trials, and its equivalent in other countries or regulatory jurisdictions in the Territory.

**1.23** "Know-How" means all technical, scientific and other know-how and information, trade secrets, knowledge, technology, means, methods, processes, practices, formulas, instructions, skills, techniques, procedures, experiences, ideas, technical assistance, designs, drawings, assembly procedures, computer programs, specifications, data, results and other material, including, pre- clinical and clinical trial results, manufacturing procedures, test procedures, and purification and isolation techniques, (whether or not confidential, proprietary, patented, or patentable) in written, electronic or any other form, and all other discoveries, developments, information and inventions (whether or not confidential, proprietary, patented, or patentable), and tangible embodiments of any of the foregoing, including any discoveries, developments, information, or inventions relating to the stability, safety, efficacy, operation, manufacture, ingredients, preparation, indications, presentation, formulation, means of delivery, or dosage of any pharmaceutical composition or preparation, in all cases whether or not (i) confidential, proprietary, patented or patentable, (ii) reduced to written, electronic or any other form, and (iii) now known or hereinafter developed.

**1.24** "Law" means all statutes, regulations, directives, ordinances, orders, rulings, agency, or court interpretations (including common law), or other action or requirement of any Governmental Authority in any jurisdiction in the world whether currently in force or enacted during the Term applicable to the Development, Manufacture, and/or Commercialization of the Licensed Products.

**1.25** "Licensed Product" means any pharmaceutical product including any metabolite, salt, hydrate, solvate, polymorph, isotopologue, isomer, or enantiomer thereof. suitable for administration to humans or animals where such formulation contains the molecule set forth in Schedule B, attached hereto.

**1.26** "Licensee Indemnified Parties" means Licensee and its Affiliates and their respective equity holders, directors, officers, managers, employees, and agents.

**1.27** "Licensee Intellectual Property" means all Know-How (including associated Patents and other intellectual property rights) owned or controlled by Licensee, excluding Company Intellectual Property.

**1.28** "Loss" or "Losses" means all claims, losses, liabilities, damages, fines, penalties, and related costs, expenses, and other charges, including reasonable legal fees, costs of investigation, litigation, settlement, judgement, and appeal, remediation, obligations, and corrective actions required by Law, and any taxes imposed, interest, fines, and penalties with respect to the foregoing.

**1.29** "Manufacture" and "Manufacturing" means all activities related to the manufacturing process development and associated validation, quality assurance, quality control activities, scale-up and/or analytic process development, actual production, manufacture, processing, filling, finishing, packaging, labeling, storing and shipping of a pharmaceutical product for pre-clinical, clinical and commercial use, including product characterization, quality assurance, and quality control but excluding those process development, qualification and validation, and scale-up activities included in Development activities.

**1.30** "Net Revenues**"** means sales revenue received from the sale of Licensed Product(s) by Licensee or its Affiliates, less the following deductions:

1.30.1 credits or allowances actually granted for damaged Licensed Product, returns or rejections of Licensed Product, price adjustments and billing errors;

1.30.2 normal and customary trade, cash and quantity discounts, allowances and credits actually allowed or paid, including the following:

1.30.2.1 those granted on account of price adjustments, billing errors, rejected goods, damaged goods, returns and rebates,

1.30.2.2 administrative and other fees and reimbursements and similar payments to wholesalers and other distributors, buying groups, specialty pharmacies, pharmacy benefit management organizations, health care insurance carriers and other institutions,

1.30.2.3 allowances and rebates paid to distributors, and

1.30.2.4 chargebacks;

1.30.3 commissions allowed or paid to Third Party distributors, brokers, or agents with respect to the distribution of Licensed Product, other than sales personnel, sales representatives and sales agents employed by Licensee or its Affiliates;

1.30.4 transportation costs, including insurance, for outbound freight related to delivery of Licensed Product;

1.30.5 sales taxes, VAT taxes and other taxes directly related to the sales or delivery of the Licensed Product;

1.30.6 customs and excise duties and other duties related to the sales to the extent that such items are included in the gross amount invoiced;

1.30.7 the actual amount of any write-offs for bad debt relating to such sales during the applicable period; and

1.30.8 rebates and similar payments made with respect to sales paid for by any Governmental Authority or Regulatory Authority such as, by way of illustration and not in limitation of the Parties' rights hereunder, Federal or state Medicaid, Medicare or similar state program or equivalent foreign governmental program.

**1.31** "Patent" means patents and patent applications, as well as any continuations, continuations-in-part, divisionals, utility models, extensions (including extensions under the USA Patent Term Restoration Act, extensions of patents under the Japanese Patent Law and Supplementary Protection Certificates), renewals, substitutions and additions thereof and all reissues, revalidations and re-examinations thereof, including any and all foreign counterparts thereof, as well as any other patent rights that contain at least one Valid Claim that would be infringed by the manufacture, import, use, offering for sale, or sale of Licensed Product(s) (if such activity were performed by a Third Party).

**1.32** "Person" means an individual, a partnership, a limited liability company, a corporation, an association, a joint stock company, a trust, a joint venture, an unincorporated organization, or any other type of legal entity.

**1.33** "Regulatory Approval" means, with respect to a country or regulatory jurisdiction in the Territory, any and all approvals, licenses, registrations or authorizations of any Regulatory Authority necessary to commercially import, distribute, sell or market a Licensed Product in such country and including, where applicable, (i) pricing or reimbursement approval in such country, (ii) pre- and post-approval marketing authorizations (including any prerequisite manufacturing approval or authorization related thereto), (iii) labeling approval, and (iv) technical, medical and scientific licenses.

**1.34** "Regulatory Authority" means any applicable supra-national, federal, national, regional, state, provincial or local regulatory agencies, departments, bureaus, commissions, councils, or other Governmental Authorities regulating or otherwise exercising authority with respect to the Development, Manufacture or Commercialization of the Licensed Products in the Territory.

**1.35** "Sublicense" means a written agreement pursuant to which Licensee grants rights to the Company Intellectual Property to a Sublicensee to make, have made, offer to sell, and/or sell the Licensed Product in the Territory in compliance with, and subject to, the terms of this Agreement.

**1.36** "Sublicensee" means any entity to which an express sublicense has been granted under the Patent Rights. For clarity, a Third Party wholesaler or distributor who has no significant responsibility for marketing and promotion of the Licensed Product within its distribution territory or field (i.e., the Third Party simply functions as a reseller), and who does not pay any consideration to Licensee or an Affiliate for wholesale or distributor rights, shall not be deemed a Sublicensee; and the resale by such a wholesaler or distributor shall not be treated as royalty bearing Net Revenues by a Sublicensee provided that a royalty is being paid by Licensee for the initial transfer to the wholesaler or distributor pursuant to this Agreement.

**1.37** "Term" has the meaning set forth in Section 7.1.

**1.38** "Termination Notice" means a written notice specifying that a Party is electing to terminate the Agreement in accordance with the terms of Section 7.

**1.39** "Territory" means worldwide.

**1.40** "Third Party" means any Person other than Company or Licensee and their respective Affiliates.

**1.41** "Valid Claim" means a claim of a pending or issued and unexpired patent which has not been held permanently revoked, unenforceable or invalid by a decision of a court or other governmental agency of competent jurisdiction, unappealable or unappealed within the time allowed for appeal and that is not admitted to be invalid or unenforceable through reissue, disclaimer or otherwise (i.e., only to the extent the subject matter is disclaimed or is sought to be deleted or amended through reissue).

## 2 ARTICLE 2 – LICENSE GRANT; DEVELOPMENT, MANUFACTURE AND COMMERCIALIZATION

**2.1** Grant of License Rights to Licensee. Subject to the terms and conditions of this Agreement, Company hereby grants to Licensee during the Term an exclusive (to the extent forth in Section 2.2, below), royalty-bearing, license with a right to sublicense (as set forth in Section 2.5 below) the Company Intellectual Property and within the Field, to Develop, have Developed, Manufacture, have Manufactured, Commercialize, and have Commercialized the Licensed Product(s) in the Territory.

**2.2** Exclusivity. During the Term of this Agreement, Company shall not grant rights to the Company Intellectual Property to any Third Party in the Territory to Develop, Manufacture or Commercialize Licensed Product(s). During the Term, Company shall not Develop, Manufacture or Commercialize (or enter into any arrangement with any Person to Develop, Manufacture or Commercialize) Licensed Product(s).

**2.3** All Rights Reserved. Company hereby reserves all rights not expressly granted to Licensee under this Agreement, and without limiting the foregoing, all rights granted to Licensee under this Agreement are subject to Company's reserved right to use the Company Intellectual Property for the Development, Manufacture, and/or Commercialization of any products or services which are not Licensed Product(s), including within the Territory

.

**2.4** Subcontracting. Licensee may permit the use of Third-Party subcontractors for purposes of conducting subcontracted obligations pursuant to the license granted herein by Company to Licensee pursuant to Section 2.1. Licensee shall remain primarily liable to Company for all of Licensee's duties and obligations contained in this Agreement, including the payments due pursuant to Article 4. Any act or omission of any subcontractor, whether permitted or not, that would be a breach of this Agreement if committed or omitted by Licensee shall be considered a breach by Licensee.

**2.5** Sublicensing. Licensee has the right to grant Sublicenses to Sublicensees within the Territory. Each such Sublicensee shall agree in writing to be bound by the terms and conditions of this Agreement. Licensee and each Sublicensee hereby covenant and agree that (A) Sublicensee shall not exceed the scope and rights of the License granted to Licensee hereunder, (B) Licensee will remain fully responsible and liable to Company for any acts or omissions of a Sublicensee, including in respect of compliance with this Agreement, as if Licensee had committed such action or inaction itself, and (C) Company shall be entitled to enforce the terms and conditions of this Agreement that are applicable to a Sublicense against Licensee and/or such Sublicensee. Licensee shall deliver to Company a true, complete, and correct copy of each Sublicense granted by Licensee, and any modification or termination thereof, within thirty (30) days following the execution, modification, or termination of each Sublicense.

**2.6** Development. Subject to the terms and conditions of this Agreement, Licensee shall have the exclusive right to Develop, and shall be responsible for the Development of, the Licensed Product in the Field in the Territory during the Term. Licensee shall bear all Development Costs to Develop the Licensed Product.

**2.7** Manufacture. Licensee shall be solely responsible for the Manufacture of the Licensed Product in the Field in the Territory at its cost and expense. Company shall reasonably cooperate with Licensee in the technology transfer of the formulation and manufacturing process of the Licensed Product to Licensee or its designee, including as may be more particularly described in any Ancillary Agreement(s) executed by the Parties for Company services.

**2.8** Commercialization. Licensee shall have the exclusive right to control, and shall be responsible for, the Commercialization of the Licensed Product in the Field in the Territory at its cost and expense.

**2.9** Right to Purchase. Licensee is relying on the business experience, knowledge and ability of the current owners or management of Company to make the arrangements contemplated by this Agreement for the support in the Development, Manufacture, and Commercialization of the Licensed Products. Accordingly, if Company consummates a transaction pursuant to which: (i) fifty-one percent (51%) or more of the equity of Company becomes directly or indirectly owned or controlled by a Third Party pursuant to a sale or a transfer of Company equity, by operation of law or otherwise; or (ii) Company enters into receivership or otherwise commences bankruptcy proceedings, (collectively a "Change of Control"), Company shall give Licensee prompt written notice of its Change of Control. Following written notice, Licensee shall have the right, upon written notice to Company (or its successor-in-interest) to purchase, for $[***], the Company Patents (the "Purchase Option"). Upon exercise of the Purchase Option, Company shall enter, or cause to be entered, assignments to Licensee of all right, title, and interest in and to the Company Patents. The Parties shall thereafter continue to perform and remain subject to their respective obligations under this Agreement and Licensee shall maintain the Company Patents in its reasonable discretion, subject to rescission of such assignment, and reversion to Company, due to discontinuance by Licensee of Company Patent maintenance, discontinuance of Development and Commercialization of Licensed Product(s) as required by this Agreement, or other triggering event by Licensee as set forth in this Agreement.

## 3 ARTICLE 3 - FURTHER COVENANTS AND AGREEMENTS

**3.1** Compliance with Laws. Each Party shall perform its obligations under this Agreement and any Ancillary Agreement in accordance with applicable Law. Each Party hereby agrees that it shall not employ or otherwise use in any capacity for the purpose of performing Development or Manufacturing for any Licensed Product, the services of any Person (including any employee or subcontractor): (i) that is currently excluded, debarred, suspended, or otherwise ineligible to participate in any governmental healthcare programs, (ii) that has been convicted of a criminal offense related to the provision of healthcare items or have been excluded, debarred, suspended, or otherwise declared ineligible to participate in any governmental healthcare programs, or (iii) that, to such Party's knowledge, is under investigation or involved in any dispute with a Governmental Authority that may result in such Person being excluded, debarred, suspended, or otherwise declared ineligible to participate in any governmental healthcare programs.

**3.2** Regulatory Matters. Licensee shall have sole responsibility for preparing, filing, and prosecuting with Regulatory Authorities the application for the applicable Regulatory Approval for the Licensed Product, in its own name, subject to reasonable cooperation by Company as may be requested by Licensee.

## 4 ARTICLE 4 – PAYMENTS

**4.1** Payments. In partial consideration of the license and other rights granted herein, subject to the terms and conditions set forth in this Agreement, Licensee shall make the following non-refundable payments to Company on the applicable date or event (each such payment being due only once):

| PAYMENT EVENT | PAYMENT |
|---|---|
| Execution Fee: due upon full execution of the Agreement | $[***] |
| Due upon MMLS discovery of acceptable (in MMLS's sole discretion) toxicology data of EB-002 | $[***] |
| Due upon MMLS production of a stable (in MMLS's sole discretion) salt of the EB-002 product. | $[***] |
| Due upon first patient-first visit (FPFV) in the first Phase I Clinical Trial | $[***] |

**4.2** Milestone Fees. Licensee shall promptly inform Company of the achievement of each of the Development and Sales milestone events as set forth below by Licensee or any of its Affiliates or Sublicensees. In partial consideration of the license and other rights granted herein, and subject to the terms and conditions set forth in this Agreement, Licensee shall make the following non- refundable milestone fee payments to Company within thirty (30) days of the occurrence of each applicable event (each such payment being due only once, irrespective of the number of Licensed Products, or the number of clinical indications or trials conducted therefor):

| DEVELOPMENT MILESTONE EVENT | MILESTONE FEE |
|---|---|
| 1. First Phase I Clinical Trial Completion | $[***] |
| 2. First Phase II/IIb Clinical Trial Completion | $[***] |
| 3. First Phase II/III or III Clinical Trial Completion | $[***] |

Note: For these Development Milestone Events, "Completion" shall be defined as 60 days after data lock of a study the first Licensed Product to be clinically evaluated in each phase.

| SALES MILESTONE EVENT | MILESTONE FEE |
|---|---|
| 1. Reaching $300 Million in aggregate sales of Licensed Product | $[***] |
| 2. Reaching $1 Billion in aggregate sales of Licensed Product | $[***] |
| 3. Reaching $2 Billion in aggregate sales of Licensed Product | $[***] |

**4.3** Maintenance Fees. Following the Effective Date, Licensee shall be responsible for the maintenance and prosecution of the Company Patents in jurisdictions mutually agreed to by the Parties in a separate writing. If Licensee elects not to pay the applicable patent fees for a particular jurisdiction, Company will have the option to pay those unpaid fees, however upon Company's payment all rights will revert to Company for that specific patent in that specific jurisdiction and will no longer be deemed part of Company Intellectual Property.

**4.4** Royalties. In partial consideration of the license and other rights granted herein, and subject to the terms and conditions set forth in this Agreement, Licensee shall pay to Company, and shall cause Sublicensees to pay to Company, on a quarterly basis, royalties based on Net Revenues, of the Licensed Product on a Licensed Product-by-Licensed Product and country-by-country basis in the Territory in accordance with the following:

| **LICENSED PRODUCT SALES (per Licensed Product)** | **ROYALTY RATE (per Licensed Product)** |
|---|---|
| 1. Net Revenues from $[***] to $[***] ..... | [***]% |
| 2. Net Revenues above $[***] ..... | [***]% |

4.4.1 Royalty Stacking. If, during the Term, Licensee is required (in its sole judgement) to take a royalty-bearing license under intellectual property rights owned by a Third Party in order to make, use, offer to sell, sell, or import a Licensed Product, Licensee may deduct from those affected royalties due under this Agreement on the Net Revenues of that Licensed Products the royalties actually paid by Licensee to each Third Party for that Licensed Product; provided that total deductions for under both Sections 4.4.1 and 4.4.2 shall be limited to a maximum of fifty percent (50%) of the royalties owed by Licensee to Company under each applicable reporting period.

4.4.2 Combination Products. If a Licensed Product is sold in combination with other services or products (collectively a "Combination Product"), Net Revenues shall be determined by multiplying the Net Revenues by the fraction A/(A+B) wherein "A" is the value of the Net Revenues of the Licensed Product and "B" is the Net Revenues of any other service(s) or product(s) included the Combination Product when sold separately during the same period, in the same geographic region to the same class of customer. If, on a country-by-country basis, either the Licensed Product and/or the other service(s) and/or product(s) included in the Combination Product are not sold separately in said country, Net Revenues shall be determined by Licensee in good faith. The total deductions under both Sections 4.4.1 and 4.4.2 shall be limited to a maximum of fifty percent (50%) of the royalties owed by Licensee to Company under any applicable reporting period.

4.4.3 Patent Expiration. On a country-by-country basis, following the last-to-expire of the Company Patents, but during the Term, royalties on Net Revenues shall automatically be reduced by fifty percent (50%), and no further deductions with regard to royalty-stacking or combination products shall apply to royalties paid on Net Revenues of such Licensed Products.

4.4.4 Quarterly Royalty Reports. Within sixty (60) days after the end of a calendar quarter during which there are sales of a Licensed Product in any country of the Territory, Licensee shall provide Company with a written report (the "Quarterly Royalty Report") setting forth (i) the date of First Commercial Sale of each Licensed Product in each country; (ii) the amount of Net Revenues, specifying the gross sales and the deductions taken to arrive at the Net Revenues, listed by Licensed Product and by country, and any other credits or offsets; and (iii) the total royalty payments due to Company by Licensed Product and by country. Along with each Quarterly Royalty Report, Licensee shall pay to Company the royalties due and payable under this Agreement. If no royalties or fees are due and payable, Licensee shall so report.

4.4.5 Records Pertaining to Sales or Other Disposition of Licensed Product. Licensee shall keep complete, true, and accurate books and records relating to Development or Manufacturing activities conducted by Licensee, its Affiliates, or its designees under this Agreement for the period required by applicable Laws. In addition, Licensee shall keep (and cause its Affiliates and Sublicensees to keep) complete and accurate records pertaining to the sale or other disposition of Licensed Products in sufficient detail to permit Company to confirm the accuracy of royalties and sales milestones due hereunder, for at least three (3) years following the calendar quarter to which the information relates.

4.4.6 Examination Rights Pertaining to Sales or Other Disposition of Licensed Product. During the Term and for three (3) years thereafter, Company shall have the right to appoint an independent certified public accountant to examine the applicable Net Revenue records of Licensee and its Affiliates to verify the accuracy of the relevant Quarterly Royalty Reports and royalties and milestones payable, by inspection of relevant books of accounts and records, subject to the following terms:

4.4.6.1 Licensee and its Affiliates shall make their books and records available for inspection by the accountant solely to verify the accuracy of its Quarterly Royalty Reports and royalties and sales milestones payable.

4.4.6.2 Company shall give at least thirty (30) days prior notice to Licensee of when its accountant shall visit Licensee and its Affiliates or Sublicensees.

4.4.6.3 Licensee and its Affiliates shall give access to the accountant to the relevant books and records during regular business hours at the place or places where the books and records are usually kept. While inspecting such accounts and records, the accountant shall abide by all of Licensee's (or its Affiliate's) standard rules and regulations.

4.4.6.4 The accountant shall prepare and deliver to each Party a report setting out its findings no later than thirty (30) days after the examination has been completed.

4.4.6.5 Company's examination right under this Section may not be exercised more than once every calendar year and only once for each examined calendar quarter.

4.4.6.6 Company shall bear the examination costs, except where the examination shows that Licensee has underpaid Company by five percent (5%) or more of the total amount due for a calendar year, in which case Licensee shall bear the reasonable out-of-pocket examination costs.

4.4.6.7 Where there has been an underpayment, Licensee shall pay to Company the underpayment with a monthly interest rate as set forth in Section 12.11 (together with reasonable and documentable examination costs if applicable) due within thirty (30) days of its receipt of the accountant's report. In the case of overpayment by Licensee, any future payments payable to Company shall be offset by the amount of overpayment.

4.4.7 Payment Exchange Rate. In the case of sales by Licensee and its Affiliates outside the United States, the rate of exchange to be used in computing the amount of currency equivalent in U.S. Dollars due Company shall be made at the rate of exchange established by Oanda.com, prevailing on the third to the last business day of the month prior to the month in which such sales are recorded by Licensee and its Affiliates.

**4.5** [***].

**4.6** Buyout Option. Throughout the Term of this Agreement, Licensee shall have the option to buy out all payment obligations otherwise set forth in Sections 4.1 through 4.4, by making a one-time cash payment to Company in accordance with the following, and upon rendering of such payment to Company, no further amounts shall be due or payable under Sections 4.1 through 4.4:

| **BUYOUT EVENTS** | **BUYOUT PAYMENT** |
|---|---|
| 1. On or before first Phase I Clinical Trial Completion of any Licensed Product for any indication(s)..... | $[***] |
| 2. After No. 1 above, but before first Phase II/IIb Clinical Trial Completion of any Licensed Product for any indication(s) ..... | $[***] |
| 3. After No. 2 above, but before first Phase II/III or Phase III Clinical Trial Completion of any Licensed Product for any indication(s)..... | $[***] |
| 4. Upon first Regulatory Approval of any Licensed Product for any indication(s) ..... | [***]% of Discounted Cash Flow (DCF) value of all Licensed Products then being Commercialized by Licensee, on a country-by-country and Licensed Product-by-Licensed Product basis over the remaining term(s) of the Patent(s) that include Valid Claim(s) actually covering such Licensed Product(s) in such country(ies), and as anticipated by this Agreement and as calculated by an independent Third Party mutually selected by the Parties |

Note: If the Parties do not mutually agree, within ten (10) days, on an independent Third-Party accountant, then each Party shall select an independent Third-Party accountant, and those two Third Party accountants shall select a third qualified individual or entity, and all three will establish DCF value as described in 4.6.4 above.

## 5 ARTICLE 5 - CONFIDENTIALITY

**5.1** Confidentiality. Each Party shall, and shall cause its Affiliates, and each of its and their current and former respective officers, directors, employees and agents, including subcontractors (collectively, Receiving Party's "Representatives") to, keep completely confidential and not publish or otherwise disclose and not use, directly or indirectly, by or on behalf the other Party for any purpose, any Confidential Information furnished or otherwise made known to it, directly or indirectly, by or on behalf of the other Party, except to the extent such disclosure or use is expressly permitted by the terms of this Agreement or such use is reasonably necessary for the performance of the Receiving Party's obligations, or the exercise by the Receiving Party of its rights, under this Agreement. "Confidential Information" means any information provided by or on behalf of one Party or its Affiliates (the "Disclosing Party") to the other Party or its Affiliates (the "Receiving Party") relating to the terms of this Agreement, the Licensed Product, the performance of Development activities, Manufacturing activities, Commercial activities or the scientific, regulatory, or business affairs or other activities of the Disclosing Party or the Disclosing Party's Affiliates. Each Receiving Party shall (and shall cause its Affiliates to) take reasonable actions to protect against any use or disclosure of the Confidential Information of the Disclosing Party except as expressly permitted under this Article 5. A Party's Representatives that receive or otherwise have access to the Disclosing Party's Confidential Information under this Article 5 shall have a need to know such information and shall be bound by obligations of confidentiality and non-use substantially similar to the Receiving Party's obligations hereunder. Notwithstanding the foregoing, Confidential Information shall not include any information that:

5.1.1 is or hereafter becomes part of the public domain by public use, publication, general knowledge or the like through no wrongful act, fault, or negligence on the part of Receiving Party or its Representatives;

5.1.2 can be demonstrated by documentation or other competent proof to have been in the Receiving Party's possession prior to disclosure by or on behalf of the Disclosing Party without any obligation of confidentiality with respect to said information;

5.1.3 is subsequently received by the Receiving Party from a Third Party who is not bound by any obligation of confidentiality with respect to said information; or

5.1.4 can be demonstrated by documentation or other competent evidence to have been independently developed by or for the Receiving Party without reference to the Disclosing Party's Confidential Information.

Specific aspects or details of Confidential Information shall not be deemed to be within the public domain or in the possession of the Receiving Party merely because the Confidential Information is embraced by more general information in the public domain or in the possession of the Receiving Party. Further, any combination of Confidential Information shall not be considered in the public domain or in the possession of the Receiving Party merely because individual elements of such Confidential Information are in the public domain or in the possession of the Receiving Party unless the combination and its principles are in the public domain or in the possession of the Receiving Party.

**5.2** Permitted Disclosures. Each Receiving Party may disclose Confidential Information disclosed to it by the Disclosing Party to the extent that such disclosure by the Receiving Party is:

5.2.1 made in response to a valid order of a court of competent jurisdiction or other Governmental Authority of competent jurisdiction or, if in the reasonable opinion of the Receiving Party's legal counsel, such disclosure is otherwise required by applicable Law; provided, however, that the Receiving Party, where reasonably possible, shall give notice, to the extent legally permitted, to the Disclosing Party and given the Disclosing Party (at its sole expense) a reasonable opportunity to oppose the order and to obtain a protective order requiring that the Confidential Information and documents that are the subject of such order be held in confidence by such court or agency or, if disclosed, be used only for the purposes for which the order was issued; and provided, further that if a disclosure order is not quashed or a protective order is not obtained, the Confidential Information disclosed in response to such court or governmental order shall be reasonably limited to the information that is legally required to be disclosed in response to such court or governmental order and such information disclosed shall be considered Confidential Information for all other purposes;

5.2.2 otherwise required by applicable Law or the requirements of a national securities exchange or stock market; provided that the Receiving Party shall (i) if not prohibited by applicable Law, provide the Disclosing Party with reasonable advance notice of, and an opportunity to comment on, any such required disclosure, to the extent such advance notice is legally permitted, (ii) if not prohibited by applicable Law, if requested by the Disclosing Party, seek confidential treatment with respect to any such disclosure to the extent available, and (iii) if not prohibited by applicable Law, consider the comments of the Disclosing Party in any such disclosure or request for confidential treatment;

5.2.3 made by the Receiving Party to a Regulatory Authority as required in connection with obtaining or maintaining any Regulatory Approval for the Licensed Product; provided, however, that reasonable measures shall be taken to seek confidential treatment of such information;

5.2.4 made by the Receiving Party as appropriate to file or prosecute Patents, prosecute, or defend litigation, file Regulatory Approval applications, or otherwise establish rights or enforce obligations under this Agreement;

5.2.5 made by the Receiving Party or its Representative to its actual or prospective attorneys, auditors, advisors, consultants, contractors, Sublicensees or other Third Parties in connection with the performance of its obligations or exercise or potential exercise of its rights as contemplated by this Agreement; provided, however, that such Persons shall be subject to obligations of
confidentiality and non-use with respect to such Confidential Information that are substantially similar to the Receiving Party's obligations hereunder; and

5.2.6 made by the Receiving Party or its Representative to actual or prospective acquirers, merger candidates, or investors (and to their respective Affiliates, representatives and financing sources); provided that (i) each such Third Party signs an agreement that contains obligations that are substantially similar to the Receiving Party's obligations hereunder, and (ii) each such representative or financing source to whom information is disclosed shall (a) be subject to reasonable obligations of confidentiality, (b) be informed of the confidential nature of the Confidential Information so disclosed, and (c) agree to hold such Confidential Information subject to the terms thereof.

**5.3** Use of Name. Except as expressly provided in this Agreement, neither Party shall mention or otherwise use the corporate names or any other name or trademark of the other Party (or any abbreviation, acronym, adaptation, translation or transliteration thereof) in any publication, press release, marketing and promotional material, or other form of publicity without the prior written approval of that other Party in each instance. The restrictions imposed by this Section 5.3 shall not prohibit either Party from making any disclosure that is otherwise permitted under this Article 5 or with respect to which written consent has previously been obtained. Further, the restrictions imposed on each Party under this Section 5.3 are not intended, and shall not be construed, to prohibit a Party from identifying the other Party in its internal business communications, provided that any Confidential Information in such communications remains subject to this Article 5.

**5.4** Press Releases. Neither Party shall issue any press release or other similar public communication relating to the execution of or the terms of this Agreement, its subject matter or the transactions covered by it, or the activities of the Parties under or in connection with this Agreement, without the prior written approval of the other Party, except for communications required by applicable Law or the requirements of a national securities exchange or stock market as reasonably advised by the issuing Party's counsel (provided, that, the issuing Party complies with the provision set forth in Section 5.2.2). Notwithstanding the above, the Parties acknowledge and agree that, within four (4) business days from the Effective Date, the Parties shall issue a mutually agreed to press release announcing the execution of this Agreement. Thereafter, the Parties shall mutually agree in good faith with respect to any additional press releases prior to the issuance thereof. In addition, following any initial press release(s) announcing this Agreement, required disclosures pursuant to applicable Law, or other public disclosure approved by both Parties, either Party shall be free to disclose, without the other Party's prior written consent, the existence of this Agreement, the identity of the other Party and those terms of the Agreement which have already been publicly disclosed in accordance herewith.

**5.5** Return or Destruction of Confidential Information. Within ninety (90) days after the earlier of (i) the expiration of the Term, or (ii) the termination of this Agreement in its entirety, each Receiving Party shall, at the Disclosing Party's discretion and written request, promptly destroy or return to the Disclosing Party all documentary, electronic, or other tangible embodiments of the Disclosing Party's Confidential Information to which the Receiving Party does not retain rights hereunder and any and all copies thereof, and destroy those portions of any documents that incorporate or are derived from the Disclosing Party's Confidential Information to which the Receiving Party does not retain rights hereunder, and provide a written certification of such destruction, except that the Receiving Party may retain (a) one copy thereof for archival purposes, and (b) such additional copies of or any computer records or files containing such Confidential Information that have been created solely by the Receiving Party's automatic archiving and back-up procedures, to the extent created and retained in a manner consistent with the Receiving Party's standard archiving and back-up procedures, but not for any other use or purpose.

**5.6** Survival of Confidentiality Obligations. The confidentiality and non-use obligations imposed on each Party under this Article 5 shall continue with respect to a particular item of Confidential Information of the other Party until seven (7) years after termination or expiration of this Agreement; provided, however, that the confidentiality and non-use obligations imposed by this Agreement with respect to Company Technology which comprises a trade secret shall continue for as long as such Company Technology remains eligible for trade secret protection under applicable federal and state trade secret Laws, but only with respect to those trade secrets that were expressly identified as such in writing at the time of first transmission thereof to Licensee.

## 6 ARTICLE 6 - INTELLECTUAL PROPERTY

**6.1** Company Intellectual Property.

6.1.1 Ownership. As between the Parties, Company shall have sole and exclusive ownership of all right, title and interest on a worldwide basis in and to all Company Intellectual Property and Improvements developed solely by Company. Any Improvements to Company Intellectual Property shall automatically be subject to and included in the license grants from Company to Licensee as set forth in this Agreement. Company will promptly disclose to Licensee all Improvements and will respond promptly to reasonable requests from Licensee for more information relating thereto.

6.1.2 Company Patents. Promptly following the Effective Date, Licensee shall assume responsibility, at its sole cost and expense, and in Company's name, for preparing, filing, prosecuting, and maintaining (including with respect to (i) related interference, derivation, re-issuance, re- examination, opposition and other post-grant proceedings, and (ii) patent term extensions, including supplementary protection certificates and any other extensions or patent term adjustments that are now or become available in the future, wherever applicable) (collectively, "Prosecution") Company Patents including any Company Patents that are Improvements. Licensee shall have the right to select counsel with respect to the responsibility assumed by Licensee in this Section 6.1.2. Company shall, and shall ensure that its officers, directors, employees, agents, and any inventors of Company Patent or Improvements to Company Intellectual Property, reasonably cooperate with Licensee in connection with Prosecution, including without limitation in obtaining patent term extension, supplemental protection certificate or their equivalents in any country in the Territory.

**6.2** Licensee Intellectual Property. As between the Parties, Licensee shall have the sole and exclusive ownership of all right, title and interest on a worldwide basis in and to all Licensee Intellectual Property and any Improvements developed by Licensee. Company is granted no rights therein or thereto.

**6.3** Infringement. In the event of infringement by a Third Party of the Company Patents ("Infringement"), Licensee shall have the first right, but not the obligation, to bring and control, at its expense, a suit or other action before a government or private tribunal against any person or entity allegedly engaged in Infringement (an "Infringement Action"). If either Party becomes aware of a suspected Infringement or any Infringement Action, such Party shall promptly notify the other Party of that suspected or actual Infringement. Company shall join an Infringement Action as a party if, in Licensee's reasonable judgement, joinder is required for purposes of bringing or maintaining the Infringement Action. Licensee will have a period of one hundred eighty (180) days to elect to initiate an Infringement Action (or to settle or otherwise secure the abatement of such Infringement). In the event Licensee does not so elect (or settle or otherwise secure the abatement of such Infringement) within the aforementioned period of time or ten (10) days before the time limit, if any, for the filing of an Infringement

Action, it will notify Company in writing and Company will then have the right to commence a suit or take action to enforce the applicable Company Patents, at Company's sole cost and expense.

**6.4** Cooperation. Each Party shall cooperate with and assist the other Party, at the cost and expense of the Party leading an Infringement Action, to fully effect this Article 6, including by executing such documents and taking such actions, and making its employees and using Commercially Reasonable Efforts to make independent contractors available to execute documents and provide information to such other Party or to such other Party's authorized attorneys, agents, or representatives, as necessary.

**6.5** No Implied Licenses. Except as specifically set forth in this Agreement, neither Party shall acquire any license or other intellectual property interest, by implication or otherwise, in any information disclosed to it under this Agreement or under any patents, patent applications or other intellectual property owned or controlled by the other Party or its Affiliates.

## 7 ARTICLE 7 - TERM AND TERMINATION

**7.1** Term. This Agreement shall become effective on the Effective Date and, unless earlier terminated pursuant to this Article 7, shall continue until the longer of: (a) the last to expire of the Company Patents that Cover a Licensed Product; or (b) ten (10) years following First Commercial Sale, on a country-by-country basis (the "Term"), and following expiration of the Term all rights granted to Company Technology hereunder shall become fully paid-up and irrevocable.

**7.2** Termination for Breach. Either Party may terminate this Agreement by providing a Termination Notice in the event the other Party materially breaches this Agreement, in the following time periods:

7.2.1 if the material breach is a payment default and has continued for sixty (60) days after receipt of written notice by the allegedly breaching Party;

7.2.2 for material breaches that are capable of being cured within ninety (90) days, if the breach has continued for ninety (90) days after receipt of written notice by the allegedly breaching Party; and

7.2.3 for material breaches that are not capable of being cured within ninety (90) days, if the breach has continued for ninety (90) days after receipt of written notice by the allegedly breaching Party and the breaching Party has not commenced good faith efforts to cure the breach within its ninety (90) day cure period. For avoidance of doubt, any material default or breach of an Ancillary Agreement, shall not constitute breach of this Agreement.

**7.3** Termination for Failure to Develop. In the event Licensee: (i) does not demonstrate Commercially Reasonable Efforts to Develop the Licensed Product for a period of at least nine (9) consecutive months, or (ii) elects, by written notice to Company, to discontinue Development or Commercialization of the Licensed Product, the Company may terminate this Agreement by providing a Termination Notice.

**7.4** Termination for Inadequate Research Results. In the event Licensee discovers unacceptable (in its sole discretion) toxicology data as to EB-002, is unable (in its sole discretion) to identify and produce a stable salt of EB-002 or discovers that Company failed to communicate relevant EB-002 data to Licensee prior to such discovery, Licensee may terminate this Agreement by providing a Termination Notice.

**7.5** Termination for Insolvency. Company shall have the right to terminate this Agreement upon Termination Notice if Licensee:

7.5.1 passes a resolution for winding-up of all or a material part of its assets or business (other than a winding-up for the purpose of, or relating to, any solvent amalgamation or reconstruction) or a court enters an order to that effect;

7.5.2 has entered against it an order for relief recognizing it as a debtor under any insolvency or bankruptcy laws (or any equivalent order in any jurisdiction); or

7.5.3 enters into any composition or arrangement with its creditors with respect to all or a material part of its assets or business (other than relating to a solvent restructuring). Notwithstanding the foregoing, in the case of any involuntary bankruptcy proceeding, such right to terminate shall only become effective if Licensee consents to the involuntary bankruptcy or if such proceeding is not dismissed or stayed within forty-five (45) days after the filing thereof.

**7.6** Rights in Bankruptcy. All rights and licenses granted under or pursuant to this Agreement by Company to Licensee are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code, licenses of rights to "intellectual property" as defined under the U.S. Bankruptcy Code. The Parties agree that Licensee, as licensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code. The Parties further agree that, in the event of the commencement of a Bankruptcy proceeding by or against Company under the U.S. Bankruptcy Code (the "Party subject to such proceeding"), Licensee (the "non-subject Party") shall be entitled to a complete duplicate of (or complete access to, as appropriate) all data relating to Development and Regulatory Approval of the Licensed Product, and all embodiments of such intellectual property related thereto, which shall be promptly delivered (i) upon any such commencement of a Bankruptcy proceeding upon Licensee's written request therefor, unless Company (x) elects to and does continue to perform all of its obligations under this Agreement, or (y) rejects this Agreement and Licensee elects to treat this Agreement as terminated, or (ii) if not delivered under clause (i) above, following the rejection of this Agreement by or on behalf of Company, upon written request therefor and the election by Licensee to retain its rights under this Agreement. The provisions of this Section 7.6 are without prejudice to any rights that a Party may have arising under any applicable insolvency statute or other applicable law, including the right of a Party to assert that this Agreement is not an executory contract subject to rejection under Section 365 of the U.S. Bankruptcy Code.

**7.7** Effects of Termination of this Agreement. Upon termination of this Agreement, all rights licensed by Company to Licensee shall terminate. Notwithstanding the foregoing, Licensee, its Affiliates and Sublicensees shall be entitled to continue to sell (but not to actively promote after the effective date of termination) any existing inventory of Licensed Products in each terminated country of the Territory in accordance with the terms and conditions of this Agreement for a period of one (1) year following the effective date of such termination, and any Licensed Product sold or disposed of during this period shall be subject to the same consideration including without limitation the obligation to pay royalties for Licensed Product as would have applied had this Agreement otherwise remained in full force and effect. Following such period, Licensee, its Affiliates and Sublicensees shall not sell such terminated Licensed Products in such terminated country(ies). All rights and licenses of Sublicensees shall terminate upon termination of the Agreement; provided, that if a Sublicensee is in good standing (*i.e.*, not in uncured material breach of the applicable Sublicense Agreement and not responsible for Licensee's material breach of this Agreement) and agrees in writing to assume all of the obligations of Licensee and provides Company with written notice thereof within ninety (90) days after termination of the Agreement, then such Sublicense Agreement shall survive with Company assuming such Sublicense Agreement but without assuming any obligations beyond those obligations already owed under this Agreement.

**7.8** Other Remedies. Termination or expiration of this Agreement for any reason shall not release either Party from any liability or obligation that already has accrued prior to expiration or termination, nor affect the survival of any provision hereof to the extent it is expressly stated to survive termination. Subject to and without limiting the terms and conditions of this Agreement, expiration or termination of this Agreement shall not preclude a Party from (i) claiming any other damages, compensation or relief that it may be entitled to upon expiration or termination, (ii) any right to receive amounts accrued under this Agreement prior to the expiration or termination date but which are unpaid or become payable thereafter and (iii) any right to obtain performance of any obligation provided for in this Agreement which shall survive expiration or termination.

**7.9** Survival. Termination or expiration of this Agreement shall not affect rights or obligations of the Parties under this Agreement that have accrued prior to the date of termination or expiration of this Agreement. Notwithstanding anything to the contrary, the following provisions shall survive and apply after expiration or termination of this Agreement: Sections 4.4.5, 4.4.6, 8.4 and Articles 1 (to the extent necessary to interpret other surviving sections), 5, 7, 9, 10, 11, and 12. All provisions not surviving in accordance with the foregoing shall terminate upon expiration or termination of this Agreement and be of no further force and effect.

## 8 ARTICLE 8 - REPRESENTATIONS, WARRANTIES AND COVENANTS; DISCLAIMER

**8.1** Mutual Representations, Warranties and Covenants. Each Party represents and warrants to the other Party that:

8.1.1 Due Incorporation or Formation; Authorization of Agreement. Such Party is duly incorporated, organized, or formed, validly existing and in good standing under the laws of the jurisdiction of its incorporation, organization or formation and has the corporate, company, or partnership power and authority to own its property and carry on its business as owned and carried on at the date hereof and as contemplated hereby. Such Party has the necessary power and authority to execute and deliver this Agreement and the Ancillary Agreements and to perform its obligations hereunder, and the execution, delivery and performance of this Agreement and the Ancillary Agreements by such Party has been duly authorized by all necessary corporate, company or partnership action of that Party. This Agreement and each Ancillary Agreement (when entered into) constitutes (and shall constitute) the legal, valid and binding obligation of such Party and is (and shall be) enforceable against it in accordance with its (and their) terms, subject to the effects of bankruptcy, insolvency, or other laws of general application affecting the enforcement of creditor rights and judicial principles affecting the availability of specific performance and general principles of equity.

8.1.2 No Conflicts. Neither the execution, delivery or performance of this Agreement and the Ancillary Agreements by such Party nor the consummation by such Party of the transactions contemplated hereby or thereby (i) conflicts with, violates, or will result in a breach in any material respect of any of the terms, conditions or provisions of any applicable Law, (ii) conflicts with, violates, or will result in a breach of or constitute a default under any of the terms, conditions or provisions of, where relevant, the articles of incorporation, bylaws, operating agreement, partnership agreement, or other organizational documents of such Party, (iii) conflicts with, violates, or will result in a breach of, constitute a default under (whether with notice or lapse of time or both), accelerate or permit the acceleration of the performance required by, give to others any material interests or rights within the Field or require any consent, authorization or approval under any agreement or instrument to which such Party is a party or by which that Party or any of their properties or assets is bound, in each case that would have a material adverse effect on that Party's ability to perform under this Agreement within the Field, or (iv) results or will result in the creation or imposition of any lien upon any of the properties or assets of such Party, in each case would have a material adverse effect on such Party's ability to perform under this Agreement or any Ancillary Agreement.

8.1.3 Government Authorizations; Consents. Any registration, declaration or filing with, or consent, approval, license, permit, or other authorization or order by, or exemption or other action of, any Government Authority, or any approval or consent of any other Person, that was or is required in connection with the valid execution, delivery, acceptance, and performance by such Party under this Agreement or any Ancillary Agreement were completed, made, or obtained on or before the Effective Date (other than with respect to (i) obtaining Regulatory Approval for the Licensed Product, which shall be sought in accordance with this Agreement, and (ii) post-Effective Date notifications to and/or consents from Governmental Authorities as required by applicable Law).

**8.2** Company. Company represents and warrants to Licensee that:

8.2.1 Compliance with Laws. Company has not employed or otherwise used in any capacity the services of any Person (including any employee or subcontractor) in performing any activities with respect to such Company Intellectual Property: (i) that is currently excluded, debarred, suspended, or otherwise ineligible to participate in any governmental healthcare programs, (ii) that has been convicted of a criminal offense related to the provision of healthcare items or has been excluded, debarred, suspended, or otherwise declared ineligible to participate in any governmental healthcare programs, or (iii) that, to Company's knowledge, is under investigation or involved in any dispute with a Governmental Authority that may result in such Person being excluded, debarred, suspended, or otherwise declared ineligible to participate in any governmental healthcare programs.

8.2.2 Company Intellectual Property. Company: (i) has the authority to grant the licenses herein, (ii) has not granted to a Third Party any right or license or option to practice for any purpose the Company Intellectual Property within the Field, (iii) does not own or control any Patents that may reasonably be necessary or useful to Develop, Manufacture, and/or Commercialize Licensed Products other than the Company Patents, and (iv) has no knowledge of any Patents owned or controlled by any Third Party that may be infringed (with respect to pending patent applications, if the claims as currently pending were granted) by the Development, Manufacture, and/or Commercialization of Licensed Products.

8.2.3 Litigation. As of the Effective Date, there are no actions, suits, proceedings, or investigations pending, or, to the knowledge of Company, threatened against Company relating to any of the Licensed Product or the Development or Manufacture thereof before or by any Government Authority or any arbitrator, and there exist no facts or circumstances likely to give rise to any of the foregoing.

8.2.4 Other License Grants. Company has not granted and will not grant after the Effective Date and during the Term, any right to a Third Party within the Field that would conflict with the rights granted to Licensee hereunder.

**8.3** Licensee. Licensee represents and warrants to Company that:

8.3.1 Compliance with Laws. Licensed Products prepared and sold by Licensee shall be in compliance with all applicable Laws and that any Person (including any employee or subcontractor) in performing any activities with respect to Commercialization of the Company Intellectual Property, and all Licensed Products shall be Manufactured in accordance with Regulatory Approvals and all other applicable Laws, Manufacturing processes, and quality requirements, and shall not be adulterated or misbranded under applicable Laws. Licensee has not employed or otherwise used in any capacity the services of any Person (including any employee or subcontractor) in performing any activities with respect to Company Intellectual Property: (i) that is currently excluded, debarred, suspended, or otherwise ineligible to participate in any governmental healthcare programs, (ii) that has been convicted of a criminal offense related to the provision of healthcare items or has been excluded, debarred, suspended, or otherwise declared ineligible to participate in any government healthcare programs, or (iii) that, to Licensee's knowledge, is under investigation or involved in any dispute with a Government Authority that may result in such Person being excluded, debarred, suspended, or otherwise declared ineligible to participate in any governmental healthcare programs.

8.3.2 Export Compliance. Licensee shall observe all applicable United States and foreign laws and regulations with respect to the research, development, manufacture, marketing and transfer of Licensed Products and related technical data, including, without limitation, the International Traffic in Arms Regulations (ITAR) and the Export Administration Regulation and hereby represents and covenants that Licensee: (a) is neither a national of, nor controlled by a national of, any country to which the United States prohibits the export or re-export of goods, services, or technology; (b) is not a Person specifically designated as ineligible to export from the United States or deal in U.S. origin goods, services, or technologies; (c) shall not export or re-export, directly or indirectly, any goods, services, or technology to any country or Person (including juridical Persons) to which the United States prohibits the export of goods, technology or services; and (d) in the event that a United States government license or authorization is required for an export or re-export of goods, services, or technology (including technical information acquired Company under this Agreement and/or any products created by using such technical information or any part thereof), shall obtain any necessary United States government license or other authorization prior to undertaking the export or re-export.

**8.4** Disclaimer. EXCEPT AS OTHERWISE SET FORTH IN THIS ARTICLE 8, NEITHER COMPANY NOR LICENSEE MAKE ANY OTHER REPRESENTATIONS OR WARRANTIES WITH RESPECT TO THIS AGREEMENT OR ANY ANCILLARY AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY OR THEREBY, AND EACH OF COMPANY AND LICENSEE EXPRESSLY DISCLAIMS ALL OTHER WARRANTIES WITH RESPECT TO THIS AGREEMENT AND THE ANCILLARY AGREEMENTS AND THE TRANSACTIONS CONTEMPLATED HEREBY OR THEREBY, WHETHER EXPRESS, STATUTORY OR IMPLIED, INCLUDING THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

## 9 ARTICLE 9 - INDEMNIFICATION

**9.1** Indemnity by Company. Company shall indemnify, defend, and hold harmless the Licensee Indemnified Parties from and against any and all Losses to the extent arising out of or relating to Third Party Claims asserted, brought, commenced, or threatened against any Licensee Indemnified Party arising from, out of, or in connection with (i) Company's breach of its representations, warranties, covenants or obligations under this Agreement or any Ancillary Agreement; or (ii) Company's willful misconduct, gross negligence, fraudulent acts or omissions of Company, or any violation of applicable Law by Company.

**9.2** Indemnity by Licensee. Licensee shall indemnify, defend, and hold harmless the Company Indemnified Parties from and against any and all Losses to the extent arising out of or relating to Third Party Claims asserted, brought, commenced, or threatened against any Company Indemnified Party arising from, out of, or in connection with: (i) Licensee's breach of its representations, warranties, covenants or obligations under this Agreement or any Ancillary Agreement; (ii) Licensee's willful misconduct, gross negligence, fraudulent acts or omissions of Licensee, or any violation of applicable Law by Licensee; or (iii) any bodily injury or death or property damage arising from or in connection with the Development, Manufacture or Commercialization of a Licensed Product (in each case excluding Claims for which Company is required to indemnify Licensee in accordance with Section 9.1, or in connection with Company's willful misconduct, gross negligence, fraudulent acts or omissions of Company, or any violation of applicable Law by Company).

**9.3** Indemnification Procedures.

9.3.1 Notice of Claim. Any Licensee Indemnified Party or Company Indemnified Party asserting a right of indemnification under this Article 9 (an "Indemnitee") shall notify the indemnifying party (an "Indemnitor") in writing (the "Indemnity Notice") promptly after receiving written notice of a Third Party Claim against it, describing the Third Party Claim, the amount thereof (if known and quantifiable) and the basis thereof; provided, that, the failure to so notify an Indemnitor shall not relieve the Indemnitor of its obligations hereunder except to the extent that (and only to the extent that) the Indemnitor has been materially prejudiced thereby.

9.3.2 Defense of Third Party Claims. The Indemnitor shall assume the defense of each Claim brought by a Third-Party giving rise to a right of indemnification ("Third Party Claim"). The Indemnitor shall, at the Indemnitor's expense and with counsel of its choosing, conduct and control the defense and the disposition or, subject to Section 9.3.2.3, settlement of the Third-Party Claim (including all decisions relative to litigation, appeal, and settlement), provided that:

9.3.2.1 The Indemnitee shall be entitled to participate in the defense of such Third-Party Claim and to employ counsel of its choice for such purpose; provided that the fees and expenses of separate counsel shall be borne by the Indemnitee; and

9.3.2.2 the Indemnitor shall obtain the prior written consent of the Indemnitee before entering into any settlement of a Third-Party Claim if, pursuant to or as a result of settlement or cessation, injunctive or other equitable relief will be imposed against Indemnitee or if settlement does not expressly and unconditionally release the Indemnitee from all liabilities and obligations with respect to the Third Party Claim, without prejudice.

## 10 ARTICLE 10 - LIMITATION OF LIABILITY

Limitation of Liability**.** EXCEPT WITH RESPECT TO PAYMENTS OWED OR THE OBLIGATIONS OF EACH PARTY SET FORTH IN ARTICLE 5, ARTICLE 6, AND ARTICLE 9, NEITHER PARTY NOR ITS AFFILIATES SHALL BE LIABLE FOR PUNITIVE, EXEMPLARY, CONSEQUENTIAL, OR SPECIAL DAMAGES, OR LOST PROFITS, LOST REVENUE, OR LOST SAVINGS, CONNECTED WITH, OR ARISING OR RESULTING FROM, ANY PERFORMANCE OR LACK OF PERFORMANCE UNDER THIS AGREEMENT OR ANY ANCILLARY AGREEMENT, EVEN IF SUCH DAMAGES WERE FORESEEABLE OR THE PARTY SOUGHT TO BE HELD LIABLE WAS ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, AND IN EACH CASE REGARDLESS OF WHETHER A CLAIM IS BASED ON CONTRACT, WARRANTY, TORT (INCLUDING NEGLIGENCE OR STRICT LIABILITY), OR ANY OTHER LEGAL OR EQUITABLE PRINCIPLE. NEITHER PARTY SHALL ALLEGE THAT ANY REMEDY OR ANY PROVISION OF THIS AGREEMENT OR ANY ANCILLARY AGREEMENT FAILS OF ITS ESSENTIAL PURPOSE. ARTICLE 11 - dispute resolution

Any Dispute shall be resolved as provided in this Article 11 and, to the extent applicable, Article 12.

**10.1** Informal Dispute Resolution. The Parties shall attempt in good faith to resolve any Dispute in the first instance utilizing the dispute resolution procedures set forth in this Section 11.1. In the event of any Dispute, each Party may initiate the dispute resolution procedures set forth in this Section 11.1 by providing written notice of the Dispute to the other Party. The Parties shall first attempt to resolve its Dispute in good faith by escalating the Dispute to an authorized representative of each Party. The authorized representatives of each Party shall work in

good faith to develop a plan to resolve the Dispute. If the matters are not resolved within twenty (20) days ("Resolution Period") through such discussions, either Party may elect to seek resolution of the Dispute as provided in Section 10.2 hereof upon failure to timely agree upon a resolution.

**10.2** Arbitration. If, in accordance with Section 11.1, the Parties have not reached a mutually acceptable resolution to the applicable Dispute following the informal dispute resolution process set forth in Section 11.1, either Party may submit such Dispute to final and binding arbitration in accordance with the Arbitration Rules of American Arbitration Association ("AAA") for the time being in force, which rules are deemed to be incorporated by reference in this clause. The arbitration shall be conducted in English and the arbitration venue shall be in the State of Delaware. The arbitrator(s) shall not have the authority or power to act as an amicable compositeur or to fashion any relief or remedy that would have the effect of modifying or amending the terms of this Agreement or creating additional rights or obligations of a Party. The decision of the arbitration tribunal shall be final and binding upon the Parties and may be enforced in any court of competent jurisdiction, and no Party shall seek redress against the other in a court or tribunal except solely for the purpose of obtaining execution of the arbitral award or of obtaining a judgment consistent with the award. Any monetary award made in arbitration shall be made and payable in U.S. Dollars. Subject to Section 11.1 and this Section 11.2, either Party may initiate litigation as outlined in Section 11.3 or seek equitable relief as outlined in Section 12.14.

**10.3** Formal Proceedings; Equitable Relief. Notwithstanding anything to the contrary in this Article 11, each Party may institute formal court proceedings at any time in order to avoid the expiration of any applicable limitations period, to preserve a position with respect to creditors, or to seek equitable relief in accordance with Section 12.14.

## 11 ARTICLE 12 – MISCELLANEOUS

**11.1** Assignment. This Agreement shall be binding on the Parties and their respective successors and permitted assigns. Except as expressly set forth in this Agreement (and subject to Section 2.9), neither Party may assign this Agreement (including by operation of law, change of control, merger, or sale of assets) without the prior written consent of the other Party; provided, however, that: (i) either Party may, without consent (a) collaterally assign, transfer or pledge its rights under this Agreement, in whole or in part, to any person for financing purposes, or (b) assign, delegate or otherwise transfer, in whole or in part, this Agreement or its rights or obligation hereunder, to an Affiliate, provided that Party shall remain responsible and liable for the performance by its Affiliate of its obligations hereunder; and (ii) either Party may, without consent, assign or otherwise transfer this Agreement in whole or in part, and its rights and obligations hereunder to any Third Party in connection with the transfer or sale of all or substantially all of its business, or in the event of its merger, consolidation, change in control or similar transaction, to or with such Third Party.

**11.2** Complete Agreement. This Agreement and the Ancillary Agreements contain the complete agreement among the Parties and supersede any prior understandings, agreements, or representations by or between the Parties, written or oral, which may have related to the subject matter hereof in any way. The Schedules and Exhibits to this Agreement shall be deemed incorporated into this Agreement by reference and shall form a part of this Agreement. The various parts of this Agreement and the Ancillary Agreements are intended to be complementary; however, unless explicitly stated otherwise in any Ancillary Agreement, any inconsistency, ambiguity, or conflict between this Agreement, its Attachments, Exhibits, and Schedules, any Ancillary Agreements and any Attachments, Exhibits, and Schedules thereto shall be resolved in the following order of precedence (with (i) having the highest priority): (i) the main body of this Agreement; (ii) Attachments, Exhibits, and Schedules to this Agreement; (iii) Ancillary Agreements; and (iv) Attachments, Exhibits, and Schedules to any Ancillary Agreement.

**11.3** Amendment/Waiver. Except as expressly set forth in this Agreement, this Agreement (including any Attachments, Exhibits and Schedules) may be amended only in a writing executed by Licensee and Company. Except as expressly set forth in this Agreement, no provision of this Agreement may be waived except in a writing executed and delivered by the Party against whom such waiver is sought to be enforced. No course of dealing between or among any Persons having any interest in this Agreement shall be deemed effective to modify, amend, waive, or discharge any part of this Agreement or any rights or obligations of any Person under or by reason of this Agreement.

**11.4** Consents and Approvals. Whenever a term of this Agreement requires agreement, consent, permission, or approval of a Party, that Party will act reasonably and in good faith and will not unreasonably withhold, delay, or condition such agreement, consent, permission, or approval, unless this Agreement expressly establishes some other standard with respect thereto, such as exercise of a Party's sole discretion or the right to withhold any of the foregoing for any reason or no reason.

**11.5** Governing Law. The internal law (and not the law of conflicts) of the State of Delaware, United States, shall govern all questions concerning the construction, validity and interpretation of this Agreement and the performance of the obligations imposed by this Agreement.

**11.6** Severability. Whenever possible, each provision of this Agreement shall be interpreted in a manner as to be effective and valid under applicable Law, but if any provision of this Agreement is held to be prohibited by or invalid under applicable Law, that provision shall be ineffective only to the extent of such prohibition or invalidity, without invalidating the remainder of provisions or the remaining provisions of this Agreement.

**11.7** Notices. All notices, demands and other communications to be given or delivered under or by reason of the provisions of this Agreement shall be in writing and shall be deemed to have been given (i) if personally delivered, on the date of delivery, (ii) if delivered by overnight courier service of national standing for next day delivery (with charges prepaid), on the business day following the date of delivery to such courier service, (iii) if deposited in the United States mail, first-class postage prepaid, on the fifth ($5^{th}$) business day following the date of such deposit, or (iv) if delivered by fax, provided the relevant transmission report indicates a full and successful transmission, (a) on the date of such transmission, if such transmission is completed at or prior to 5:00 p.m., local time of the recipient party, on the date of such transmission, and (b) on the next business day following the date of transmission, if such transmission is completed after 5:00 p.m., local time of the recipient party, on the date of such transmission. Notices, demands and communications to Company and Licensee shall, unless another address is specified in writing pursuant to the provisions of this Agreement, be sent to the following address:

Notices to Company:

***Enveric Biosciences, Inc.***
4851 Tamiami Trail N, Suite 200
Naples, FL 34103 Attention: Joseph Tucker Phone: (508) 627-0485
Email: jtucker@enveric.com

with a copy to (which shall not constitute notice to Company):

***Dickinson Wright PLLC***
1850 North Central Avenue, Suite 1400
Phoenix, Arizona 85004
Attention: Bradley J. Wyatt
Email: bwyatt@dickinsonwright.com

Notices to Licensee:

***MycoMedica Life Sciences, PBC***
50 SE Nelson Road
Shelton, WA 98584-7217
Attention: Sanjay Dubé
Phone: +1 949-992-3540
Email: sdube@mycomedica.com

with a copy to (which shall not constitute notice to Licensee):

***MycoMedica Life Sciences, PBC***
50 SE Nelson Road
Shelton, WA 98584-7217
Attention: Ryan Murphy
Phone: 415-605-4553
Email: rmurphy@mycomedica.com

Either Party may change its address(es) set forth in this Section 12.7 at any time by giving prior written notice to the other Party of such change as provided above.

**11.8** Force Majeure. Neither Party shall be held liable or responsible to the other Party or be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement (other than an obligation to make any payment) to the extent such failure or delay directly results from events beyond the reasonable control of the non-performing Party, including fires, floods, earthquakes, or other similar natural disasters or acts of God, epidemics, quarantines, war, acts of war (whether war be declared or not), terrorist acts, insurrections, riots, or civil commotion (each, a "Force Majeure Event"). The non-performing Party shall notify the other Party of a Force Majeure Event promptly (but in any event within five (5) days) after the occurrence of such Force Majeure Event by giving written notice to the other Party stating the nature of such Force Majeure Event, its anticipated duration, and any action being taken to avoid or minimize its effect. The suspension of performance shall be of no greater scope and no longer duration than is necessary and the non-performing Party shall use Commercially Reasonable Efforts to promptly remedy its inability to perform and recommence performance.

**11.9** Third Party Beneficiaries. Except as expressly stated in this Agreement or any Ancillary Agreement with respect to each Party's Affiliates and the indemnitees described in Article 9, the terms and provisions of this Agreement or any Ancillary Agreement are intended solely for the benefit of each Party and its respective successors or permitted assigns, and it is not the intention of the Parties to confer third-party beneficiary rights upon any other Person, including employees.

**11.10** Relationship of the Parties**.** In no event shall this Agreement or any Ancillary Agreement be deemed to create: (i) a partnership, joint venture, or other joint business arrangement between Licensee or any of its Affiliates, on the one hand, and Company, on the other hand; (ii) any fiduciary duty owed by a Party or any of its Affiliates to the other Party or any of its Affiliates; (iii) a relationship of employer and employee between a Party or any of its Affiliates and the other Party or any of its Affiliates; or (iv) any basis for any employee of a Party to claim that he or she is an employee of the other Party.

**11.11** Payments. All monetary amounts set forth in this Agreement or any Ancillary Agreement are in U.S. Dollars, and all payments to be made under this Agreement or any Ancillary Agreement shall be made by wire transfer of immediately available funds into an account designated by the receiving Party or otherwise pursuant to reasonable instructions set forth in the applicable invoice delivered by the receiving Party. Unless stated otherwise, all payments shall be due and payable within thirty (30) days of: (i) the applicable payment period, or payable event, or (ii) receipt of an applicable invoice. All late payments under this Agreement or any Ancillary Agreement shall bear interest from the date due until paid at a rate equal to the lesser of (i) one-half percent (0.5%) per month, and (ii) the maximum amount permitted by applicable Law. The payment of interest shall not limit the receiving Party from exercising any other right it may have as a consequence of the lateness of any payment.

**11.12** Construction. Each of Licensee and Company confirm that it and its respective counsel have reviewed, negotiated, and adopted this Agreement as the joint agreement and understanding of the Parties and the language used in this Agreement shall be deemed to be the language chosen by the Parties to express their mutual intent, and no rule of strict construction shall be applied against any Person. The captions used in this Agreement are for convenience of reference only and do not constitute a part of this Agreement and shall not be deemed to limit, characterize, or in any way affect any provision of this Agreement, and all provisions of this Agreement shall be enforced and construed as if no such caption had been used in this Agreement. Except where the context otherwise requires, wherever used, the singular shall include the plural, the plural the singular, the use of any gender shall be applicable to all genders and the word "or" is used in the inclusive sense (and/or) (for clarity, the use of the word either shall not mean "and/or"). The terms "include," "includes," and "including" as used herein are not limiting and shall be deemed to be followed (whether or not so followed) by "without limitation" so as not to limit the generality of any description preceding such term.

**11.13** Further Assurances. Each Party agrees that from time-to-time, at the request of the other Party and without further consideration, it shall execute and deliver such other documents and take such other actions as the other Party may reasonably request to effectuate the transactions contemplated by this Agreement.

**11.14** Specific Performance. The Parties agree that if any of the provisions of this Agreement are not performed in accordance with their specific terms or are otherwise breached, irreparable damage may occur, no adequate remedy at law may exist and damages would be difficult to determine, and that each Party shall be entitled to seek an injunction and/or specific performance of the terms of this Agreement, without the need to prove irreparable damage or otherwise post a bond or other security.

**11.15** Counterparts. This Agreement may be executed in one or more counterparts with the same effect as if both Parties had signed the same document, each of which shall be deemed an original, shall be construed together and shall constitute one and the same instrument. This Agreement and any signed agreement or instrument entered into in connection with this Agreement, and any amendments hereto or thereto, to the extent delivered by means of a telecopy machine or electronic mail (any such delivery, an "Electronic Delivery") shall be treated in all manner and respects as an original agreement or instrument and shall be considered to have the same binding legal effect as if it were the original signed version thereof delivered in person. At the request of any Party hereto or to any such agreement or instrument, each other Party hereto or thereto shall re-execute original forms thereof and deliver them to all other Parties. No Party hereto or to any such agreement or instrument shall raise (i) the use of Electronic Delivery to deliver a signature or (ii) the fact that any signature or agreement or instrument was transmitted or communicated through the use of Electronic Delivery, as a defense to the formation of a contract, and each such Party forever waives any such defense, except to the extent such defense relates to lack of authenticity.

**IN WITNESS WHEREOF**, the Parties (in the case of Company and Licensee, through their duly authorized representatives) have executed this Agreement in multiple counterparts as of the date and year first above written.

**ENVERIC BIOSCIENCES, INC.**

By: DocuSigned by: Joseph Tucker 248C860F46CF446...

Name: Joseph Tucker
Title: Chief Executive Officer

**MYCOMEDICA LIFE SCIENCES, PBC**

By: DocuSigned by: SDwbé CFC5A402184444C...

Name: Sanjay Dube, MD
Title: Chief Executive Officer and Chief Medical Officer

**SCHEDULE A**
**COMPANY INTELLECTUAL PROPERTY**

[***]

## SCHEDULE B

[***]

**Exhibit 21**

**SUBSIDIARIES OF ENVERIC BIOSCIENCES, INC.**

| Subsidiary | Jurisdiction of Organization |
|---|---|
| Jay Pharma Inc. | Ontario, Canada |
| 1306432 B.C. Unlimited Liability Company | British Columbia, Canada |
| 1236567 B.C. Unlimited Liability Company | British Columbia, Canada |
| Enveric Biosciences Canada, Inc. | British Columbia, Canada |
| MagicMed USA, Inc. | Massachusetts, USA |
| Akos Biosciences, Inc. | Delaware, USA |
| Enveric Therapeutics Pty. Ltd. | Adelaide, Australia |

**Exhibit 23.1**

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM'S CONSENT

We consent to the incorporation by reference in the Registration Statements of Enveric Biosciences, Inc. on Form S-1 (File No. 333-281934), Form S-3 (File No. 333-276473) and Form S-8 (File No.'s 333-269330 and 333-286066) of our report dated March 28, 2025, which includes an explanatory paragraph as to the Company's ability to continue as a going concern with respect to our audits of the consolidated financial statements of Enveric Biosciences, Inc. as of and for the years ended December 31, 2024 and 2023, which report is included in this Annual Report on Form 10-K of Enveric Biosciences, Inc. for the year ended December 31, 2024.

/s/ Marcum LLP

Marcum LLP
Morristown, New Jersey
March 28, 2025

**Exhibit 31.1**

**CERTIFICATION PURSUANT TO SARBANES–OXLEY ACT OF 2002**

I, Joseph Tucker, certify that:

1. I have reviewed this Annual Report on Form 10–K of Enveric Biosciences, Inc;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a–15(e) and 15d–15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a–15(f) and 15d–15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

March 28, 2025

By: */s/ Joseph Tucker*
Joseph Tucker, Ph.D.
Chief Executive Officer
(Principal Executive Officer)

**Exhibit 31.2**

**CERTIFICATION PURSUANT TO SARBANES–OXLEY ACT OF 2002**

I, Kevin Coveney, certify that:

1. I have reviewed this Annual Report on Form 10–K of Enveric Biosciences, Inc;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a–15(e) and 15d–15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a–15(f) and 15d–15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

March 28, 2025

By: */s/ Kevin Coveney*
Kevin Coveney
Chief Financial Officer
(Principal Financial and Accounting Officer)

**Exhibit 32**

**CERTIFICATION PURSUANT TO SECTION 906**
**OF THE SARBANES–OXLEY ACT OF 2002**

In connection with the Annual Report of Enveric Biosciences, Inc. (the "Company") on Form 10-K for the year ended December 31, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned, in the capacities and on the dates indicated below, hereby certifies pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

March 28, 2025 By: */s/ Joseph Tucker*
Joseph Tucker, Ph.D.
Chief Executive Officer
(Principal Executive Officer)

March 28, 2025 By: */s/ Kevin Coveney*
Kevin Coveney
Chief Financial Officer
(Principal Financial and Accounting Officer)