

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

FORM S-1

REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

MIRA PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Florida
(State or other jurisdiction of
incorporation or organization)

2834
(Primary Standard Industrial
Classification Code Number)

85-3354547
(I.R.S. Employer
Identification No.)

**855 N Wolfe Street, Suite 601
Baltimore, Maryland 21205
(813) 864-2562**

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

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(Name, address, including zip code, and telephone number including area code, of agent for service)

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Approximate date of commencement of proposed sale to the public: As soon as practicable after this Registration Statement becomes effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, as amended (the "Securities Act"), check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

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
Non-accelerated filer

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 7(a)(2)(B) of the Securities Act.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until this Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell, and it is not soliciting an offer to buy, these securities in any state where the offer or sale is not permitted.

Subject to completion, dated _____, 2023

PROSPECTUS

Shares of Common Stock



This is the initial public offering of _____ shares of our common stock.

Prior to this offering, there has been no public market for our common stock. It is currently estimated that the initial public offering price will be between \$ _____ and \$ _____ per share. We intend to apply to have shares of our common stock on the Nasdaq Capital Market (“Nasdaq”) under the symbol “MIRA”.

We are an “emerging growth company” as defined in the federal securities laws, and, as such, are subject to reduced public company reporting requirements. See “Prospectus Summary — Implications of Being an Emerging Growth Company.”

Investing in shares of our common stock involves risks. See “Risk Factors” beginning on page 14 to read about factors you should consider before buying shares of our common stock.

Neither the Securities and Exchange Commission (“SEC”) nor any state securities commission or other regulatory body has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

	Per Share	Total
Initial public offering price	\$ _____	\$ _____
Underwriting discounts and commissions ⁽¹⁾	\$ _____	\$ _____
Proceeds, before expenses, to us	\$ _____	\$ _____

(1) See “Underwriting” for a description of the compensation payable to the underwriters.

The underwriters have the option for a period of 45 days from the date of this prospectus to purchase up to a maximum of _____ additional shares of our common stock from us at the initial public offering price, less the underwriting discounts and commissions. If the underwriters exercise the option in full, the total underwriting discounts and commissions payable by us will be \$ _____, and the total proceeds, before expenses, to us will be \$ _____.

The underwriters expect to deliver the shares to investors on or about _____, 2023.

KINGSWOOD

division of Kingswood Capital Partners, LLC

The date of this prospectus is _____, 2023

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Please read this prospectus carefully. It describes our business, financial condition, results of operations and prospects, among other things. We are responsible for the information contained in this prospectus and in any free-writing prospectus we have authorized. Neither we nor the underwriters have authorized anyone to provide you with different information, and neither we nor the underwriters take responsibility for any other information others may give you. Neither we nor the underwriters are making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. The information contained in this prospectus is accurate only as of the date on the front of this prospectus, regardless of the time of delivery of this prospectus or any sale of securities. You should not assume that the information contained in this prospectus is accurate as of any date other than its date.

INDUSTRY AND MARKET DATA

We are responsible for the disclosure in this prospectus. However, this prospectus includes industry data that we obtained from internal surveys, market research, publicly available information, and industry publications. We did not fund and are not otherwise affiliated with any of the sources cited in this prospectus. The market research, publicly available information, and industry publications that we use generally state that the information contained therein has been obtained from sources believed to be reliable. The information therein represents the most recently available data from the relevant sources and publications, and we believe remains reliable. However, this data involves a number of assumptions and limitations regarding our industry which are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in the section titled “*Risk Factors*.” Forward-looking information obtained from these sources is also subject to the same qualifications and additional uncertainties regarding the other forward-looking statements in this prospectus.

TRADEMARKS AND COPYRIGHTS

We own or have rights to various trademarks, service marks and trade names that we use in connection with the operation of our business. This prospectus may also contain trademarks, service marks and trade names of third parties, which are the property of their respective owners. Our use or display of third parties’ trademarks, service marks and trade names or products in this prospectus is not intended to, and does not imply a relationship with, or endorsement or sponsorship by us. Solely for convenience, the trademarks, service marks and trade names referred to in this prospectus may appear without the ®, trademark (™) or servicemark (SM) symbols, but the omission of such references is not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the right of the applicable owner of these trademarks, service marks and trade names.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements. In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “contemplate,” “believe,” “estimate,” “predict,” “potential”, or “continue” or the negative of these terms or other similar expressions. In particular, statements about the markets in which we operate, including growth of our various markets, and our expectations, beliefs, plans, strategies, objectives, prospects, assumptions, or future events or performance contained in this prospectus under the headings “Prospectus Summary,” “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Business” are forward-looking statements.

We have based these forward-looking statements on our current expectations, assumptions, estimates and projections. While we believe these expectations, assumptions, estimates, and projections are reasonable, such forward-looking statements are only predictions and involve known and unknown risks and uncertainties, many of which are beyond our control. These and other important factors, including those discussed in this prospectus under the headings “Prospectus Summary,” “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Business,” may cause our actual results, performance, or achievements to differ materially from any future results, performance or achievements expressed or implied by these forward-looking statements, or could affect our share price. Important factors that could cause actual results or events to differ materially from those expressed in forward-looking statements include, but are not limited to, the following:

- our use of the net proceeds from this offering;
- our ability to obtain and maintain regulatory approval of our product candidates;
- our ability to successfully commercialize and market our product candidates, if approved;
- our ability to contract with third-party suppliers, manufacturers and other service providers and their ability to perform adequately;
- the potential market size, opportunity, and growth potential for our product candidates, if approved;
- our ability to obtain additional funding for our operations and development activities;
- the accuracy of our estimates regarding expenses, capital requirements and needs for additional financing;
- the initiation, timing, progress and results of our pre-clinical studies and clinical trials, and our research and development programs;

- the timing of anticipated regulatory filings;
- the timing of availability of data from our clinical trials;

- our future expenses, capital requirements, need for additional financing, and the period over which we believe that the net proceeds from this offering, together with our existing cash and cash equivalents, will be sufficient to fund our operating expenses and capital expenditure requirements;
- our ability to retain the continued service of our key professionals and to identify, hire and retain additional qualified professionals;
- our ability to advance product candidates into, and successfully complete, clinical trials;
- our ability to recruit and enroll suitable patients in our clinical trials;
- the timing or likelihood of the accomplishment of various scientific, clinical, regulatory, and other product development objectives;
- the pricing and reimbursement of our product candidates, if approved;
- the rate and degree of market acceptance of our product candidates, if approved;
- the implementation of our business model and strategic plans for our business, product candidates, and technology;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and technology;
- developments relating to our competitors and our industry;
- the development of major public health concerns, including the novel coronavirus outbreak or other pandemics arising globally, and the future impact of it and COVID-19 on our clinical trials, business operations and funding requirements; and
- other risks and factors listed under “Risk Factors” and elsewhere in this prospectus.

Given the risks and uncertainties set forth in this prospectus, you are cautioned not to place undue reliance on such forward-looking statements. The forward-looking statements contained in this prospectus are not guarantees of future performance and our actual results of operations, financial condition, and liquidity, and the development of the industry in which we operate, may differ materially from the forward-looking statements contained in this prospectus. In addition, even if our results of operations, financial condition and liquidity, and events in the industry in which we operate, are consistent with the forward-looking statements contained in this prospectus, they may not be predictive of results or developments in future periods.

Any forward-looking statement that we make in this prospectus speaks only as of the date of such statement. Except as required by federal securities laws, we do not undertake any obligation to update or revise, or to publicly announce any update or revision to, any of the forward-looking statements, whether as a result of new information, future events or otherwise, after the date of this prospectus.

GLOSSARY OF CERTAIN SCIENTIFIC TERMS

The medical and scientific terms used in this prospectus have the following meanings:

“API” stands for Active Pharmaceutical Ingredient, which is the main ingredient in a medicine that causes the desired effect of the medicine.

“Agonist” is a substance which initiates a physiological response when combined with a receptor.

“AMES test” is a biological assay to assess the mutagenic potential of chemical compounds. It utilizes bacteria to test whether a given chemical can cause mutations in the DNA of the test organism.

“Biosensor assay” is a biological assay used for the detection of a chemical substance that combines a biological component with a physicochemical detector.

“CDMO” stands for Contract Development and Manufacturing Organization, a specialized type of supplier of development and production services to the pharmaceutical industry.

“cGMP” is the current Good Manufacturing Practices under the US Food and Drug Administration’s standards. cGMP contains the minimum requirements for the methods, facilities, and controls used in the manufacturing, processing, and packing of a drug product. The regulations make sure that a product is manufactured under conditions and tested to ensure that it meets standards of identity, strength, quality, and purity .

“CNS” or the central nervous system is the brain and spinal cord.

“CSA” is the Controlled Substances Act, a U.S. regulatory framework that governs the classification of certain substances, and therefore the market access available to such substances; based on the CSA, the Drug Enforcement Agency (DEA) determines if a compound should be considered “Scheduled” or not. There are 5 levels of scheduling with certain substances such as marijuana categorized as Schedule 1, with no currently acceptable medical use or high potential for abuse.

“DNA” is the molecule that carries genetic information for the development and functioning of an organism.

“FDA” is the U.S. Food and Drug Administration.

“GPCRs” are G-protein-coupled receptors that form a large group of proteins which are expressed on the cell surface of eukaryotic cells to detect molecules outside the cell and activate cellular responses.

“GMP” is good manufacturing practice - a standard that is observed in regulated pharmaceutical-manufacturing facilities.

“Intraperitoneal” is within or through a thin, transparent membrane that lines the walls of the abdomen.

“Maximum tolerated dose” is the highest dose of a drug or treatment that does not cause unacceptable side effects. The maximum tolerated dose is determined in clinical trials by testing increasing doses on different subjects until the highest dose with acceptable side effects is found.

“Metabolic Profiling” is the measurement in biological systems of metabolites and their intermediates that reflects the dynamic response to genetic modification and physiological, pathophysiological, and/or developmental stimuli.

“Metabolite” is a substance made or used when the body breaks down food, drugs or chemicals, or its own tissue

“Micronucleus Assay” is used to determine if a compound causes DNA damage.

“Neuroinflammation” is the inflammation of nervous system.

PROSPECTUS SUMMARY

The following summary highlights selected information about our company and this offering that is included elsewhere in this prospectus in greater detail. It does not contain all of the information that you should consider before investing in our common stock. Before investing in our common stock, you should read this entire prospectus carefully, including the information presented under the heading “Risk Factors” and in our financial statements and notes thereto.

In this prospectus, unless we indicate otherwise or the context requires, “MIRA,” “the company,” “our company,” “we,” “our,” “ours” and “us” refer to MIRA Pharmaceuticals, Inc.

Business Summary

We are an early pre-clinical -stage pharmaceutical company focused on the development and commercialization of a new molecular synthetic cannabinoid analog under investigation for the treatment of adult patients with anxiety and cognitive decline typically associated with early-stage dementia. Our target patient population is also typically presenting with chronic pain. Our drug candidate, MIRA1a, if approved by the FDA, may be a significant advancement in the treatment of neuropsychiatric, inflammatory, and neurologic diseases and disorders. Based on pre-clinical and animal studies conducted by us, we believe that MIRA1a enhances the therapeutic potential for treating anxiety, cognitive decline and chronic pain by potentially striking a balance between the beneficial effects of THC and CBD. MIRA1a achieves this by selectively targeting the cannabinoid type 1 (“CB1”) and cannabinoid type 2 (“CB2”) receptors. Cannabinoid receptors, located throughout the body, are part of the endocannabinoid system, which is involved in a variety of physiological processes and responses including appetite, pain-sensation, mood, and memory. With respect to THC, our pre-clinical studies have shown that MIRA1a may have less potency at CB1 but maintains high activation at CB2. Since CB1 activation corresponds to intoxication, we believe that MIRA1a is potentially less intoxicating than THC while still providing beneficial therapeutic effects. In addition, by curbing the negative effects of THC (e.g. cognitive impairment), studies suggest that MIRA1a may be capable of unmasking positive therapeutic effects not previously seen with THC (e.g. cognitive performance enhancement).

Our Product Candidate in Development

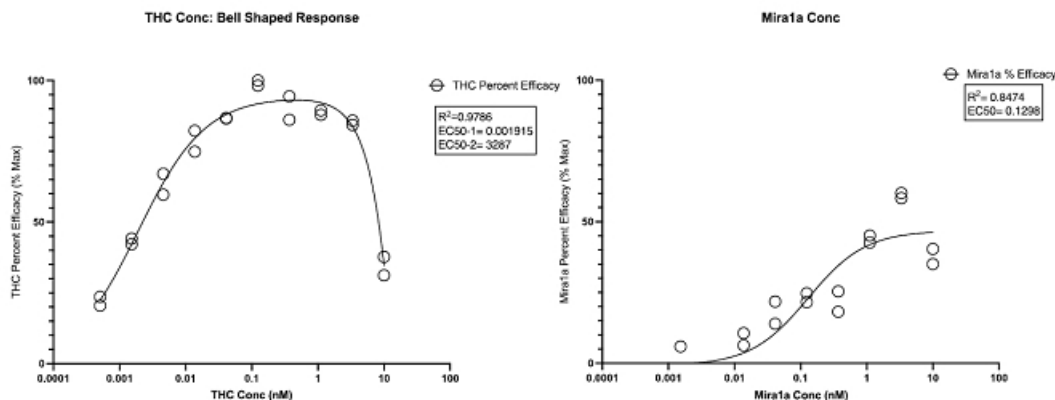
Our objective is to develop and commercialize new treatment options for neuropsychiatric, inflammatory, neurologic, and oncologic diseases and disorders. Cannabinoids are a class of chemical compounds that are naturally occurring and are primarily found in cannabis plant extracts. The two major cannabinoids found in cannabis plant extracts include THC and CBD. These compounds bind to CB1 and CB2 cannabinoid receptors, which are found throughout the body. Specifically, CB1 receptors are concentrated in the central nervous system (“CNS”), while CB2 receptors are found mostly in peripheral organs and are associated with the immune system. When the chemical compounds bind to these cannabinoid receptors, the process elicits certain physiological responses. Physiological responses to cannabinoids may vary among individuals. Some of the effects of cannabinoids have been shown to impact nervous system functions, immune responses, muscular motor functions, gastrointestinal maintenance, blood sugar management, and the integrity of ocular functions. Our product candidate, MIRA1a, has a strong selectivity for CB2 versus CB1, and is designed to minimize the risk of psychoactive adverse events associated with CB1 activation. On November 28, 2022, the U.S. Drug Enforcement Agency, or DEA, confirmed in writing that it conducted a scientific review of the chemical structure of MIRA1a in accordance with the definitions within the CSA and its implementing regulations and determined that MIRA1a is not a controlled substance or listed chemical.

Mechanism of Action of MIRA1a

We believe that the effects of MIRA1a at the cannabinoid receptors CB1 and CB2 is predicted to account for the majority of its potential therapeutic effects, especially as it relates to its anti-anxiety, anti-pain and anti-inflammatory properties. For example, the difference in the dose-response effects of MIRA1a compared with THC on CB1 receptors appears to coincide with its improved therapeutic profile.

THC is notorious for having biphasic physiological effects, which have been described for over 40 years: at low levels THC has positive effects while high doses cause the opposite, undesirable symptoms. Examples of biphasic effects at low versus high levels of THC include the anti-anxiety versus pro-anxiety effects, respectively. We obtained the following dose-response effects for MIRA1a and THC at the CB1 receptor (see below). In contrast to THC, which displays an initial maximally stimulatory and then inhibitory response at CB1, MIRA1a appears to act as a monophasic partial agonist where it is stimulatory throughout its dose range, achieving a moderate activation of the CB1 even at high doses. We believe that this accounts for the potential broad therapeutic efficacy of MIRA1a and the observed absence of negative symptoms even at maximal doses of the drug.

1



Unlike CB1 receptors, that mediate many of the psychotropic effects of cannabinoids on the CNS, CB2 receptors are present on cells of the immune system. Based on preliminary results of our GPCR biosensor assays, the agonist effects of MIRA1a on CB2 receptors are 8-fold more potent than THC and 30-fold more potent than

CBD, which predicts that MIRA1a is likely much more efficacious as a potential therapeutic for inflammatory, autoimmune, and neurodegenerative conditions.

Pre-Clinical Developments and Studies

As of the end of fiscal 2022, we completed several pre-clinical studies of MIRA1a, including, but not limited to, computational mutagenicity analysis, radio-ligand binding assay, elevated plus maze (“EPM”) model of anxiety and hot plate model thermal sensitivity testing.

We have studied the effects of acute administration of MIRA1a on anxiety-related phenotypes in mice to model human conditions. An intraperitoneal injection of Placebo [PBO] (e.g. saline) or MIRA1a (e.g. 50mg/kg = Treatment) was administered to 8-12 week-old C57Bl/6 mice (n=5/group). Thirty minutes following injection, mice were tested in anxiety related measures using the Elevated Plus Maze (EPM). The EPM is a widely used pre-clinical behavioral assay for rodents and it has been validated to assess the anti-anxiety effects of pharmacological agents. We found that MIRA1a has potent anti-anxiety at doses that lacked side effects of sedation or intoxication. The EPM is a test measuring anxiety in rodents as a screening test for putative anxiolytic compounds and as a general research tool in neurobiological anxiety research such as Generalized Anxiety Disorder (GAD) or Post-Traumatic Stress Disorder (PTSD). The model is based on the animal’s aversion to open spaces which are present in the open arms (Open Arm) of the maze. Anti-anxiety effects of test agents are demonstrated by an increase in the percentage of time spent in the Open Arm with treatment compared to placebo. The total distance traveled is a measure of the overall level of arousal and mobility of the mice undergoing testing on the EPM and is used to rule out any sedating or intoxicating effects of the test agent.

Pre-clinical studies also have shown MIRA1a’s potential for relieving pain. A number of clinically approved pharmacological agents used to treat pain, including opioids, have been demonstrated to delay or ameliorate the onset of heat sensitivity upon paw exposure of mice to heat. Thirty minutes after treatment with either a placebo (control) or MIRA1a, mice were placed on a heated plate to measure the time it took for each mouse to lift its paw in response to the mild pain they felt from the heat. Mice treated with pain alleviating drugs took significantly longer to become bothered by the heat and to lift their paws. Similarly, mice treated with MIRA1a took statistically significantly more time to lift their legs, indicating MIRA1a’s potential effectiveness as a possible treatment for pain in this model.

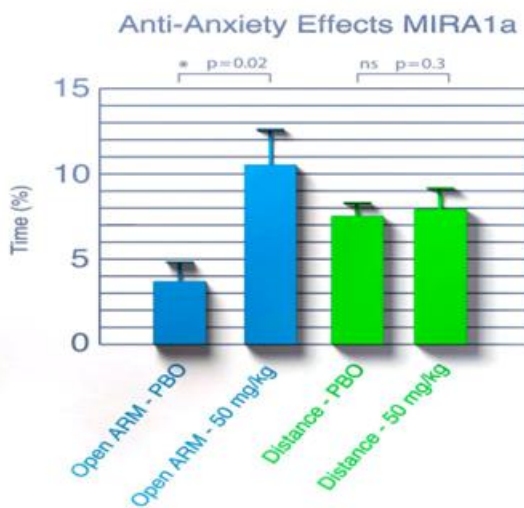
MIRA1a is a CB2 agonist which may be an optimal treatment for neurodegenerative diseases associated with neuroinflammation caused by microglial activation. CB2 agonism has been shown in pre-clinical studies to regulate neuroinflammatory processes, reducing the neuronal damage characteristic of degeneration. We believe there may be a strong rationale for CB2 agonism in neurodegenerative diseases, given increased CB2 expression in patients with these diseases as well as preliminary results from animal models. We see potential for a potent CB2 agonist to treat a range of neurodegenerative diseases. MIRA1a, through its robust activity at CB2 compared to CB1, was designed to minimize the risk of psychotropic adverse events associated with CB1 activation.

Our pre-clinical development program for MIRA1a has included a variety of testing. Summarized below are the tests we have completed.

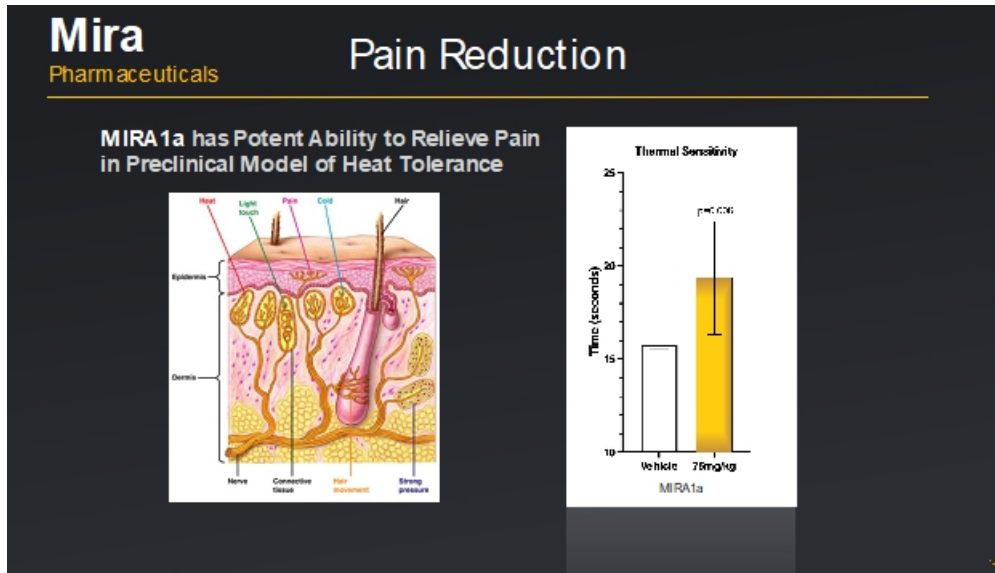
Table: Pre-clinical Tests

Status	Completed Tests
Group 1	<ul style="list-style-type: none"> ● Computational Mutagenicity Analysis ● Radioligand Binding ● EPM model of anxiety ● Thermal Sensitivity Model of Pain ● Trace Fear Conditioning Model of Cognition ● Rat Psychomotor Vigilance Test (“PVT”) of Cognition
Group 2	<ul style="list-style-type: none"> ● Insilico ICH7/M7 ● Micronucleus Assay ● AMES Test ● Metabolic Profiling ● Safety Screen 44

- EPM Model of Anxiety Test:
 - Method: We studied the effect of acute administration of MIRA1a on anxiety-related phenotypes in mice to model human conditions.
 - An intraperitoneal (i.p.) injection of Placebo (e.g. saline) or MIRA1a (e.g. 50mg/kg = Treatment) was administered to 8-12 week-old C57Bl/6 mice (n=5/group)
 - 30 minutes following injection, mice were tested in anxiety related measures using EPM
 - Outcome: The following chart demonstrates MIRA1a’s anti-anxiety effects:

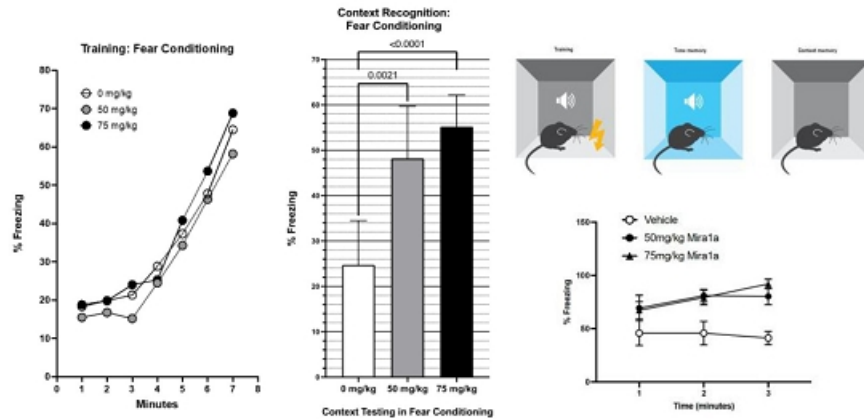


- Thermal Sensitivity Model of Pain:
 - Method: We studied the potential for pain reduction in pre-clinical models of heat tolerance using a hot plate methodology.
 - Outcome: MIRA1a provided significantly delayed thermal sensitivity and enhanced pain tolerance.

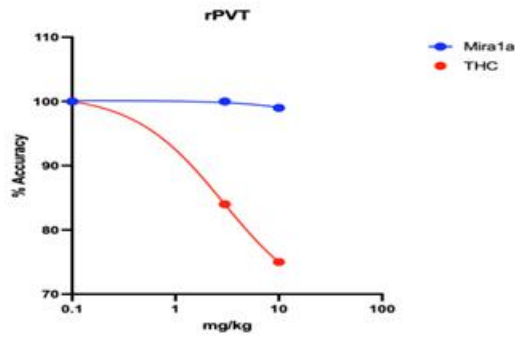


- Trace Fear Conditioning Model of Cognition:
 - Method: We studied the potential for improving recall in healthy mice using a fear conditioning model.
 - Outcome: MIRA1a sharply improves cognitive recall as dosage rises.

Cognition in Mouse Model of Fear Conditioning



- Rat PVT of Cognition
 - Method: We performed a PVT to evaluate simple reaction time.
 - Outcome: MIRA1a does not impair cognition. At 3 mg/kg and 10 mg/kg MIRA1a causes minimal impairment in rat PVT whereas THC has a clear negative effect even at these low doses.



In 2023, our pre-clinical work will include the conduct of several other pre-clinical studies and initiation of a 7-day maximum tolerated dose study of MIRA1a in rats and dogs.

Status	Planned Activity
Drug Substance Preparation	<ul style="list-style-type: none"> Analytical Development NonGMP Production Refinement GMP Production Refinement
Testing	<ul style="list-style-type: none"> MTD/7D DRF Dog MTD/7D DRF Rat Dog 28-day Toxicology Rat 28-day Toxicology Cardiovascular Study Dog (Telemetry) Respiratory Study Rat hERG (Manual Patch-Clamp) Neurobehavioral Evaluation Rats Neurobehavioral Evaluation Mice

We further plan on neurobehavioral evaluation of orally and intraperitoneal administered MIRA1a in rats and mice, respiratory evaluation of orally administered MIRA1a in rats, and *in vitro* testing for effects of MIRA1a on hERG (the human Ether-à-go-go-Related Gene) channel currents. The hERG is an early *in vitro* assay required by the FDA to alert companies of any potential cardiac abnormalities by the product before proceeding with dose studies in humans. hERG is a gene that codes for a protein known as the alpha subunit of a potassium ion channel. This ion channel (sometimes simply denoted as 'hERG') is best known for its contribution to the electrical activity of the heart: the hERG channel mediates the repolarizing current in the cardiac action potential, which helps coordinate the heart's beating. When this channel's ability to conduct electrical current across the cell membrane is inhibited or compromised, either by application of drugs or by rare mutations in some individuals, it can result in a potentially fatal disorder called long QT syndrome.

Testing is anticipated to conclude in the first quarter of 2024. Additionally, a 28-day toxicology analysis for dogs and rats is expected to begin at the end of the fourth quarter of 2023 and continue through the first quarter of 2024.

We have started the analytical development and manufacturing of MIRA1a as of January 2023. By the third quarter of 2023, we anticipate our suppliers will be developing MIRA1a at scale and manufactured under cGMP conditions, expanding on earlier non-GMP volumes of MIRA1a for use in our initial testing programs. We plan to work closely with our suppliers to generate sufficient volumes of cGMP-grade MIRA1a materials for the planned pre-clinical toxicity programs, expanded animal testing and human trials expected to be performed in 2024, subject to FDA approval.

Our Clinical Development Program

Following the pre-clinical development plan outlined above, we plan to submit to the FDA an Investigational New Drug application (“IND”) focused on investigating MIRA1a for the treatment of anxiety and cognitive decline in elderly patients.

Our first IND application submission investigating MIRA1a for the treatment of elderly patients suffering from anxiety with some cognitive decline is currently planned for the end of the second quarter of 2024, as we believe this is a patient population with unmet needs. If allowed to proceed by the FDA, a Phase I trial will be initiated 30 days post-IND submission. After the Phase I trial is complete, a Phase II trial in this same study subject population is planned to commence by the end of the fourth quarter of 2024. We believe that an overlapping (hybrid) Phase I and Phase II can be designed and allowed to proceed by the FDA, allowing us to accelerate the development of MIRA1a.

Our second IND application will focus on investigating MIRA1a for the treatment of chronic pain and is planned for submission during the third quarter of 2025. A Phase II trial will begin in the third quarter of 2026.

All development plans depend on FDA acceptance of our IND applications. As appropriate and pursuant to discussions with the FDA, we may periodically adjust the timeline for certain filings and associated clinical trials. It is important to note that the process for conducting clinical trials is uncertain and there is no assurance that our clinical development activities will meet the planned timelines set forth above.

Manufacture of Product for Clinical Development Activities

Curia Global (formerly AMRI), a leading global CDMO, is currently developing a large-scale synthesis protocol for us and will be supplying quantities of MIRA1a needed for our pre-clinical and clinical development activities. We are currently in discussions with other partners to have MIRA1a formulated into solid oral dosage forms for clinical trials.

Market Opportunity

MIRA1a, if approved by FDA, will compete in 3 key overlapping growth markets: the anxiety, cognitive decline (dementia), and chronic pain markets where multiple products with varying safety and efficacy profiles are already on the market. MIRA1a competes at the intersection of these three markets given the target patient profile previously outlined.

According to IQVIA's Global Use of Medicines 2023 analysis (the "IQVIA Report"), the global market for medicines is expected to grow to \$1.9 trillion by 2027, driven by a variety of factors including the launch of new medicines, an expansion in specialized medicines and biosimilars. Our key competitive market, the US market, is expected to grow between one and two percent on a net price basis to \$763 billion by 2027 due to a variety of variables including the impact of loss of exclusivity, biosimilars, and discounting associated with the Inflation Reduction Act.

MIRA1a will compete primarily within the central nervous system ("CNS") market that encapsulates anxiety, dementia, other pain, Alzheimer's, migraines and related conditions. The IQVIA Report estimates that by 2027, the global CNS market will be worth \$81 billion, growing between two and five percent during the period from 2023 to 2027. Within that market opportunity, anxiety is worth between approximately \$20 billion and \$25 billion in annual sales.

Anxiety and pain are expected to grow approximately five percent over the same period, while Alzheimer is expected to grow approximately twelve percent. This is critical given MIRA1a's focus on early-stage patients with dementia, as, according to IQVIA's Global Use of Medicines 2023 analysis (the "IQVIA Report"), approximately 10 million new cases of dementia emerge globally each year, with Alzheimer's disease as the leading cause. Thus, Alzheimer's case directions are an important signal and gateway for MIRA1a-related opportunities.

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MIRA1a's other key market will be the traditional pain market, which the IQVIA Report estimates will be worth \$42 billion in 2027 and grow between three and six percent during the forecast period. Note that this sizing is inclusive of chronic and acute pain, and MIRA1a is likely to only be used in the chronic segment of the market (approximately 40% to 50% of the market). Factors such as a rise in oncology related pain, diabetic neuropathy, and pain associated with aging (e.g. joint pain) are among the key drivers of patient and prescription growth. We believe that MIRA1a's expected safety and toxicity profile should provide it with an edge over existing medicines categories such as opioids, allowing it to gain share in that market as well. Given the overlap across indications and the fact that the target patient is presenting across these markets, MIRA1a will be competing in a complex market valued by the IQVIA Report at over an estimated \$120 billion globally per annum.

Thus, our initial focus will be a dual path: potentially winning in traditional markets as well as the marijuana analog markets using a safe, effective and FDA-approved treatment option. Today, legal medical marijuana is a \$13.2 billion industry whereas legal recreational marijuana is a \$25.6 billion industry. Both are sub-sets of the traditional pain and anxiety markets. However, in many patient populations, non-US legal, and cultural settings, marijuana may not be the first or a viable option for treatment of neurological disorders. As a result, these patients will typically use non-steroidal anti-inflammatory drugs (NSAIDs) or various mood management drugs, opening them up to a range of non-ideal outcomes. MIRA1a's objective is to offer physicians and patients with an approved, viable synthetic option. Thus, if approved by the FDA, we believe that MIRA1a may potentially provide a preferred alternative in such patient populations, as it is not derived from the marijuana plant.

Our Strategy

Our goal is to develop therapeutics targeting well-characterized CB1 and CB2 receptors with optimized pharmacological properties to transform the lives of patients with neurological and oncologic diseases. Key elements of our strategy to achieve this goal include:

- Advance our MIRA1a through clinical development and approval.
- Continue pre-clinical development of MIRA1a across a range of CNS diseases associated with neurodegeneration and progress into clinical development.
- Identify additional product candidates and expand our current candidate into additional neurological diseases.
- Explore strategic collaborations to maximize the value of our product candidates.

Intellectual Property

Our company owns U.S. Patent 10,787,675 B2, titled "Purified Synthetic Marijuana and Methods of Treatment by Administering Same," which covers the MIRA1a compound *per se* as a racemic mixture, an isolated R-enantiomer, or an isolated S-enantiomer, as well as pharmaceutical formulations of the compound. This patent also covers MIRA1a in methods of treating Alzheimer's disease, anxiety, depression, and addictions.

Foreign patents covering MIRA1a and its therapeutic uses have issued in Australia, Belgium, Canada, Czech Republic, France, Germany, Greece, Netherlands, Hungary, Ireland, Israel, Italy, Malta, Poland, Portugal, Romania, South Korea, Spain, Sweden, and the United Kingdom, and corresponding applications are pending in China and Japan. MyMD Pharmaceuticals, Inc. (NASDAQ: MYMD, "MyMD"), a publicly traded New Jersey corporation, currently owns these foreign patents and patent applications. Although we currently have no plans to develop the MIRA1a compound for approval and commercialization outside of the United States, we have a perpetual license from MyMD to use MyMD's Supera-CBD™ as a synthetic intermediate in the manufacture of MIRA1a for research and development activities and has the rights for commercial uses in the United States and in jurisdictions outside of those mentioned above in which MyMD holds foreign patent rights to MIRA1a. Except for this license, we do not license any patent rights or other intellectual property for MIRA1a from third parties.

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Implications of Being an Emerging Growth Company

As a company with less than \$1.235 billion in annual gross revenue during our last fiscal year, we qualify as an "emerging growth company" as defined in Section 2(a) of the Securities Act. An emerging growth company may take advantage of specified reduced reporting and other requirements that are otherwise applicable generally to public companies. These provisions include:

- we are required to present only two years of audited financial statements and related management's discussion and analysis of financial condition and results of operations in the registration statement of which this prospectus is a part;
- we are exempt from compliance with the requirement that our independent registered public accounting firm provide an attestation report on the effectiveness of our internal control over financial reporting;
- we are exempt from compliance with any requirement that the Public Company Accounting Oversight Board (the "PCAOB") has adopted regarding communication of critical accounting matters and may adopt regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- we are exempt from the "say on pay," "say when on pay," and "say on golden parachute" non-binding advisory vote requirements; and

- we can provide reduced disclosures about our executive compensation arrangements.

We currently intend to take advantage of each of the exemptions described above. It is possible, therefore, that some investors will find our common stock less attractive, which may result in a less active trading market for our common stock and higher volatility in our stock price.

We may take advantage of these provisions until the last day of our fiscal year following the fifth anniversary of the completion of this offering or such an earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company upon the earliest of: (i) the last day of the first fiscal year in which our annual gross revenues are \$1.235 billion or more; (ii) the date on which we have, during the previous three-year period, issued more than \$1 billion in non-convertible debt securities; or (iii) the date on which we are deemed to be a “large accelerated filer,” which will occur as of the end of any fiscal year in which we (x) have an aggregate market value of our common stock held by non-affiliates of \$700 million or more as of the last business day of our most recently completed second fiscal quarter, (y) have been required to file annual and quarterly reports under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), for a period of at least 12 months and (z) have filed at least one annual report pursuant to the Exchange Act.

In addition, emerging growth companies may take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. In other words, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We intend to take advantage of the benefits of this extended transition period. For risks related to our status as an emerging growth company, see “Risk Factors — Risks Related to Ownership of Our Common Stock — Taking advantage of the reduced disclosure requirements applicable to “emerging growth companies” may make our common stock less attractive to investors.”

Implications of Being a Smaller Reporting Company

We are a “smaller reporting company” as defined in Item 10(f)(1) of Regulation S-K. Smaller reporting companies may take advantage of certain reduced disclosure obligations, including, among other things, providing only two years of audited financial statements. We will remain a smaller reporting company until the last day of any fiscal year for so long as either: (i) the market value of our shares of common stock held by non-affiliates does not equal or exceed \$250 million as of the prior June 30th; or (ii) our annual revenues did not equal or exceed \$100 million during such completed fiscal year. To the extent we take advantage of such reduced disclosure obligations, it may also make comparison of our financial statements with other public companies difficult or impossible.

Corporate Information

MIRA Pharmaceuticals, Inc. is the registrant and the issuer of the common stock being sold in this offering. Our corporate headquarters is located at 855 N Wolfe Street, Suite 601, Baltimore, Maryland 21205. Our telephone number is 813-864-2562.

Our principal website address is www.mirapharmaceuticals.com. The information contained on, or that can be accessed through, our website is deemed not to be incorporated in this prospectus or to be part of this prospectus. You should not consider information contained on our website to be part of this prospectus.

This prospectus includes trademarks, trade names and service marks owned by us. This prospectus also contains trademarks, trade names and service marks of other companies, which are the property of their respective owners. Solely for convenience, trademarks, trade names and service marks referred to in this prospectus may appear without the ®, trademark (TM), or servicemark (SM) symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights to these trademarks, trade names, and service marks. We do not intend our use or display of other parties’ trademarks, trade names, or service marks to imply, and such use or display should not be construed to imply a relationship with, or endorsement or sponsorship of us by, these other parties.

The Offering

Common stock offered by us	_____ shares.
Shares of common stock outstanding before this offering	_____ shares.
Shares of common stock to be outstanding after this offering	_____ shares (or _____ shares if the representative exercises its option to purchase additional shares from us in full).
Use of proceeds	We estimate that we will receive net proceeds from the sale of shares of our common stock in this offering of approximately \$ _____ million, assuming an initial public offering price of \$ _____ per share (the midpoint of the range set forth on the cover of this prospectus), and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We intend to use the net proceeds from this offering to advance the clinical development of our programs, to fund our research and development activities, and for working capital and general corporate purposes. Our management will have broad discretion in the application of the net proceeds from this offering and investors will be relying on the judgment of our management regarding the application of the proceeds. See “Use of Proceeds.”
Lock up	Our directors, officers, and shareholders who beneficially own 3% or more of the outstanding shares of our common stock have agreed with the underwriters not to offer for sale, issue, sell, contract to sell, pledge or otherwise dispose of any of our common stock or securities convertible into common stock for a period of 180 days, commencing on the date of this prospectus, except with the prior written consent of the underwriters.
Representative’s warrants	We have agreed to issue to the representative of the underwriters or its designees at the closing of this offering, warrants to purchase the number of shares of our common stock equal to 5.0% of the aggregate number of shares sold in this offering (the “Representative’s Warrants”). The Representative’s Warrants will be exercisable at any time and from time to time, in whole or in part, during the four-and-a-half-year period commencing six months after the commencement of sales in this offering. The exercise price of the Representative’s Warrants will equal 100% of the initial public offering price per share, subject to adjustments.
Risk factors	Investing in our common stock involves a high degree of risk. See “Risk Factors” beginning on page 14 of this prospectus for a discussion of factors you should carefully consider before investing in our common stock.

The number of shares of our common stock that will be outstanding immediately after this offering is based on _____ shares of our common stock outstanding as of _____, 2023.

The number of shares of our common stock to be outstanding after this offering excludes:

- _____ shares of our common stock issuable upon the exercise of stock options outstanding as of _____, 2023, under our 2022 Omnibus Incentive Plan (the “2022 Omnibus Plan”) at a weighted-average exercise price of \$1.00 per share;
- _____ shares of our common stock reserved for future issuance under the 2022 Omnibus Plan, as well as any automatic increases in the number of shares of common stock reserved for future issuance under the plan; and
- _____ shares of our common stock issuable to a consultant upon the completion of this offering pursuant to consulting agreement entered into in May 2023.

Unless the context otherwise requires, the information in this prospectus:

- assumes that the shares of our common stock to be sold in this offering are sold at \$ _____ per share (the midpoint of the range set forth on the cover of this prospectus);
- assumes that all shares of our common stock offered hereby are sold; and
- assumes no exercise by the representative of its option to purchase additional shares.

Summary Financial Data

The following tables summarize our financial and other data. We have derived the summary statements of operations data for the years ended December 31, 2022 and 2021, and the balance sheet data as of December 31, 2022 and 2021, from our audited financial statements included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results that may be expected in the future.

The following summary financial and other data should be read in conjunction with the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our audited financial statements and related notes included elsewhere in this prospectus.

Statement of Operations:

	Year ended December 31,	
	2022	2021
Revenues	\$ -	\$ -
Operating costs:		
General and administrative expenses	2,992,125	770,115
Related party travel costs	1,704,350	697,600
Research and development expenses	2,351,465	684,447
Total operating costs	<u>7,047,940</u>	<u>2,152,162</u>
Interest expense	(10,250)	(24,374)
Net loss	<u>\$ (7,058,190)</u>	<u>\$ (2,176,536)</u>

Balance Sheets:

	December 31,	December 31,
	2022	2021
ASSETS		
Current assets:		
Cash	\$ 350,978	\$ 2,809,552
Deferred offering costs	143,427	100,000
Total current assets	<u>494,405</u>	<u>2,909,552</u>
Operating lease, right of use assets	164,910	-
Related party operating lease, right of use assets	198,759	-
Advances to affiliates	-	445,612
Total assets	<u>\$ 858,074</u>	<u>\$ 3,355,164</u>
LIABILITIES AND STOCKHOLDERS’ (DEFICIT) EQUITY		
Current liabilities:		
Trade accounts payable and accrued liabilities	\$ 811,738	\$ 228,406
Related party accounts payable	116,350	547,600
Related party line of credit	133,062	293,062
Related party accrued interest	34,987	24,738
Current portion of operating lease liabilities	75,143	-
Related party current portion of operating lease liabilities	198,759	-
Total current liabilities	<u>1,370,039</u>	<u>1,093,806</u>

Non-current operating lease liabilities	84,267	-
Total liabilities	1,454,306	1,093,806
Stockholders' (Deficit) Equity		
Preferred Stock, \$0.0001 par value, 5,000,000 shares authorized and none issued or outstanding	-	-
Common Stock, \$0.0001 par value; 95,000,000 shares authorized, 66,565,000 and 63,369,000 issued and outstanding at December 31, 2022 and December 31, 2021, respectively	6,657	6,337
Additional paid-in capital	8,699,830	4,499,550
Accumulated deficit	(9,302,719)	(2,244,529)
Total stockholders' (deficit) equity	(596,232)	2,261,358
Total liabilities and stockholders' (deficit) equity	\$ 858,074	\$ 3,355,164

RISK FACTOR SUMMARY

There are a number of risks that you should understand before making an investment decision regarding this offering. These risks are discussed more fully in the section entitled "Risk Factors" following this prospectus summary. If any of these risks actually occur, our business, financial condition, or results of operations would likely be materially and adversely affected. In such a case, the trading price of our common stock would likely decline, and you may lose all or part of your investment. These risks include, but are not limited to:

- We are development-stage company that has no revenues and has incurred losses since our inception. We expect to incur losses for the foreseeable future and may never achieve or maintain profitability.
- Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.
- We are dependent on the success of our product candidates, some of which may not receive regulatory approval or be successfully commercialized.
- We face risks related to health, pandemics, epidemics, and outbreaks, including the novel coronavirus ("COVID-19"), which could significantly disrupt our pre-clinical studies and clinical trials, commercialization efforts, supply chain, regulatory and clinical development activities, and other business operations, in addition to the impact of a global economic slowdown.
- We are a development-stage company that has no revenues and has incurred losses since our inception. We expect to incur losses for the foreseeable future and may never achieve or maintain profitability.
- Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.
- We are dependent on the success of our product candidates, some of which may not receive regulatory approval or be successfully commercialized.
- We face risks related to health, pandemics, epidemics, and outbreaks, including the novel coronavirus ("COVID-19"), which could significantly disrupt our pre-clinical studies and clinical trials, commercialization efforts, supply chain, regulatory and clinical development activities, and other business operations, in addition to the impact of a global economic slowdown.
- We may fail to expand our anticipated outsourced manufacturing capability in time to meet market demand for our products and product candidates, and the FDA may refuse to accept the facilities of our contract manufacturers as being suitable to produce our products and product candidates. Any problems in our manufacturing process could have a material adverse effect on our business, results of operations and financial condition.
- Our future success will largely depend on the success of our product candidates, which development will require significant capital resources and years of clinical development effort.
- There is a high rate of failure for drug candidates proceeding through clinical trials.
- The legalization and use of medical and recreational marijuana in the U.S. and elsewhere may impact our business.
- We rely on, and expect to continue to rely on, third parties to conduct our clinical trials for our product candidates. If these third parties do not successfully carry out their contractual duties, comply with regulatory requirements or meet expected deadlines, we may not be able to obtain marketing approval for or commercialize our product candidates, and our business could be substantially harmed.
- We rely on third parties to manufacture our clinical product supplies, and we intend to rely on third parties for at least a portion of the manufacturing process of our product candidates, if approved. Our business could be harmed if those third parties fail to provide us with sufficient quantities of product or fail to do so at acceptable quality levels or prices or fail to maintain or achieve satisfactory regulatory compliance.
- Even if any of our product candidates receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors, and others in the medical community necessary for commercial success.
- If we are unable to obtain and maintain intellectual property protection for our technology and products, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors could commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology and products may be impaired.

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below, the section of this prospectus entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes, before investing in our common stock. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that affect us. If any of the following risks occur, our business, operating results and prospects could be materially harmed. In that event, the price of our common stock could decline, and you could lose part or all of your investment.

Risks Related to Our Operations and Financial Condition

We are an early development-stage company with no revenues.

As an early development-stage enterprise that is focused on the development of a pre-clinical pharmaceutical product, we have generated no revenue and have an accumulated deficit of \$9.3 million through December 31, 2022 and \$2.2 million through December 31, 2021. There can be no assurance that sufficient funds required to pursue our development program will be generated from operations or that funds will be available from external sources, such as debt or equity financings or other potential sources. The lack of additional capital resulting from the inability to generate cash flow from operations, or to raise capital from external sources would force us to substantially curtail or cease operations and would, therefore, have a material adverse effect on business. Furthermore, there can be no assurance that any such required funds, if available, will be available on attractive terms or that they will not have a significant dilutive effect on our existing stockholders.

We seek to overcome the circumstances that impact our ability to remain a going concern in the future through the growth of revenues with interim cash flow deficiencies being addressed through additional equity and debt financing. We anticipate raising additional funds through public or private financing, strategic relationships, or other arrangements in the near future to support our business operations; however, we may not have commitments from third parties for a sufficient amount of additional capital. We cannot be certain that any such financing will be available on acceptable terms, or at all, and our failure to raise capital when needed could limit our ability to continue operations. Our ability to obtain additional funding will determine our ability to continue as a going concern. Failure to secure additional financing in a timely manner and on favorable terms would have a material adverse effect on our financial performance, results of operations and stock price and require us to curtail or cease operations, sell off our assets, seek protection from our creditors through bankruptcy proceedings, or otherwise. Furthermore, additional equity financing may be dilutive to the holders of our common stock, and debt financing, if available, may involve restrictive covenants, and strategic relationships, if necessary, to raise additional funds, and may require that we relinquish valuable rights.

Because we have a limited operating history, you may not be able to accurately evaluate our operations.

We have had limited operations to date. Therefore, we have a limited operating history upon which to evaluate the merits of investing in our company. Potential investors should be aware of the difficulties normally encountered by new companies and the high rate of failure of such enterprises. The likelihood of success must be considered in light of the problems, expenses, difficulties, complications, and delays encountered in connection with the operations that we plan to undertake. These potential problems include, but are not limited to, unanticipated problems relating to the ability to generate sufficient cash flow to operate our business, and additional costs and expenses that may exceed current estimates. We expect to continue to incur significant losses into the foreseeable future. We recognize that if the effectiveness of our business plan is not forthcoming, we will not be able to continue business operations. There is no history upon which to base any assumption as to the likelihood that we will prove successful, and it is doubtful that we will generate any operating revenues or ever achieve profitable operations. If we are unsuccessful in addressing these risks, our business will most likely fail.

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We are dependent on additional financing for continuation of our operations.

Because we have generated no revenues and currently operate at a loss, we are completely dependent on the continued availability of financing in order to continue our business operations. There can be no assurance that financing sufficient to enable us to continue our operations will be available to us in the future.

We will need additional funds to complete further development of our business plan to achieve a sustainable level where ongoing operations can be funded out of revenues. We expect that the proceeds from this Offering will provide adequate resources to fund our operations and initial clinical development programs through _____. We will require further funding to fully implement our business plan to its fullest potential and achieve our growth plans. There is no assurance that any additional financing will be available or if available, on terms that will be acceptable to us.

Our failure to obtain future financing or to produce levels of revenue to meet our financial needs could result in our inability to continue as a going concern in the future and, as a result, our investors could lose their entire investment.

Our operating results may fluctuate, which could have a negative impact on our ability to grow our client base, establish sustainable revenues and succeed overall.

Our results of operations may fluctuate as a result of a number of factors, some of which are beyond our control including but not limited to:

- general economic conditions in the geographies and industries where we sell our services and conduct operations; legislative policies where we sell our services and conduct operations;
- the budgetary constraints of our customers; seasonality;
- success of our strategic growth initiatives;
- costs associated with the launching or integration of new or acquired businesses; timing of new product introductions by us, our suppliers and our competitors; product and service mix, availability, utilization and pricing;
- the mix, by state and country, of our revenues, personnel, and assets; movements in interest rates or tax rates;
- changes in, and application of, accounting rules; changes in the regulations applicable to us; and litigation matters.

As a result of these factors, we may not succeed in our business, and we could go out of business.

As a growing company, we have yet to achieve a profit and may not achieve a profit in the near future, if at all.

We have not yet produced any revenues or profit and may not in the near future, if at all. We cannot be certain that we will be able to realize sufficient revenue to achieve profitability. Further, many of our competitors have a significantly larger industry presence and revenue stream but have yet to achieve profitability. Our ability to continue as a going concern in the future is dependent upon raising capital from financing transactions, increasing revenue and keeping operating expenses below our revenue levels in order to achieve positive cash flows, none of which can be assured.

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Risks Relating to Our Business and Our Industry

Our future success will largely depend on the success of MIRA1a and any future product candidates, which development will require significant capital resources and years of clinical development effort.

We currently have no drug products on the market, and all of our drug development projects are in a pre-clinical stage of development. Our business depends almost entirely on the successful pre-clinical and clinical development, FDA regulatory approval, and commercialization of our product candidates, principally MIRA1a. Investors need to be aware that substantial additional investments including pre-clinical and clinical development and FDA regulatory submission and approval efforts will be required before we are permitted to undertake clinical studies and market and commercialize our product candidates, if ever. It may be several years before we can commence clinical trials, if ever. Any clinical trial will be subject to extensive and rigorous review and regulation by numerous government authorities in the United States and other jurisdictions where we intend, if approved, to market our product candidates. Before obtaining regulatory approvals for any of our product candidates, we must demonstrate through pre-clinical testing and clinical trials that the product candidate is safe and effective for its specific application. This process can take many years and may include post-marketing studies and surveillance, which would require the expenditure of substantial resources. Of the large number of drugs in development for approval in the United States (and the rest of the world), only a small percentage will successfully complete the FDA regulatory approval process or be granted authorization to be marketed in the rest of the world. Accordingly, even if we obtain the sufficient financing to fund our planned research, development, and clinical programs, we cannot assure you that any of our product candidates will be successfully developed or commercialized.

We may be unable to formulate or scale-up any or all of our product candidates. There is no guarantee that any of the product candidates will be or are able to be manufactured or produced in a manner to meet the FDA's criteria for product stability, content uniformity and all other criteria necessary for product approval in the United States and other markets. Any of our product candidates may fail to achieve their specified endpoints in clinical trials.

Furthermore, product candidates may not be approved even if they achieve their specified endpoints in clinical trials. The FDA may disagree with our trial design and our interpretation of data from clinical trials or may change the requirements for approval even after it has reviewed and commented on the design for our clinical trials. The FDA may also approve a drug for fewer or more limited indications than we request or may grant approval contingent on the performance of costly post-approval clinical trials (i.e., Phase IV trials). In addition, the FDA may not approve the labeling claims that we believe are necessary or desirable for the successful commercialization of our product candidates.

If we are unable to expand our pipeline and obtain regulatory approval for our product candidates within the timelines we anticipate, we will not be able to execute our business strategy effectively and our ability to substantially grow our revenues will be limited, which would have a material adverse impact on our long-term business, results of operations, financial condition, and prospects.

We are dependent on the success of our current and future product candidates, some of which may not receive regulatory approval or be successfully commercialized.

Our success will depend on our ability to successfully commercialize our product candidates. Our ability to successfully commercialize our product candidates will depend on, among other things, our ability to:

- successfully complete pre-clinical and other nonclinical studies and clinical trials;
- receive regulatory approvals from the FDA;
- produce, through a validated process, in manufacturing facilities inspected and approved by regulatory authorities, including the FDA, sufficiently large quantities of product candidates to permit successful commercialization;
- obtain reimbursement from payers such as government health care programs and insurance companies and achieve commercially attractive levels of pricing;
- secure acceptance of our product candidates from physicians, health care payers, patients, and the medical community;
- create positive publicity surrounding our product candidates;

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- manage our spending as costs and expenses increase due to clinical trials and commercialization; and
 - obtain and enforce sufficient intellectual property for our product candidates.

Our failure or delay with respect to any of the factors above could have a material adverse effect on our business, results of operations and financial condition.

Our business may be materially and adversely affected in the future by the evolving effects of the COVID-19 pandemic as a result of the current and potential future impacts on our commercialization efforts, supply chain, regulatory and clinical development activities, and other business operations, in addition to the impact of a global economic slowdown.

Our business could be materially and adversely affected in the future by the evolving effects of the COVID-19 pandemic. If we are unable to obtain adequate supplies of personal protective equipment due to shortages or encounter other challenges related to the evolving COVID-19 pandemic, we may have to place or may experience additional limitations on our in-person activities. In addition, our increased reliance on personnel working from home may negatively impact productivity or disrupt, delay or otherwise adversely impact our business. This could also increase our cybersecurity risk, create data accessibility concerns, and make us more susceptible to communication disruptions, any of which could adversely impact our business operations. Impacts related to the COVID-19 pandemic could materially and adversely affect our business, our ability to generate sales of and revenues from our approved products, and our ability to advance the development of our products and product candidates, as described elsewhere in this "Risk Factors" section. The magnitude of such impacts will depend, in large part, on the ultimate duration and severity of the evolving effects of the COVID-19 pandemic.

The effects of the COVID-19 pandemic continue to rapidly evolve. These effects have increased market volatility and could result in a significant long-term disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. In addition, market corrections resulting from the effects of the COVID-19 pandemic could materially affect our business and the value of our common stock. The extent to which the evolving effects of the COVID-19 pandemic impact our business, our ability to generate sales of and revenues from our approved products, and our clinical development and regulatory efforts will depend on future developments that are highly uncertain and cannot be predicted with confidence, such as the ultimate duration and severity of the pandemic, government actions, such as travel restrictions, quarantines and social distancing requirements in the U.S. and in other countries, business closures or business disruptions and the effectiveness of actions taken in the U.S. and in other countries to contain and treat the disease. Accordingly, we do not yet know the full extent of potential delays or impacts on our business, sales of our products, our clinical and regulatory activities, our research programs, healthcare systems or the global economy as a whole. However, these effects could materially and adversely affect our business, financial condition, results of operations and growth prospects. In addition, to the extent the evolving effects of the COVID-19 pandemic adversely affect our business, financial condition, results of operations and growth prospects, they may also have the effect of heightening many of the other risks and uncertainties described elsewhere in this "Risk Factors" section. It is also possible that future global pandemics could also occur and also materially and adversely affect our business, financial condition, results of operations and growth prospects.

Results of pre-clinical studies and earlier clinical trials are not necessarily predictive indicators of future results.

Any positive results from future pre-clinical testing of our product candidates and potential future clinical trials may not necessarily be predictive of the results from Phase I, Phase II or Phase III clinical trials. In addition, our interpretation of results derived from clinical data or our conclusions based on our pre-clinical data may prove inaccurate. Frequently, pharmaceutical and biotechnology companies have suffered significant setbacks in clinical trials after achieving positive results in pre-clinical testing and early phase clinical trials, and we cannot be certain that we will not face similar setbacks. These setbacks may be caused by the fact that pre-clinical and clinical data can be

susceptible to varying interpretations and analyses. Furthermore, certain product candidates may perform satisfactorily in pre-clinical studies and clinical trials, but nonetheless fail to obtain FDA approval or appropriate approvals by the appropriate regulatory authorities in other countries. If we fail to produce positive results in our clinical trials for our product candidates, the development timeline and regulatory approval and commercialization prospects for them and as a result our business and financial prospects, would be materially adversely affected.

We have limited marketing experience, and we do not anticipate at this time establishing a sales force or distribution and reimbursement capabilities, and we may not be able to successfully commercialize any of our product candidates if they are approved in the future.

Our ability to generate revenues ultimately depends on our ability to sell our approved products and secure adequate third-party reimbursement. We currently have limited experience in marketing and selling our products. We currently do not have any products approved for sale in the United States or in any other country.

The commercial success of our product candidates will depend on a number of factors beyond our control, including the willingness of physicians to prescribe our products to patients, payers' willingness and ability to pay for the drugs, the level of pricing achieved, patients' response to our drugs and the ability of our marketing partners to generate sales. There can be no guarantee that we will be able to establish or maintain the personnel, systems, arrangements and capabilities necessary to successfully commercialize MIRA1a or any product candidate approved by the FDA in the future. If we fail to establish or maintain successful marketing, sales and reimbursement capabilities or fail to enter into successful marketing arrangements with third parties, our product revenues may suffer.

Should we later determine it is in our best interest to develop a sales force we may be unable to effectively train and equip our sales force, therefore our ability to successfully commercialize our products may be harmed.

We will be required to expend significant time and resources to train our sales force to be credible, persuasive and compliant with applicable laws in marketing MIRA1a or our other product candidates to physicians for their approved uses. In addition, we must continue to train our sales force to ensure that a consistent and appropriate message about MIRA1a or our other product candidates are being delivered to our potential customers. If we are unable to effectively train our sales force and equip them with effective materials, including medical and sales literature to help them inform and educate potential customers about the benefits of MIRA1a and our product candidates and its proper administration, our efforts to successfully commercialize MIRA1a and our product candidates could be jeopardized, which would negatively impact our ability to generate product revenues.

We will need to further increase the size and complexity of our organization in the future, and we may experience difficulties in managing our growth and executing our growth strategy.

Our management and personnel, systems, and facilities currently in place may not be adequate to support our business plan and future growth. As a result, we may need to further expand certain areas of our organization.

Our need to effectively manage our operations, growth and various projects requires that we:

- continue to improve our operational, financial, management and regulatory compliance controls and reporting systems and procedures;
- attract and retain enough talented employees;
- manage our clinical trials effectively;
- manage our external manufacturing operations with contract research organizations effectively and in a cost-effective manner;
- manage our development efforts effectively while carrying out our contractual obligations to contractors and other third parties; and

In addition, we may utilize the services of part-time outside consultants and contractors to perform several tasks for us, including tasks related to compliance programs, clinical trial management, regulatory affairs, formulation development and other drug development functions. Our growth strategy may entail expanding our use of consultants and contractors to implement these and other tasks going forward. If we are not able to effectively expand our organization by hiring new employees and expanding our use of consultants and contractors, we may be unable to successfully implement the tasks necessary to effectively execute on our planned research, development, manufacturing, and commercialization activities and, accordingly, may not achieve our research, development and commercialization goals.

Our product candidates, if approved, may be unable to achieve the expected market acceptance and, consequently, limit our ability to generate revenue from new products.

Even when product development is successful and regulatory approval has been obtained, our ability to generate sufficient revenue depends on the acceptance of our products by physicians and patients. We cannot assure you that our product candidates will achieve the expected level of market acceptance and revenue if and when they obtain the requisite regulatory approvals. The market acceptance of any product depends on a number of factors, including the indication statement and warnings required by regulatory authorities in the product label. Market acceptance can also be influenced by continued demonstration of efficacy and safety in commercial use, physicians' willingness to prescribe the product, reimbursement from third-party payers such as government health care programs and private third-party payers, the price of the product, the nature of any post-approval risk, management activities mandated by regulatory authorities, competition, and marketing and distribution support. Further, an ineffective or inefficient distribution model at launch may lead to the inability to fulfill demand, and consequently a loss of revenue. Any factors preventing or limiting the market acceptance of our products could have a material adverse effect on our business, results of operations and financial condition.

If the price for any future approved products decreases or if governmental and other third-party payers do not provide coverage and adequate reimbursement levels, our revenue and prospects for profitability will suffer.

Patients who are prescribed medicine for the treatment of their conditions generally rely on third-party payers to reimburse all or part of the costs associated with their prescription drugs. Reimbursement systems in international markets vary significantly by country and by region, and reimbursement approvals generally must be obtained on a country-by-country basis. Coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payers is critical to new product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower-cost therapeutic alternatives are already available or subsequently become available. Even if we obtain coverage for products we may market, the resulting reimbursement payment rates may require co-payments that patients find unacceptably high. Patients may not use our products if coverage is not provided, or reimbursement is inadequate to cover a significant portion of its cost.

In addition, the market for our products will depend significantly on access to third-party payers' drug formularies or lists of medications for which third-party payers provide coverage and reimbursement. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical companies. Also, third-party payers may refuse to include a particular branded drug in their formularies or otherwise restrict patient access to a branded drug when a less costly generic equivalent or other alternative is available, even if not approved for the indications for which our products are approved.

Third-party payers or governmental or commercial entities are developing increasingly sophisticated methods of controlling healthcare costs. The current environment is putting pressure on companies to price products below what they may feel is appropriate. Selling our products at less than an optimized price could impact our revenues and overall success as a company. It will be difficult to determine the optimized price for our products. In addition, in the U.S., no uniform policy of coverage and reimbursement for drug products exists among third-party payers. Therefore, coverage and reimbursement for our products may differ significantly from payer to payer. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payer separately, with no assurance that coverage will be obtained. If we are unable to obtain coverage of, and adequate payment levels for, products we may market to third-party payers, physicians may limit how much or under what circumstances they will prescribe or administer them, and patients may decline to purchase them. This in turn could affect our ability to successfully commercialize products we may market, and thereby adversely impact our profitability, results of operations, financial condition, and future success.

In addition, where we have chosen to collaborate with a third party on product candidate development and commercialization, our partner may elect to reduce the price of our products in order to increase the likelihood of obtaining reimbursement approvals. In many countries, products cannot be commercially launched until reimbursement is approved and the negotiation process in some countries can exceed 12 months. In addition, pricing and reimbursement decisions in certain countries can be affected by decisions taken in other countries, which can lead to mandatory price reductions and/or additional reimbursement restrictions across a number of other countries, which may thereby adversely affect our sales and profitability. In the event that countries impose prices that are not sufficient to allow us or our partners to generate a profit, our partners may refuse to launch the product in such countries or withdraw the product from the market, which would adversely affect sales and profitability. Events, such as price decreases, government mandated rebates or unfavorable reimbursement decisions, could affect the pricing and reimbursement of MIRA1a and our other product candidates and could have a material adverse effect on our business, reputation, results of operations and financial condition.

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

Demand for synthetic cannabinoids such as MIRA1a, will likely be dependent on a number of social, political, legislative, and economic factors that are beyond our control. While we believe that there will be a demand for such drugs, and that the demand will grow, there is no assurance that such demand will happen, that we will benefit from any demand or that our business, in fact, will ever generate revenues from our drug development programs or become profitable.

The emerging markets for synthetic cannabinoids and medical research and development is and will likely remain competitive. The development and commercialization of drugs and medicines is highly competitive. We compete with a variety of multinational pharmaceutical companies and specialized biotechnology companies, as well as products and processes being developed by universities and other research institutions. Many of our competitors have developed, are developing, or will develop drugs and processes which may be competitive with our drug candidates. Competitive therapeutic treatments include those that have already been approved by medicines regulators and accepted by the medical community and any new treatments that may enter the market. For some of our drug development programs / areas of therapeutic interest, other treatment options are currently available, under development, and may become commercially available in the future. If any of our product candidates are approved for the diseases and conditions we are currently pursuing, they may compete with a range of medicines or therapeutic treatments that are either in development, will be developed in the future or currently marketed.

Established companies may have a competitive advantage over us due to their size and experiences, financial resources, and institutional networks. Many of our competitors may have significantly greater financial, technical, and human resources than we do. Due to these factors, our competitors may have an advantage in marketing their approved drugs and may obtain regulatory approval of their drug candidates before we are able to, which may limit our ability to develop or commercialize our drug candidates. Our competitors may also develop drugs / medicines that are safer, more effective, more widely used and less expensive than ours. These advantages could materially impact our ability to develop and, if approved, commercialize our product candidates successfully. Furthermore, some of these competitors may make acquisitions or establish collaborative relationships among themselves or with third parties to increase their ability to rapidly gain market share.

Our product candidates may compete with other synthetic cannabinoids, as well as with cannabinoid or cannabis-based drugs, in addition to competing with state-licensed medical and recreational marijuana, in markets where the recreational and/or medical use of marijuana is legal. There is continuing support in the USA for further state legalization of marijuana. In markets where recreational and/or medical marijuana is not legal, our product candidates, once approved by regulators, may compete with marijuana or marijuana-based products purchased in the illegal drug market. This may or may not affect the commercial price that we may be able to achieve for our synthetic regulatory-approved medicines, should they be approved by the FDA.

Moreover, as generic versions of drug products enter the market, the price for such medicines may be expected to decline rapidly and substantially. Even if we are the first to obtain FDA approval of one of our product candidates, the future potential approval of generics could adversely affect the price we are able to charge, and the profitability of our product(s) will likely decline.

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in more resources being concentrated among a smaller number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

These companies may compete with us in recruiting and retaining qualified scientific, management and commercial personnel, utilizing contract manufacturing facilities or contract research organizations (CROs), or establishing clinical trial sites and subject registration for clinical trials, as well as in acquiring technologies complementary to our research projects.

Product shipment delays could have a material adverse effect on our business, results of operations and financial condition.

The shipment, import and export of MIRA1a and our other product candidates require import and export licenses. In the U.S., FDA, U.S. Customs and Border Protection and the DEA, and in other countries similar regulatory authorities, regulate the import and export of pharmaceutical products that contain controlled substances. Specifically, the import and export process require the issuance of import and export licenses by the relevant controlled substance authority in both the importing and exporting country. We may not be granted, or if granted, maintain, such licenses from the authorities in certain countries. Even if we obtain the relevant licenses, shipments of MIRA1a and our product candidates may be held up in transit, which could cause significant delays and may lead to product batches being stored outside required temperature ranges. Inappropriate storage may damage the product shipment resulting in a partial or total loss of revenue from one or more shipments of MIRA1a or our other product candidates. A partial or total loss of revenue from one or more shipments of MIRA1a or our other product candidates could have a material adverse effect on our business, results of operations and financial condition. Even though the DEA has confirmed in writing that it conducted a scientific review of the chemical structure of MIRA1a in accordance with the definitions within the CSA and its implementing regulations and determined that MIRA1a is not a controlled substance or listed chemical, there is no assurance that the DEA may not change its position.

Problems in our manufacturing process, failure to comply with manufacturing regulations or unexpected increases in our manufacturing costs could harm our business, results of operations and financial condition.

The manufacturing of our product candidates necessitates compliance with cGMP and other regulatory requirements in jurisdictions internationally. We must ensure chemical consistency among our batches of products, including clinical batches and, if approved, marketing batches. Demonstrating such consistency may require typical manufacturing controls as well as clinical data. We must also ensure that our batches conform to complex release specifications. If we are unable to manufacture our product candidates in

accordance with regulatory specifications, including cGMP, or if there are disruptions in our manufacturing process due to damage, loss or otherwise, or failure to pass regulatory inspections of our manufacturing facilities, we may not be able to meet current demand or supply sufficient product for use in clinical trials, and this may also harm our ability to commercialize our product candidates on a timely or cost-competitive basis, if at all.

We may fail to expand our manufacturing capability in time to meet market demand for our products and product candidates, and the FDA may refuse to accept our facilities or those of our contract manufacturers as being suitable for the production of our products and product candidates. Any problems in our manufacturing process could have a material adverse effect on our business, results of operations and financial condition.

In addition, before we can begin commercial manufacture of any product candidates for sale in the U.S., we must obtain FDA regulatory approval for the product, which requires a successful FDA inspection of our manufacturing facilities and those of our contract manufacturers, processes, and quality systems in addition to other product-related approvals. Although we may successfully navigate this pre-approval inspection process as it relates in the U.S., pharmaceutical manufacturing facilities are continuously subject to post-approval inspection by the FDA and foreign regulatory authorities. Due to the complexity of the processes used to manufacture our product candidates, we may be unable to initially or continue to pass federal, state or international regulatory inspections in a cost-effective manner. If we are unable to comply with manufacturing regulations, we may be subject to fines, unanticipated compliance expenses, recall or seizure of any approved products, total or partial suspension of production and/or enforcement actions, including injunctions, and criminal or civil prosecution. These possible sanctions would adversely affect our business, results of operations and financial condition.

Business interruptions could delay us in the process of developing our product candidates and could disrupt our product sales.

Our research and development activities are conducted through outside contractors and manufacturers. Loss of our contracted manufacturing facilities, stored inventory or laboratory facilities through fire, theft or other causes, or loss of our raw material, could have an adverse effect on our ability to continue product development activities and to conduct our business. Failure to supply our partners with commercial product may lead to adverse consequences, including the right of partners to take over responsibility for product supply. We currently do not have insurance coverage to compensate us for such business interruptions. Our contract manufacturers and suppliers provide that in their separate operations; however, such coverage may prove insufficient to fully compensate us for the damage to our business resulting from any significant property or casualty loss to those facilities.

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

Our operations have consumed substantial amounts of cash since inception. For the year ended December 31, 2022, we reported a net operating cash outflow of \$5.6 million and a net cash inflow from investing activities of \$3.1 million. For the year ended December 31, 2021, we reported a net operating cash outflow of \$1.4 million and a net cash inflow from investing activities of \$4.2 million.

Research and development, and general and administrative expenses, and cash used for operations will continue to be significant and may increase substantially in the future in connection with new research and development initiatives and continued product commercialization efforts. We may 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 products.

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

- the timing of FDA approval, if any;
- the DEA continuing to classify MIRA1a as a substance not subject to CSA;
- the timing and amount of revenue from sales of our products, or revenue from grants or other sources;
- the rate of progress and cost of our clinical trials and other product development programs;
- costs of establishing or outsourcing sales, marketing, and distribution capabilities;
- costs and timing of completion of expanded in-house manufacturing facilities as well as any outsourced commercial manufacturing supply arrangements for our product candidates;
- costs of filing, prosecuting, defending, and enforcing any patent claims and other intellectual property rights associated with our product candidates;
- costs of operating as a U.S. public company;
- 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 a number of sources including existing cash balances, future cash flows from operations and the proceeds from further public offerings, we cannot assure you that any of these funding sources will be available to us on favorable terms, or at all. Further, even if we can raise funds from all of the above sources, the amounts raised may not be sufficient to meet our future capital requirements.

Operating results may vary significantly in future periods.

Our expenses and operating results have fluctuated in the past and our revenues, expenses, and operating results are likely to fluctuate significantly in the future. Our financial results are unpredictable and may fluctuate, for among other reasons, due to:

- commercial sales of our products;
- our achievement of product development objectives and milestones;
- clinical trial enrollment and expenses;
- research and development expenses; and
- the timing and nature of contract manufacturing and contract research payments.

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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. Because of these factors, our financial results in one or more future quarters may fail to meet the expectations of securities analysts or investors, which could cause our share price to decline.

If product liability lawsuits are successfully brought against us, we will incur substantial liabilities and may be required to limit the commercialization of MIRA1a and our product candidates.

Although we have never had any product liability claims or lawsuits brought against us, we face potential product liability exposure related to the testing of our product candidates in human clinical trials. We may face exposure to claims by an even greater number of persons when we begin to market and distribute our products commercially in the U.S., Europe and elsewhere. Now, and in the future, an individual may bring a liability claim against us alleging that MIRA1a or one of our product candidates caused an injury. While we continue to take what we believe are appropriate precautions, we may be unable to avoid significant liability if any product liability lawsuit is brought against us. Large judgments have been awarded in class action or individual lawsuits based on drugs that had unanticipated side effects. If we cannot successfully defend ourselves against product liability claims, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for MIRA1a and our product candidates if such product candidates are approved;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs of related litigation;
- substantial monetary awards to patients and others;
- increased cost of liability insurance;
- loss of revenue; and
- the inability to successfully commercialize our products.

Counterfeit versions of our products could harm our business.

Counterfeiting activities and the presence of counterfeit products in a number of markets and over the Internet continue to be a challenge for maintaining a safe drug supply for the pharmaceutical industry. Counterfeit products are frequently unsafe or ineffective and can be life-threatening. To distributors and users, counterfeit products may be visually indistinguishable from the authentic version. Reports of adverse reactions to counterfeit drugs along with increased levels of counterfeiting could be mistakenly attributed to the authentic product, affect patient confidence in the authentic product and harm the business of companies such as ours. If our products were to be the subject of counterfeits, we could incur reputational and financial harm.

We depend upon our key personnel and our ability to attract and retain employees.

Our future growth and success depend on our ability to recruit, retain, manage, and motivate our employees. 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. Due to this intense competition, 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.

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

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA or foreign regulations, provide accurate information to FDA or other regulatory authorities, comply with applicable manufacturing standards, comply with other foreign, federal, and state laws and regulations, report information or data accurately or disclose unauthorized activities to us. Employee misconduct could also involve the improper use of information, including information obtained during clinical trials, or illegal appropriation of drug product, which could result in government investigations and serious harm to our reputation. 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 comply with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

We are subject to the U.S. Foreign Corrupt Practices Act and other anti-corruption laws, as well as export control laws, customs laws, sanctions laws and other laws governing our operations. If we fail to comply with these laws, we could be subject to civil or criminal penalties, other remedial measures, and legal expenses, which could adversely affect our business, results of operations and financial condition.

Our operations are subject to anti-corruption laws, including the U.S. Foreign Corrupt Practices Act (the "FCPA"), and other anti-corruption laws that apply in countries where we do business. The FCPA and these other laws generally prohibit us and our employees and intermediaries from bribing, being bribed or making other prohibited payments to government officials or other persons to obtain or retain business or gain some other business advantage. We and our commercial partners operate in a number of jurisdictions that pose a high risk of potential FCPA violations, and we participate in collaborations and relationships with third parties whose actions could potentially subject us to liability under the FCPA or local anti-corruption laws. In addition, we cannot predict the nature, scope, or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing laws might be administered or interpreted.

We are also subject to other laws and regulations governing our international operations, including regulations administered by the government of the U.S. and other countries in which we operate or plan to operate, including applicable export control regulations, economic sanctions on countries and persons, customs requirements, and currency exchange regulations, (collectively referred to as the "Trade Control laws").

However, there is no assurance that we will be completely effective in ensuring our compliance with all applicable anti-corruption laws, including the FCPA or other legal requirements, including Trade Control laws. If we are not in compliance with the FCPA and other anti-corruption laws or Trade Control laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses, which could have an adverse impact on our business, financial condition, results of operations and liquidity, as well as our reputation. Likewise, any investigation of any potential violations of the FCPA, other anti-corruption laws or Trade Control laws by the U.S. or other authorities could also have an adverse impact on our reputation, our business, results of operations and financial condition.

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 will collect and store sensitive data, including valuable and commercially sensitive intellectual property, clinical trial data, our proprietary business information and that of our customers, suppliers and business partners, and personally identifiable information of our customers, clinical trial subjects and employees, and patients, in our data centers, on our networks, and with our third-party cloud service providers. The secure processing, maintenance and transmission of this information is critical to our operations. Despite our security measures, our information technology and infrastructure, and that of our third parties, may be vulnerable to attacks by hackers or breached due to employee error, malfeasance, or other disruptions. Any 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 MIRA1a or other product candidates.

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

Our business is increasingly dependent on critical, complex, and interdependent information technology (“IT”) systems, including Internet-based systems, some of which are managed or hosted by third parties, to support business processes as well as internal and external communications. The size and complexity of our IT systems make us potentially vulnerable to IT system breakdowns, malicious intrusion, and computer viruses, which may result in the impairment of our ability to operate our business effectively.

We are continuously evaluating and, where appropriate, enhancing our IT systems to address our planned growth, including to support our planned manufacturing operations. There are inherent costs and risks associated with implementing the enhancements to our IT systems, including potential delays in access to, or errors in, critical business and financial information, substantial capital expenditures, additional administrative time and operating expenses, retention of sufficiently skilled personnel to implement and operate the enhanced systems, demands on management time, and costs of delays or difficulties in transitioning to the enhanced systems, any of which could harm our business and results of operations. In addition, the implementation of enhancements to our IT systems may not result in productivity improvements at a level that outweighs the costs of implementation, or at all. In addition, our systems and the systems of our third-party providers and collaborators are potentially vulnerable to data security breaches which may expose sensitive data to unauthorized persons or to the public. Such data security breaches could lead to the loss of confidential information, trade secrets or other intellectual property, could lead to the public exposure of personal information (including personally identifiable information or individually identifiable health information) of our employees, clinical trial patients, customers, business partners, and others, could lead to potential identity theft, or could lead to reputational harm. Data security breaches could also result in loss of clinical trial data or damage to the integrity of that data. In addition, the increased use of social media by our employees and contractors could result in inadvertent disclosure of sensitive data or personal information, including but not limited to, confidential information, trade secrets and other intellectual property.

Any such disruption or security breach, as well as any action by us or our employees or contractors that might be inconsistent with the rapidly evolving data privacy and security laws and regulations applicable within the United States and elsewhere where we conduct business, could result in enforcement actions by U.S. states, the U.S. Federal government or foreign governments, liability or sanctions under data privacy laws, including healthcare laws such as HIPAA, that protect certain types of sensitive information, regulatory penalties, other legal proceedings such as but not limited to private litigation, the incurrence of significant remediation costs, disruptions to our development programs, business operations and collaborations, diversion of management efforts and damage to our reputation, which could harm our business and operations. Because of the rapidly moving nature of technology and the increasing sophistication of cybersecurity threats, our measures to prevent, respond to and minimize such risks may be unsuccessful.

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

In the ordinary course of our business, we, our vendors, and our third-party cloud service providers may collect and store sensitive data, including legally protected patient health information, credit card information, personally identifiable information about our employees and patients, intellectual property, and proprietary business information. We manage and maintain our applications and data utilizing cloud-based and on-site systems. These applications and data encompass 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. We have measures in place that are designed to prevent, and if necessary to detect and respond to such security incidents, breaches of privacy, and security mandates. However, 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 HIPAA and General Data Protection Regulation, or GDPR, 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 payers 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.

Legislative or regulatory reform of the health care system in the U.S. may affect our ability to profitably sell our products, if approved.

Our ability to commercialize our future products successfully, alone or with collaborators, will depend in part on the extent to which coverage and reimbursement for the products will be available from government and health administration authorities, private health insurers and other third-party payers. The continuing efforts of the U.S. government, insurance companies, managed care organizations and other payers for health care services to contain or reduce health care costs may adversely affect our ability to set prices for our products which we believe are fair, and our ability to generate revenues and achieve and maintain profitability.

Specifically, in the U.S., there have been a number of legislative and regulatory proposals to change the health care system in ways that could affect our ability to sell our products profitably. For example, certain states in the U.S. are proposing legislation mandating publicly funded health program coverage of medical cannabis. In addition, the 2010 Affordable Care Act, or the ACA, substantially changed the way healthcare is financed by both governmental and private insurers. Both Congress and the U.S. President have already taken some actions that are intended to significantly limit the ACA, and we expect efforts to further modify or repeal the ACA to continue. The success and potential effects of these efforts to repeal or modify the ACA are not clear.

We expect additional federal and state legislative proposals for health care reform, which could limit the prices that can be charged for the products we develop and may limit our commercial opportunity.

The continuing efforts of government and other third-party payers to contain or reduce the costs of health care through various means may limit our commercial opportunity. It will be time-consuming and expensive for us to go through the process of seeking coverage and reimbursement from Medicare, Medicaid, and other governmental health programs and from private payers. Our products may not be considered cost-effective, and government and third-party private health insurance coverage and reimbursement may not be available to patients for any of our future products or sufficient to allow us to sell our products on a competitive and profitable basis. Our results of operations could be adversely affected by ACA, changes to the ACA, and by other health care reforms that may be enacted or adopted in the future. In addition, increasing emphasis on managed care in the U.S. will continue to put downward pressure on the pricing of pharmaceutical products. Cost-control initiatives could decrease the price that we or any potential

collaborators could receive for any of our future products and could adversely affect our ability to generate revenue in the U.S. market and maintain profitability.

We may acquire other companies which could divert our management's attention, result in additional dilution to our shareholders and otherwise disrupt our operations and harm our operating results.

We may in the future seek to acquire businesses, products, or technologies that we believe could complement or expand our product offerings, enhance our technical capabilities or otherwise offer growth opportunities. The pursuit of potential acquisitions may divert the attention of management and cause us to incur various expenses in identifying, investigating, and pursuing suitable acquisitions, whether or not they are consummated. If we acquire additional businesses, we may not be able to integrate the acquired personnel, operations and technologies successfully, effectively manage the combined business following the acquisition or realize anticipated cost savings or synergies. We also may not achieve the anticipated benefits from the acquired business due to a number of factors, including:

- incurrence of acquisition-related costs;
- diversion of management's attention from other business concerns;
- unanticipated costs or liabilities associated with the acquisition;
- harm to our existing business relationships with collaboration partners as a result of the acquisition;
- harm to our brand and reputation;
- the potential loss of key employees;
- use of resources that are needed in other parts of our business; and
- use of substantial portions of our available cash to consummate the acquisition.

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In the future, if our acquisitions do not yield expected returns, we may be required to take charges to our operating results arising from the impairment assessment process. Acquisitions may also result in dilutive issuances of equity securities or the incurrence of debt, which could adversely affect our operating results. In addition, if an acquired business fails to meet our expectations, our business, results of operations and financial condition may be adversely affected.

Risks Related to Development and Regulatory Approval of Our Product Candidates

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

Clinical trials are expensive, time consuming and difficult to design and implement. Regulatory agencies may analyze or interpret the results 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. In addition, we, the FDA, or other regulatory authorities, including state and local authorities, or an Institutional Review Board, or IRB, with respect to a trial at its institution, may suspend, delay or terminate our clinical trials at any time, require us to conduct additional clinical trials, require a particular clinical trial to continue for a longer duration than originally planned, require a change to our development plans such that we conduct clinical trials for a product candidate in a different order, e.g., in a step-wise fashion rather than running two trials of the same product candidate in parallel, or the DEA could suspend or terminate the registrations and quota allotments we require in order to procure and handle controlled substances, for various reasons, including:

- 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 who have initiated a clinical trial but 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;
- the evolving effects of the COVID-19 pandemic;
- 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 formulation;
- delays in obtaining regulatory authorization to commence a 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 pre-clinical studies and clinical trials;
- failure of our contract research organizations, or CROs, or other third-party contractors to comply with all contractual requirements or to perform their services in a timely or acceptable manner;

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- 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 or the handling, storage, security, and recordkeeping;
- scheduling conflicts with participating clinicians and clinical institutions;
- failure to design appropriate clinical trial protocols;
- regulatory concerns with cannabinoid products generally and the potential for abuse;
- insufficient data to support regulatory approval;
- inability or unwillingness of medical investigators to follow our clinical protocols; or
- difficulty in maintaining contact with patients during or after treatment, which may result in incomplete data.

Any of the foregoing could have a material adverse effect on our business, results of operations and financial condition.

Clinical trials of synthetic cannabinoid drug candidates are novel with very limited or non-existing history; we face a significant risk that the trials will not result in commercially viable drugs and treatments.

At present, there is only a very limited documented clinical trial history from which we can derive any scientific conclusions for our product candidates or prove that our present assumptions for the current and planned research are scientifically compelling. The API content of the Investigational New Drug applications (INDs) can vary from one IMD to another – hence it is not necessarily possible to extrapolate results from studies with one product and predict efficacy of safety with another product containing a similar API and different source. Whilst the principal synthetic cannabinoid component may be similar, the APIs may differ in terms of minor cannabinoid content, impurity profiles or degradant profiles. While we are encouraged by the results of clinical trials by others (where they exist), there can be no assurance that any pre-clinical study or clinical trial will result in commercially viable drugs or treatments.

Clinical trials are expensive, time consuming and difficult to design and implement. We, as well as the regulatory authorities may suspend, delay or terminate our clinical trials at any time, may require us, for various reasons, to conduct additional clinical trials, or may require a particular clinical trial to continue for a longer duration than originally planned, including, among others:

- lack of effectiveness of any API, formulation, or delivery system during clinical trials;
- discovery of serious or unexpected toxicities or side effects experienced by trial participants or other safety issues;
- slower than expected rates of subject recruitment and enrollment rates in clinical trials;
- delays or inability in manufacturing or obtaining sufficient quantities of GMP-grade materials for use in clinical trials due to regulatory and manufacturing constraints;
- delays in obtaining regulatory authorization to commence a trial, including Institutional Review Board (“IRB”) approvals or DEA approvals, licenses required for obtaining and using synthetic cannabinoids or cannabinoid-like substances for research, either before or after a trial is commenced;
- unfavorable results from ongoing pre-clinical studies and clinical trials;
- patients or investigators failing to comply with clinical trial protocols;
- patients failing to return for post-treatment follow-up at the expected rate;
- sites participating in an ongoing clinical trial withdraw, requiring us to engage new sites;

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- third-party clinical investigators decline to participate in our clinical trials, do not perform the clinical trials on the anticipated schedule, or act in ways inconsistent with the established investigator agreement, clinical trial protocol, good clinical practices, and other IRB requirements;
- third-party entities do not perform data collection and analysis in a timely or accurate manner or at all; or
- regulatory inspections of our clinical trials require us to undertake corrective action or suspend or terminate our clinical trials.

Any of the foregoing could have a material adverse effect on our business, results of operations and financial condition.

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 governments in each of the markets where we have product candidates progressing through the approval process.

We must also adhere to all regulatory requirements including FDA’s Good Laboratory Practice, Good Clinical Practice, and current Good Manufacturing Practices requirements (“cGMP”) pharmacovigilance requirements, advertising, and promotion restrictions, reporting and recordkeeping requirements. If we or our suppliers fail to comply with applicable regulations, including FDA pre-or post-approval cGMP requirements, then FDA could sanction us. Even if a drug is FDA-approved, regulatory authorities may impose significant restrictions on a product’s indicated uses or marketing or impose ongoing requirements for potentially costly post-marketing trials. MIRA 1a, and any of our product candidates that may be approved in the U.S. in the future, 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 the U.S. 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 must continue to expend 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.

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 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 untitled or warning letters;
- seek to enjoin our activities;
- 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 into a Corporate Integrity Agreement or closing our contract manufacturers' facilities, if any; or
- seize or detain products or require a product recall.

In addition, any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our product candidates. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our business and our operating results may be adversely affected.

Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management's attention from the operation of our business and damage our reputation. We expend significant resources on compliance efforts and such expenses are unpredictable and might adversely affect our results. Changing laws, regulations and standards might also create uncertainty, higher expenses and increase insurance costs. As a result, we intend to invest all reasonably necessary resources to comply with evolving standards, and this investment might result in increased management and administrative expenses and a diversion of management time and attention from revenue-generating activities to compliance activities.

We are subject to federal and state healthcare laws and regulations and implementation of or changes to such healthcare laws and regulations could adversely affect our business and results of operations.

In the U.S., 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 product candidates. If we are found to be in violation of any of these laws or any other federal or state 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 ultimately are 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.

We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we may receive for any approved product. There have been judicial challenges to certain aspects of the ACA and numerous legislative attempts to repeal and/or replace the ACA in whole or in part, and we expect there will be additional challenges and amendments to the ACA in the future. At this time, the full effect that the ACA will have on our business in the future remains unclear. 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 payers. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize products for which we may receive regulatory approval.

The regulatory approval processes with the FDA is lengthy and inherently unpredictable.

We are not permitted to market our drug candidates as medicines in the United States or other countries until we receive approval of a New Drug Application ("NDA") from the FDA or in any foreign countries until we receive the approval from the regulatory authorities of such countries. Prior to submitting an NDA to the FDA for approval of our drug candidates we will need to have completed our pre-clinical studies and clinical trials and demonstrate that our products meet all applicable standards of identity, strength, quality, and purity throughout their expiration date. Successfully completing any clinical program and obtaining approval of an NDA is a complex, lengthy, expensive, and uncertain process, and the FDA (or other country medicines regulatory body) may delay, limit, or deny approval of product candidates for many reasons, including, among others, because:

- an inability to demonstrate that our product candidates are safe and effective in treating patients to the satisfaction of the FDA;
- results of clinical trials that may not meet the level of statistical or clinical significance required by the FDA;
- disagreements with the FDA with respect to the number, design, size, conduct or implementation of clinical trials;
- requirements by the FDA to conduct additional clinical trials;

- disapproval by the FDA of certain formulations, labeling or specifications of product candidates;
- findings by the FDA that the data from pre-clinical studies and clinical trials are insufficient;
- findings by the FDA that our API or finished products do not meet all applicable standards of identity, strength, quality, and purity;
- the FDA may disagree with the interpretation of data from pre-clinical studies and clinical trials; and
- the FDA may change their approval policies or adopt new regulations.

Any of these factors, many of which are beyond our control, could increase development time and / or costs or jeopardize our ability to obtain regulatory approval for our drug candidates.

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

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, FDA 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 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, our reputation in the industry and in the investment community might be significantly damaged and the price of our common stock could decrease significantly. 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.

If we are found in violation of federal or state “fraud and abuse” laws, we may be required to pay a penalty and/or be suspended from participation in federal or state health care programs, which may adversely affect our business, financial condition, and results of operations.

In the U.S., we are subject to various federal and state health care “fraud and abuse” laws, including anti-kickback laws, false claims laws and other laws intended to reduce fraud and abuse in federal and state health care programs, which could affect us particularly upon successful commercialization of our products in the U.S. The Medicare and Medicaid Patient Protection Act of 1987, or federal Anti-Kickback Statute, makes it illegal for any person, including a prescription drug manufacturer (or a party acting on its behalf), to knowingly and willfully solicit, receive, offer or pay any remuneration that is intended to induce the referral of business, including the purchase, order or prescription of a particular drug for which payment may be made under a federal health care program, such as Medicare or Medicaid. Under federal law, some arrangements, known as safe harbors, are deemed not to violate the federal Anti-Kickback Statute. Although we seek to structure our business arrangements in compliance with all applicable requirements, it is often difficult to determine precisely how the law will be applied in specific circumstances. Accordingly, it is possible that our practices may be challenged under the federal Anti-Kickback Statute and Federal False Claims Act. Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including fines and/or exclusion or suspension from federal and state health care programs such as Medicare and Medicaid and debarment from contracting with the U.S. government. In addition, private individuals have the ability to bring actions on behalf of the government under the federal False Claims Act as well as under the false claims laws of several states.

Many states have adopted laws similar to the federal anti-kickback statute, some of which apply to the referral of patients for health care services reimbursed by any source, not just governmental payers. There are ambiguities as to what is required to comply with these state requirements and if we fail to comply with an applicable state law requirement, we could be subject to penalties.

Neither the government nor the courts have provided definitive guidance on the application of fraud and abuse laws to our business. Law enforcement authorities are increasingly focused on enforcing these laws, and it is possible that some of our practices may be challenged under these laws. While we believe we have structured our business arrangements to comply with these laws, it is possible that the government could allege violations of, or convict us of violating, these laws. If we are found in violation of one of these laws, we could be required to pay a penalty and could be suspended or excluded from participation in federal or state health care programs, and our business, results of operations and financial condition may be adversely affected.

Serious adverse events or other safety risks could require us to abandon development and preclude, delay or limit approval of our 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 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 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 REMS in connection with approval or post-approval;
- regulatory authorities may withdraw their approval, require more onerous labeling statements, impose a more restrictive Risk Evaluation and Mitigation Strategy (“REMS”), or require us 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 product candidates that are being developed for pediatric indications.

We may voluntarily suspend or terminate our clinical trials if at any time we believe that they present an unacceptable risk to participants or if preliminary data demonstrate that our product candidates are unlikely to receive regulatory approval or unlikely to be successfully commercialized. Following receipt of approval for commercial sale of a product we may voluntarily withdraw or recall that product from the market if at any time we believe that its use, or a person’s exposure to it, may cause adverse health consequences or death. To date we have not withdrawn, recalled, or taken any other action, voluntary or mandatory, to remove an approved product from the market. 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 discontinue a clinical trial temporarily or permanently, if we elect or are forced to suspend or terminate a clinical trial of any of our 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 product candidates and impair our ability to generate revenue from the commercialization of these products either by us or by our collaboration partners.

Risks Related to Our Reliance Upon Third Parties

Our existing collaboration arrangements and any that we may enter into in the future may not be successful, which could adversely affect our ability to develop and commercialize our product candidates.

We may seek additional collaboration arrangements with pharmaceutical or biotechnology companies for the development or commercialization of our product candidates. We may, with respect to our product candidates, enter into new arrangements on a selective basis depending on the merits of retaining commercialization rights for ourselves as compared to entering into selective collaboration arrangements with leading pharmaceutical or biotechnology companies for each product candidate, both in the U.S. and internationally. To the extent that we decide to enter into collaboration agreements, we will face significant competition in seeking appropriate collaborators and the terms of any collaboration or other arrangements that we may establish may not be favorable to us.

Any existing or future collaboration that we enter may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations. Disagreements between parties to a collaboration arrangement regarding development, intellectual property, regulatory or commercialization matters can lead to delays in the development process or commercialization of the applicable product candidate and, in some cases, termination of the collaboration arrangement. These disagreements can be difficult to resolve if neither of the parties has final decision-making authority. Any such termination or expiration could harm our business reputation and may adversely affect us financially.

We depend on a limited number of suppliers for materials and components required to manufacture our product candidates. The loss of these suppliers, or their failure to supply us on a timely basis, could cause delays in our current and future capacity and adversely affect our business.

We depend on a limited number of suppliers for the materials and components required to manufacture our product candidates. As a result, we may not be able to obtain sufficient quantities of critical materials and components in the future. A delay or interruption by our suppliers may also harm our business, results of operations and financial condition. In addition, the lead time needed to establish a relationship with a new supplier can be lengthy, and we may experience delays in meeting demand in the event we must switch to a new supplier. The time and effort to qualify for and, in some cases, obtain regulatory approval for a new supplier could result in additional costs, diversion of resources or reduced manufacturing yields, any of which would negatively impact our operating results. Our dependence on single-source suppliers exposes us to numerous risks, including the following: our suppliers may cease or reduce production or deliveries, raise prices or renegotiate terms; our suppliers may become insolvent or cease trading; we may be unable to locate a suitable replacement supplier on acceptable terms or on a timely basis, or at all; and delays caused by supply issues may harm our reputation, frustrate our customers and cause them to turn to our competitors for future needs.

Risks Related to Our Intellectual Property

We may not be able to adequately protect our product candidates or our proprietary technology in the marketplace.

Our success will depend, in part, on our ability to obtain patents, protect our trade secrets and operate without infringing on the proprietary rights of others. We may rely upon a combination of patents, trade secret protection (i.e., know-how), trademarks, licenses, and confidentiality agreements to protect the intellectual property of our 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. However, patent protection for naturally occurring compounds is exceedingly difficult to obtain, defend and enforce. Filing, prosecuting and defending patents throughout the world would be prohibitively expensive, so 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 product candidates are particularly uncertain. To date, our principal product candidates have been based on specific formulations of certain previously known cannabinoids found in nature in the cannabis sativa plant. While we have sought patent protection, where appropriate, directed to, among other things, composition-of-matter for our specific formulations, their methods of use, and methods of manufacture, we do not have and will not be able to obtain composition of matter protection on these previously known cannabinoids per se. We anticipate that the products we develop in the future will continue to be based on the same or other naturally occurring compounds, as well as additional synthetic compounds we may discover. Although we have sought and expect to continue to seek patent protection for our 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 are 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 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 product candidates. We may also face competition from companies who develop a substantially similar product to one of our product candidates that is not covered by any of our patents.

If third parties claim that the Company's intellectual property, products, processes, or anything else 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 our product candidates, or our commercialization thereof, does not and will not infringe any third party's intellectual property.

We own the rights associated with our patents in the United States, however, we do not own the rights to patents covering MIRA1a in foreign jurisdictions.

We own the patent relating to MIRA1a in the United States. Foreign patents covering MIRA1a and its therapeutic uses have issued in Australia, Belgium, Canada, Czech Republic, France, Germany, Greece, Netherlands, Hungary, Ireland, Israel, Italy, Malta, Poland, Portugal, Romania, South Korea, Spain, Sweden, and the United Kingdom, and corresponding applications are pending in China and Japan.. MyMD Pharmaceuticals, Inc. (NASDAQ: MYMD, "MyMD"), a publicly traded New Jersey corporation, currently owns these foreign patents and patent applications. We may in the future seek an agreement under which we would acquire such foreign patent rights through purchase or license, but we currently have no agreement with MyMD with respect to such patent rights. If we are unable to obtain foreign patent rights to MIRA1a from MyMD, MyMD may retain such patent rights, in which case we would not have the ability to commercialize MIRA1a outside of the United States in jurisdictions in which MyMD has foreign patent rights, and MyMD potentially could develop a competing product for jurisdictions outside of the United States.

Risks Relating to our Common Stock

An investment in our securities carries a high degree of risk and should be considered as a speculative investment.

An investment in our securities carries a high degree of risk and should be considered as a speculative investment. We have a limited history of earnings, a limited operating history, have not paid dividends, and are unlikely to pay dividends in the immediate or near future. The likelihood of our success must be considered in light of the problems, expenses, difficulties, complications and delays frequently encountered in connection with the establishment of any business. An investment in our securities may result in the loss of an investor's entire investment. Only potential investors who are experienced in high-risk investments and who can afford to lose their entire investment should consider an investment in our securities.

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

As a reporting issuer, we will be subject to the reporting requirements of applicable securities legislation of the jurisdiction in which it is a reporting issuer, the listing requirements of Nasdaq and other applicable securities rules and regulations. Compliance with these rules and regulations will increase our legal and financial compliance costs, make some activities more difficult, time-consuming or costly and increase demand on its systems and resources. Applicable securities laws will require us to, among other things, file certain annual and quarterly reports with respect to its business and results of operations. In addition, applicable securities laws require us to, among other things, maintain effective disclosure controls and procedures and internal control over financial reporting.

In order to maintain and, if required, improve its disclosure controls and procedures and internal control over financial reporting to meet this standard, significant resources and management oversight are required. Specifically, due to the increasing complexity of its transactions, it is anticipated that we will improve our disclosure controls and procedures and internal control over financial reporting primarily through the continued development and implementation of formal policies, improved processes and documentation procedures, as well as the continued sourcing of additional finance resources. As a result, management's attention may be diverted from other business concerns, which could harm our business and results of operations. To comply with these requirements, we may need to hire more employees in the future or engage outside consultants, which will increase its costs and expenses.

In addition, changing laws, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time consuming. These laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We intend to continue to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to their application and practice, regulatory authorities may initiate legal proceedings against us, which could adversely affect our business and financial results.

As a public company subject to these rules and regulations, we may find it more expensive for it to obtain director and officer liability insurance, and it may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified members of its Board, particularly to serve on its Audit Committee and Compensation Committee, and qualified executive officers.

As a result of disclosure of information in filings required of a public company, our business and financial condition will become more visible, which may result in threatened or actual litigation, including by competitors and other third parties. If such claims are successful, our business and results of operations could be harmed, and even if the claims do not result in litigation or are resolved in its favor, these claims, and the time and resources necessary to resolve them, could divert the resources of our management and harm its business and results of operations.

We are an "emerging growth company," and any decision on our part to comply only with certain reduced reporting and disclosure requirements applicable to emerging growth companies could make shares of our common stock less attractive to investors.

We are an "emerging growth company," as defined in Section 2(a) of the Securities Act. For as long as we continue to be an "emerging growth company," we may choose to take advantage of exemptions from various reporting requirements applicable to other public companies that are not "emerging growth companies," including, but not limited to, not being required to have our independent registered public accounting firm audit our internal control over financial reporting under Section 404, reduced disclosure obligations regarding executive compensation in our periodic reports and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. We could be an "emerging growth company" until the fifth anniversary of the fiscal year end date following the completion of this offering, however, our status would change more quickly if we have more than US\$1.235 billion in annual revenue, if the market value of our Common Shares held by non-affiliates equals or exceeds US\$700 million as of June 30 of any year, or we issue more than US\$1.0 billion of non-convertible debt over a three-year period before the end of that period.

Investors could find our shares less attractive if we choose to rely on these exemptions. If some investors find shares less attractive as a result of any choices to reduce future disclosure, there may be a less active trading market for our shares and our share price may be more volatile.

For as long as we are an "emerging growth company", our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404. We could be an "emerging growth company" until the fifth anniversary of the fiscal year end date following the completion of this offering. An independent assessment of the effectiveness of our internal controls could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls could lead to financial statement restatements and require us to incur the expense of remediation.

If we identify material weaknesses in our internal control over financial reporting, or if we are unable to comply with the requirements of Section 404 in a timely manner or assert that our internal control over financial reporting is effective, or if our independent registered public accounting firm is unable to express an opinion as to the effectiveness of our internal control over financial reporting when required, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our securities could be negatively affected, and we could become subject to investigations by the stock exchange on which our securities are listed, the SEC, or other regulatory authorities, which could require additional financial and management resources.

Additionally, we are a "smaller reporting company" as defined in Item 10(f)(1) of Regulation S-K. Smaller reporting companies may take advantage of certain reduced disclosure obligations, including, among other things, providing only two years of audited financial statements. We will remain a smaller reporting company until the last day of any fiscal year for so long as either: (i) the market value of our shares of common stock held by non-affiliates does not equal or exceed \$250 million as of the prior June 30th; or (ii) our annual revenues did not equal or exceed \$100 million during such completed fiscal year. To the extent we take advantage of such reduced disclosure obligations, it may also make comparison of our financial statements with other public companies difficult or impossible.

Our management will have broad discretion over the use of the proceeds we receive in this offering and might not apply the proceeds in ways that increase the value of your investment.

Our management will have broad discretion over the use of our net proceeds from this offering and you will be relying on the judgment of our management regarding the

application of these proceeds. Our management might not apply our net proceeds in ways that ultimately increase the value of your investment. We expect to use the net proceeds from this offering to advance the clinical development of our programs, to fund our research and development activities and to fund working capital and for general corporate purposes. Our management might not be able to yield a significant return, if any, on any investment or use of these net proceeds. You will not have the opportunity to influence the decision on how to use the net proceeds from this offering.

If we fail to maintain compliance with Nasdaq Listing Rules, our shares may be delisted from Nasdaq, which would result in a limited trading market for our shares and make obtaining future debt or equity financing more difficult for the Company.

We are in the process of applying to have shares of our common stock sold in this offering listed on the Nasdaq under the symbol “MIRA”. However, there is no assurance that we will be able to continue to maintain our compliance with the Nasdaq continued listing requirements. If we fail to do so, our securities may lose their status on Nasdaq and they would likely be traded on the over-the-counter markets, including the Pink Sheets market. As a result, selling our securities could be more difficult because smaller quantities of shares or warrants would likely be bought and sold, transactions could be delayed, and security analysts’ coverage of us may be reduced. In addition, in the event our securities are delisted, broker dealers would bear certain regulatory burdens which may discourage broker dealers from effecting transactions in the securities and further limit the liquidity of the securities. These factors could result in lower prices and larger spreads in the bid and ask prices for the securities. Such delisting from Nasdaq and continued or further declines in the share price of the securities could also greatly impair our ability to raise additional necessary capital through equity or debt financing and could significantly increase the ownership dilution to shareholders caused by our issuing equity in financing or other transactions.

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If our shares were to be delisted from Nasdaq, they may become subject to the SEC’s “penny stock” rules.

Delisting from Nasdaq may cause the securities of the Company to become subject to the SEC’s “penny stock” rules. The SEC generally defines a penny stock as an equity security that has a market price of less than \$5.00 per share or an exercise price of less than \$5.00 per share, subject to certain exemptions. One such exemption is to be listed on Nasdaq. Therefore, if the Common Shares were to be delisted from Nasdaq, the securities of the Company could become subject to the SEC’s “penny stock” rules. These rules require, among other things, that any broker engaging in a purchase or sale of our securities provide its customers with: (i) a risk disclosure document, (ii) disclosure of market quotations, if any, (iii) disclosure of the compensation of the broker and its salespersons in the transaction, and (iv) monthly account statements showing the market values of our securities held in the customer’s accounts. A broker would be required to provide the bid and offer quotations and compensation information before effecting the transaction. This information must be contained on the customer’s confirmation. Generally, brokers are less willing to effect transactions in penny stocks due to these additional delivery requirements. These requirements may make it more difficult for shareholders to purchase or sell the Common Shares of the Company. Since the broker, not us, prepares this information, we would not be able to assure that such information is accurate, complete or current.

You will experience immediate and substantial dilution as a result of this offering and may experience additional dilution in the future.

If you purchase shares in this offering, the value of your shares based on our actual book value will immediately be less than the price you paid. This reduction in the value of your equity is known as dilution. This dilution occurs in large part because our existing stockholders paid less than the assumed public offering price when they acquired their shares of common stock. Based upon the issuance and sale of _____ shares of common stock by us in this offering at an assumed public offering price of \$___ per share, you will incur immediate dilution of in the net tangible book value per share. If the underwriters exercise their over-allotment option, or if outstanding options to purchase shares of our common stock are exercised, investors will experience additional dilution. For more information, see “Dilution.”

There is no existing market for our securities and we do not know if one will develop to provide you with adequate liquidity.

Prior to this offering, there has not been a public market for our securities. We cannot assure you that an active trading market for shares of our common stock will develop following this offering, or if it does develop, it may not be maintained. You may not be able to sell your shares of our common stock quickly or at the market price if trading in our securities is not active. The initial public offering price for the shares of common stock offered hereby will be determined by negotiations between us and the underwriter and may not be indicative of prices that will prevail in the trading market.

Securities or industry analysts may not regularly publish reports on us, which could cause the price of our securities or trading volumes to decline.

The trading market for our securities could be influenced by research and reports that industry and/or securities analysts may publish us, our business, the market or our competitors. We do not have any control over these analysts and cannot assure that such analysts will cover us or provide favorable coverage. If any of the analysts who may cover our business change their recommendation regarding our securities adversely, or provide more favorable relative recommendations about our competitors, the price of our securities would likely decline. If any analysts who may cover our business were to cease coverage or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause the price of our securities or trading volumes to decline.

We will likely conduct further offerings of our equity securities in the future, in which case your proportionate interest may become diluted.

We will likely be required to conduct equity offerings in the future to finance our current projects or to finance subsequent projects that we decide to undertake. If our common stock shares are issued in return for additional funds, the price per share could be lower than that paid by our current shareholders. We anticipate continuing to rely on equity sales of our common stock shares in order to fund our business operations. If we issue additional common stock shares or securities convertible into shares of our common stock, your percentage interest in us could become diluted.

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We may issue shares of preferred stock in the future, which could make it difficult for another company to acquire us or could otherwise adversely affect holders of our common stock, which could depress the price of our common stock.

Our certificate of incorporation authorizes us to issue one or more series of preferred stock. Our board of directors will have the authority to determine the preferences, limitations and relative rights of the shares of preferred stock and to fix the number of shares constituting any series and the designation of such series, without any further vote or action by our shareholders. Our preferred stock could be issued with voting, liquidation, dividend and other rights superior to the rights of our common stock. The potential issuance of preferred stock may delay or prevent a change in control of us, discouraging bids for our common stock at a premium to the market price, and materially adversely affect the market price and the voting and other rights of the holders of our common stock.

We have never declared or paid any cash dividends or distributions on our capital stock. We do not anticipate paying any cash dividends on our common stock in the foreseeable future.

We have never declared or paid any cash dividends or distributions on our capital stock. We currently intend to retain our future earnings, if any, to support operations and to finance expansion and therefore we do not anticipate paying any cash dividends on our common stock in the foreseeable future.

The declaration, payment and amount of any future dividends will be made at the discretion of the board of directors, and will depend upon, among other things, the results of our operations, cash flows and financial condition, operating and capital requirements, and other factors as the board of directors considers relevant. There is no assurance that future dividends will be paid, and, if dividends are paid, there is no assurance with respect to the amount of any such dividend.

USE OF PROCEEDS

The net proceeds to us from the sale of shares of common stock by us in this offering will be approximately \$ _____ million, assuming an initial public offering price of \$ _____ per share (the midpoint of the range set forth on the cover of this prospectus), and after deducting underwriting discounts and commissions and estimated offering expenses.

We intend to use the net proceeds from this offering as follows:

- approximately \$ _____ to \$ _____ to advance the clinical development of our programs;
- approximately \$ _____ to \$ _____ to fund our research and development activities; and
- the remaining amounts to fund working capital and general corporate purposes.

We cannot specify with certainty the particular uses of the net proceeds that we will receive from this offering or the amounts we actually spend on the uses set forth above. Pending the use of proceeds from this offering as described above, we plan to invest the net proceeds that we receive in this offering in short-term and intermediate-term interest-bearing obligations, investment-grade investments, certificates of deposit or direct or guaranteed obligations of the U.S. government. Our management will have broad discretion in the application of the net proceeds from this offering and investors will be relying on the judgment of our management regarding the application of the proceeds.

DIVIDEND POLICY

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all available funds and future earnings, if any, for use in the operation of our business and do not anticipate paying any cash dividends on our common stock in the foreseeable future. Investors should not purchase our common stock with the expectation of receiving cash dividends.

CAPITALIZATION

The following table sets forth our cash and cash equivalents, as well as our total capitalization, as of December 31, 2022:

- on an actual basis;
- on an as adjusted basis to give effect to our issuance and sale of _____ shares of our common stock in this offering (assuming no exercise of the underwriters' overallotment option) at an assumed initial public offering price of \$ _____ per share (the midpoint of the range set forth on the cover of this prospectus), and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

You should read this table together with our financial statements and related notes and the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" that are included elsewhere in this prospectus.

	As of December 31, 2022	
	Actual (unaudited)	As Adjusted ⁽¹⁾ (unaudited)
<i>(in thousands)</i>		
Cash and cash equivalents	\$ _____	\$ _____
Stockholders' equity:		
Total stockholders' equity	_____	_____
Total capitalization	\$ _____	\$ _____

- (1) A \$1.00 increase or decrease in the assumed initial public offering price per share of our common stock would increase or decrease each of cash, additional paid-in-capital and total capitalization on an as adjusted basis by approximately \$ _____, assuming the number of shares of our common stock offered by us remains the same and after deducting the estimated underwriting discounts and commissions and offering expenses payable by us.

DILUTION

If you invest in our common stock in this offering, your ownership interest will be immediately diluted to the extent of the difference between the public offering price per share of our common stock and the pro forma net tangible book value per share of our common stock immediately after this offering. Dilution in pro forma net tangible book value per share to new investors represents the difference between the amount per share paid by purchasers of shares of our common stock in this offering and the pro forma net tangible book value per share of our common stock immediately after completion of this offering.

Net tangible book value per share is determined by dividing our total tangible assets less our total liabilities and common stock in stockholders' equity (deficit) by the number of shares of our common stock outstanding. Our historical net tangible book value (deficit) as of December 31, 2022, was approximately \$ _____, or \$ _____ per share. After giving effect to the sale by us of shares of our common stock in this offering at the assumed public offering price of \$ _____ per share, the midpoint of the price range per share, and after deducting underwriting discounts and commissions, and estimated offering expenses payable by us, our pro forma net tangible book value as of December 31, 2022, would have been \$ _____ million, or \$ _____ per share. This represents an immediate increase in pro forma net tangible book value of \$ _____ per share to our existing stockholders and an immediate dilution in pro forma net tangible book value of \$ _____ per share to investors purchasing shares of our common stock in this offering. The following table illustrates this dilution:

Public offering price per share of common stock		\$
Historical net tangible book value (deficit) per share as of December 31, 2022	\$	
Increase per share attributable to new investors purchasing shares of common stock in this offering		
Pro forma net tangible book value per share immediately after this offering		
Dilution in pro forma net tangible book value per share to new common stock investors in this offering		\$

The following table presents, on a pro forma basis as of December 31, 2022, after giving effect to the sale by us of shares of our common stock in this offering at the assumed offering price of \$ _____ per share, the difference between the directors, officers and their affiliates and the new investors purchasing shares of our common stock in this offering with respect to the number of shares of our common stock purchased from us, the total consideration paid or to be paid to us, and the average price per share paid or to be paid to us by such persons during the last five years and new investors, before deducting underwriting discounts and commissions and estimated offering expenses payable by us:

	Shares Purchased		Total Consideration		Average Price Per Share
	Number	Percent	Amount	Percent	
			(\$ in millions)		
Directors, officers and their affiliates		%	\$	%	\$
New investors		%		%	
Total		%	\$	%	

If the underwriters exercise in full their option to purchase _____ additional shares of our common stock from us in this offering, the pro forma net tangible book value (deficit) per share after this offering would be \$ _____ per share and the dilution to new investors in this offering would be \$ _____ per share. If the underwriters exercise such option in full, the number of shares held by new investors will increase to approximately _____ shares of our common stock, or approximately _____ % of the total number of shares of our common stock outstanding after this offering.

A \$1.00 increase (decrease) in the assumed public offering price of \$ _____ per share would increase (decrease) the as-adjusted net tangible book value per share by \$ _____, and the dilution per share to new investors in this offering by \$ _____, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

In addition, we may choose to raise additional capital due to market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. To the extent that we raise additional capital through the sale of equity, as common stock, or other securities that are convertible into our common stock, such as convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis provide information which our management believes is relevant to an assessment and understanding of our results of operations and financial condition. You should read the following discussion and analysis of our results of operations and financial condition together with our financial statements and related notes and other information included elsewhere in this prospectus.

In addition to historical financial information, this discussion contains forward-looking statements based upon our current expectations that involve risks and uncertainties. Our actual results could differ materially from such forward-looking statements as a result of various factors, including those set forth under "Risk Factors" and "Cautionary Note Regarding Forward-Looking Statements" included elsewhere in this prospectus. Additionally, our historical results are not necessarily indicative of the results that may be expected for any period in the future.

Overview

We are an early pre-clinical-stage pharmaceutical company focused on the development and commercialization of a new molecular synthetic cannabinoid analog under investigation for the treatment of adult patients with anxiety and cognitive decline typically associated with early-stage dementia. Our target patient population is also typically presenting with chronic pain. Our initial drug candidate, MIRA1a, if approved by the FDA, may be a significant advancement in the treatment of neuropsychiatric, inflammatory, and neurologic diseases and disorders. Based on pre-clinical and animal studies conducted by us, we believe that MIRA1a enhances the therapeutic potential for treating anxiety, cognitive decline and chronic pain by potentially striking a balance between the beneficial effects of THC and CBD. MIRA1a achieves this by selectively targeting the cannabinoid type 1 ("CB1") and cannabinoid type 2 ("CB2") receptors. Cannabinoid receptors, located throughout the body, are part of the endocannabinoid system, which is involved in a variety of physiological processes and responses including appetite, pain-sensation, mood, and memory. With respect to THC, our clinical studies have shown that MIRA1a may have less potency at CB1 but maintains high binding at CB2. Since CB1 binding corresponds to intoxication, we believe that MIRA1a is potentially less intoxicating than THC while still providing beneficial therapeutic effects.

We had net losses of \$7.1 million for the year ended December 31, 2022 and \$2.2 million for the year ended December 31, 2021, respectively.

Supply Chain Disruption / COVID-19 Business Update

Due to the residual impact of the global COVID-19 pandemic, we have taken measures to secure our research and development activities, while work in laboratories and facilities has been organized to reduce the risk of COVID-19 transmission. The extent of the impact of the COVID-19 pandemic on our business, operations and clinical development timelines and plans remains uncertain, and will depend on certain developments, including the duration and spread of the outbreak and its impact on our clinical trials, CROs, manufacturing process, supply chain, and other third parties with whom we do business, as well as its impact on regulatory authorities and our key scientific and management personnel. While we are experiencing limited financial impacts at this time, given the global economic slowdown, the overall disruption of global supply chains and the other risks and uncertainties associated with the pandemic, our business, financial condition, and results of operations ultimately could be materially adversely affected. Some of our suppliers have experienced delays in securing critical raw materials; while this has not materially impacted their services, we have observed delays in certain activities. Therefore, we continue to closely monitor the COVID-19 pandemic as we evolve our business continuity plans, clinical development plans and response strategy.

Components of our Results of Operations

Research and Development Expenses

Research and development expenses represent costs incurred to conduct research and development of our product candidate. We recognize all research and development costs as they are incurred. Research and development expenses consist primarily of the following:

- salaries and benefits;
- contracted research and manufacturing;

- consulting arrangements; and
- other expenses incurred to advance the Company's research and development activities.

Our operating expenses have historically been the costs associated with our patent prosecution and initial investment in pre-clinical research and development activities. We expect research and development expenses will increase in the future as we advance MIRA1a into and through clinical trials and pursue regulatory approvals, which will require a significant investment in costs of clinical trials, regulatory support, and contract manufacturing. In addition, we will evaluate opportunities to acquire or in-license additional product candidates and technologies, which may result in higher research and development expenses due to license fee and/or milestone payments, as well as added clinical development costs.

The process of conducting clinical trials necessary to obtain regulatory approval is costly and time consuming. We may never succeed in timely development and achieving regulatory approval for our product candidates. The probability of success of our product candidates may be affected by numerous factors, including clinical data, competition, manufacturing capability and commercial viability. As a result, we are unable to determine the duration and completion costs of our development projects or when and to what extent we will generate revenue from the commercialization and sale of our product candidates.

General and Administrative Expenses

General and administrative expenses consist of employee-related expenses, including salaries, benefits, and travel, and other administrative functions, as well as fees paid for legal, accounting and tax services, consulting fees and facilities costs not otherwise included in research and development expense. Legal costs include general corporate legal fees and patent costs. MIRA1a expects to incur additional expenses as a result of becoming a public company, including expenses related to compliance with the rules and regulations of the SEC and Nasdaq, additional insurance, investor relations and other administrative expenses and professional services.

Interest expense

Interest expense consists of accrued interest on a related party line of credit.

Results of Operations for years ended December 31, 2022 and 2021

	Year ended December 31,	
	2022	2021
Revenues	\$ -	\$ -
Operating costs:		
General and administrative expenses	2,992,125	770,115
Related party travel costs	1,704,350	697,600
Research and development expenses	2,351,465	684,447
Total operating costs	<u>7,047,940</u>	<u>2,152,162</u>
Interest expense	(10,250)	(24,374)
Net loss	<u>\$ (7,058,190)</u>	<u>\$ (2,176,536)</u>

General and Administrative Expenses. We incurred \$3.0 million in general and administrative expenses during the year ended December 31, 2022, which consisted of payroll, consulting fees, IT-related costs, legal and accounting costs, office and rent expenses, and expenses related to investor relations, as compared to \$0.8 million during the year months December 31, 2021, which consisted of payroll, consulting fees, IT-related costs and investor relations costs.

Related party travel costs. During the year ended December 31, 2022, we incurred \$1.7 million in related party travel costs, as compared to \$0.7 million during the year ended December 31, 2021. Our related party travel costs consist of payments made in connection with an airplane lease which began in May 2021. We lease an aircraft under an operating lease with Supera Aviation I, LLC, (Supera Aviation) with monthly rental of approximately \$50,000 plus certain operating expenses. The Supera Aviation lease took effect on April 20, 2021 for a term of 24 months, but it was mutually terminated effective March 31, 2023.

Research and Development Expenses. We incurred \$2.4 million of expense during the year ended December 31, 2022, as compared to \$0.7 million during the year ended December 31, 2021, as our contract research organizations ("CROs") began substantive pre-clinical efforts on MIRA1a, primarily in the fourth quarter of 2021.

Results of Operations for years ended December 31, 2021 and 2020

	Year ended December 31,	
	2021	2020
Revenues	\$ -	\$ -
Operating costs:		
General and administrative expenses	770,115	52,982
Related party travel costs	697,600	-
Research and development expenses	684,447	14,647
Total operating costs	<u>2,152,162</u>	<u>67,629</u>
Interest expense	(24,374)	(364)
Net loss	<u>\$ (2,176,536)</u>	<u>\$ (67,993)</u>

Research and Development Expenses. We incurred \$0.7 million of expenses during the year ended December 31, 2021, as compared to \$0.01 million during the year ended December 31, 2020, as our CROs began substantive pre-clinical efforts on MIRA1a, primarily in the fourth quarter of 2021.

General and Administrative Expenses. We incurred \$0.8 million in general and administrative expenses during the year ended December 31, 2021, which consisted of payroll, consulting fees, IT-related costs, legal and accounting costs, office and rent expenses, and expenses related to investor relations, as compared to \$0.05 million during the year

ended December 31, 2020, which consisted of legal fees and website development costs.

Related party travel costs. During the year ended December 31, 2021, we incurred \$0.7 million in related party travel costs, as compared to \$0 during the year ended December 31, 2020. Our related party travel costs consist of payments made in connection with an airplane lease which began in May 2021. We lease an aircraft under an operating lease with Supera Aviation, with monthly rental of \$0.05 million plus certain operating expenses. The Supera Aviation lease took effect on April 20, 2021 for a term of 24 months which expires on April 20, 2023. The lease is renewable, at our discretion, for an additional one to three years, however, we intend to terminate the Supera Aviation lease upon the date of our IPO.

Liquidity and Capital Resources

Since the Company's inception in September 2020, we have financed our operations primarily through an unsecured line of credit with a major shareholder and through a private placement of our common stock that occurred during the fourth quarter 2021 and during 2022. We intend to finance our research and development and working capital needs from existing cash, potential new sources of debt and equity financing, including the proceeds from our anticipated initial public offering. We may enter into new licensing and commercial partnership agreements.

On April 28, 2023, we entered into a Promissory Note and Loan Agreement with the Bay Shore Trust, a trust established by our founder, Jonnie R. Williams, Sr., and under which various of his family members are beneficiaries. Under this Promissory Note and Loan Agreement (the "Bay Shore Note"), we have the right to borrow up to an aggregate of \$5,000,000 from the Bay Shore Trust at any time up to the second anniversary of the issuance of the Bay Shore Note or, if earlier, upon the completion of our initial public offering. Our right to borrow funds under the Bay Shore Note is subject to the absence of a material adverse change in our assets, operations, or prospects. The Bay Share Note, together with accrued interest, will become due and payable on the second anniversary of the issuance of the note, provided that it may be prepaid at any time without penalty. The Bay Shore Note will accrue interest at a rate equal 7% per annum, simple interest, during the first year that the note is outstanding and 10% per annum, simple interest, thereafter. The Bay Shore Note is unsecured. As of April 28, 2023, we have borrowed an aggregate of \$0.2 million under the Bay Shore Note. The Bay Shore Note replaced a Line of Credit Agreement that we entered into with The Starwood Trust, a separate trust established by our founder, in May 2021 and pursuant to which we had an outstanding principal balance of \$0.2 as of the date of the Bay Shore Note (which outstanding balance was retired with an advance under the Bay Shore Note).

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As of December 31, 2022 and December 31, 2021, we had cash of \$0.4million and \$2.8 million, respectively. We raised \$4.5 million during the year ended December 31, 2021, and an additional \$3.2 million in 2022. Substantially all of our equity capital has been raised at \$1.00 per share. We used \$5.6 million in operating activities during the year ended December 31, 2022, compared to \$1.4 million in operating activities during the year ended December 31, 2021. We expect that our existing cash and available line of credit, before our anticipated initial public offering, will be sufficient to finance our planned level of operations through the second quarter of 2024.

We currently anticipate that we will seek to monetize our initial product candidate, MIRA1a, at the end of our planned Phase 2 study. Prior to that time, we anticipate that additional capital may be required to support ongoing activities and further phases of development. Should that be required, our available capital may be consumed more rapidly than currently anticipated, resulting in the need for additional funding. In addition, there can be no assurance that additional funding, when and if required, will be available at commercially favorable terms, if at all.

Accordingly, we may need to raise additional capital, which may be available to us through a variety of sources, including:

- public equity markets;
- private equity financings;
- commercialization agreements and collaborative arrangements;
- sale of product royalty;
- grants and new license revenues;
- bank loans; and
- public or private debt.

Additional funding, capital, or loans (including, without limitation, milestone, or other payments from potential commercialization agreements) may be unavailable on favorable terms, if at all. If adequate funds are not available, we may be required to significantly reduce or refocus our operations or to obtain funds through arrangements that may require us to relinquish rights to certain technologies and drug formulations or potential markets, any of which could have a material adverse effect on us, our financial condition, and our results of operations. To the extent that additional capital is raised through the sale of equity or convertible debt securities or exercise of warrants and options, the issuance of such securities would result in ownership dilution to existing stockholders.

If we are unable to attract additional funds on commercially acceptable terms, it may adversely affect our ability to achieve our development and commercialization goals, which could have a material and adverse effect on our business, results of operations and financial condition.

Recently Issued and Adopted Accounting Pronouncements

A description of recently issued and adopted accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 8 to our financial statements appearing at the end of this prospectus.

Off-Balance Sheet Arrangements

During the periods presented, we did not have, nor do we currently have, any off-balance sheet arrangements as defined under SEC rules.

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Quantitative and Qualitative Disclosures about Market Risk

We are exposed to market risks in the ordinary course of our business. These risks primarily include interest rate risks and inflation risks. Periodically, we maintain deposits in accredited financial institutions in excess of federally insured limits. We deposit our cash in financial institutions that we believe have high credit quality and have not experienced any losses on such accounts and do not believe we are exposed to any unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

Interest Rate Risk

Our cash consists of cash in readily available checking accounts. We may also invest in short-term money market fund investments. Such interest-earning instruments carry a degree of interest rate risk; however, historical fluctuations in interest income have not been significant.

Inflation Risk

Inflation generally affects us by increasing our cost of labor and research and development contract costs. We do not believe inflation has had a material effect on our results of operations during the periods presented.

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BUSINESS

Overview

We are an early pre-clinical -stage pharmaceutical company focused on the development and commercialization of a new molecular synthetic cannabinoid analog under investigation for the treatment of adult patients with anxiety and cognitive decline typically associated with early-stage dementia. Our target patient population is also typically presenting with chronic pain. Our drug candidate, MIRA1a, if approved by the FDA, may be a significant advancement in the treatment of neuropsychiatric, inflammatory, and neurologic diseases and disorders. Based on pre-clinical and animal studies conducted by us, we believe that MIRA1a enhances the therapeutic potential for treating anxiety, cognitive decline and chronic pain by potentially striking a balance between the beneficial effects of THC and CBD. MIRA1a achieves this by targeting the cannabinoid type 1 (“CB1”) and cannabinoid type 2 (“CB2”) receptors. Cannabinoid receptors, located throughout the body, are part of the endocannabinoid system, which is involved in a variety of physiological processes and responses including appetite, pain-sensation, mood, and memory. With respect to THC, our clinical studies have shown that MIRA1a may have less potency at CB1 but maintains high binding at CB2. Since CB1 binding corresponds to intoxication, we believe that MIRA1a is potentially less intoxicating than THC while still providing beneficial therapeutic effects. In addition, by curbing the negative effects of THC (e.g. cognitive impairment), studies suggest that MIRA1a may be capable of unmasking positive therapeutic effects not previously seen with THC (e.g. cognitive performance enhancement).

On November 28, 2022, the DEA confirmed in writing that it conducted a scientific review of the chemical structure of MIRA1a in accordance with the definitions within the CSA and its implementing regulations and determined that MIRA1a is not a controlled substance or listed chemical.

We were organized as a Florida corporation in September 2020 and commenced substantive operations in late 2020, at which time we commenced our pharmaceutical development program.

We had net losses of \$7.1 million for the year ended December 31, 2022, and \$2.2 million for year ended December 31, 2021, respectively.

Our Product Candidate in Development

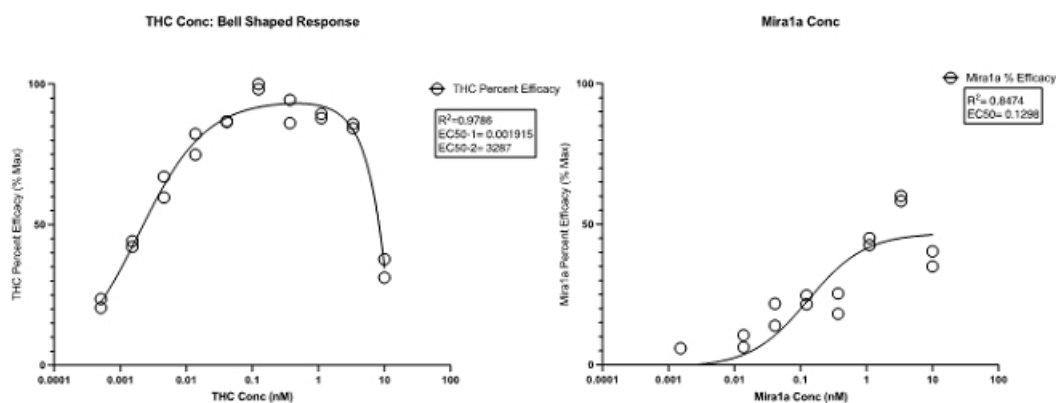
Our objective is to develop and commercialize new treatment options for neuropsychiatric, inflammatory, neurologic, and oncologic diseases and disorders. Cannabinoids are a class of chemical compounds that are naturally occurring and are primarily found in cannabis plant extracts. The two major cannabinoids found in cannabis plant extracts include THC and CBD. These compounds bind to CB1 and CB2 cannabinoid receptors, which are found throughout the body. Specifically, CB1 receptors are concentrated in the central nervous system (“CNS”), while CB2 receptors are found mostly in peripheral organs and are associated with the immune system. When the chemical compounds bind to these cannabinoid receptors, the process elicits certain physiological responses. Physiological responses to cannabinoids may vary among individuals. Some of the effects of cannabinoids have been shown to impact nervous system functions, immune responses, muscular motor functions, gastrointestinal maintenance, blood sugar management, and the integrity of ocular functions. Our product candidate, MIRA1a, has a strong selectivity for CB2 versus CB1, and is designed to minimize the risk of psychoactive adverse events associated with CB1 activation.

Mechanism of Action of MIRA1a

We believe that the effects of MIRA1a at the cannabinoid receptors CB1 and CB2 is predicted to account for the majority of its potential therapeutic effects, especially as it relates to its anti-anxiety, anti-pain and anti-inflammatory properties. For example, the difference in the dose-response effects of MIRA1a compared with THC on CB1 receptors appears to coincide with its improved therapeutic profile.

THC is notorious for having biphasic physiological effects, which have been described for over 40 years: at low levels THC has positive effects while high doses cause the opposite, undesirable symptoms. Examples of biphasic effects at low versus high levels of THC include the anti-anxiety versus pro-anxiety effects, respectively. We obtained the following dose-response effects for MIRA1a and THC at the CB1 receptor (see below). In contrast to THC, which displays an initial maximally stimulatory and then inhibitory response at CB1, MIRA1a appears to act as a monophasic partial agonist where it is stimulatory throughout its dose range, achieving a moderate activation of the CB1 even at high doses. We believe that this accounts for the potential broad therapeutic efficacy of MIRA1a and the observed absence of negative symptoms even at maximal doses of the drug.

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Unlike CB1 receptors that mediate many of the psychotropic effects of cannabinoids on the CNS, CB2 receptors are predominantly present on cells of the immune system. Based on preliminary results of our GPCR biosensor assays, the CB2 receptor agonistic effects of MIRA1a are 8-fold more potent than THC and 30-fold more potent than CBD, which predicts that MIRA1a is likely much more efficacious as a potential therapeutic for inflammatory, autoimmune, and neurodegenerative conditions.

As of the end of fiscal 2022, we completed several pre-clinical studies of MIRA1a, including, but not limited to, computational mutagenicity analysis, radio-ligand binding assay, elevated plus maze (“EPM”) model of anxiety and hot plate model thermal sensitivity testing.

We have studied the effects of acute administration of MIRA1a on anxiety-related phenotypes in mice to model human conditions. An intraperitoneal injection of Placebo [PBO] (e.g. saline) or MIRA1a (e.g. 50mg/kg = Treatment) was administered to 8-12 week-old C57Bl/6 mice (n=5/group). Thirty minutes following injection, mice were tested in anxiety related measures using the Elevated Plus Maze (EPM). The EPM is a widely used pre-clinical behavioral assay for rodents and it has been validated to assess the anti-anxiety effects of pharmacological agents. We found that MIRA1a has potent anti-anxiety at doses that lacked side effects of sedation or intoxication. The EPM is a test measuring anxiety in rodents as a screening test for putative anxiolytic compounds and as a general research tool in neurobiological anxiety research such as Generalized Anxiety Disorder (GAD) or Post-Traumatic Stress Disorder (PTSD). The model is based on the animal’s aversion to open spaces which are present in the open arms (Open Arm) of the maze. Anti-anxiety effects of test agents are demonstrated by an increase in the percentage of time spent in the Open Arm with treatment compared to placebo. The total distance traveled is a measure of the overall level of arousal and mobility of the mice undergoing testing on the EPM and is used to rule out any sedating or intoxicating effects of the test agent.

Pre-clinical studies also have shown MIRA1a’s potential for relieving pain. A number of clinically approved pharmacological agents used to treat pain, including opioids, have been demonstrated to delay or ameliorate the onset of heat sensitivity upon paw exposure of mice to heat. Thirty minutes after treatment with either a placebo (control) or MIRA1a, mice were placed on a heated plate to measure the time it took for each mouse to lift its paw in response to the mild pain they felt from the heat. Mice treated with pain alleviating drugs took significantly longer to become bothered by the heat and to lift their paws. Similarly, mice treated with MIRA1a statistically took significantly more time to lift their legs, indicating MIRA1a’s potential effectiveness as a possible treatment for pain in this model.

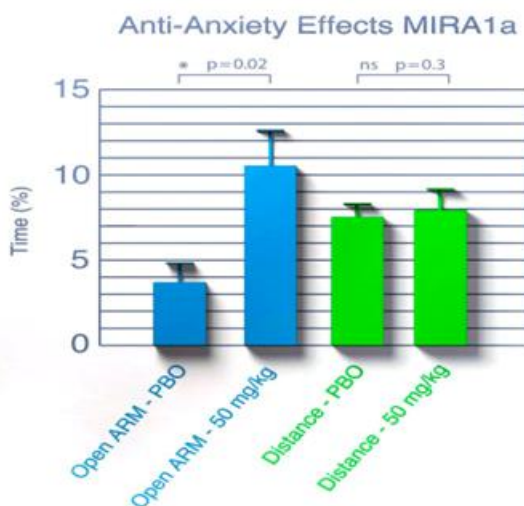
MIRA1a is a CB2 agonist which may be an optimal treatment for neurodegenerative diseases associated with neuroinflammation caused by microglial activation. CB2 agonism has been shown in pre-clinical studies to regulate neuroinflammatory processes, reducing the neuronal damage characteristic of degeneration. We believe there may be a strong rationale for CB2 agonism in neurodegenerative diseases, given increased CB2 expression in patients with these diseases as well as preliminary results from animal models. We see potential for a potent CB2 agonist to treat a range of neurodegenerative diseases. MIRA1a, through its robust activity at CB2 compared to CB1, was designed to minimize the risk of psychotropic adverse events associated with CB1 activation.

Our pre-clinical development program for MIRA1a has included a variety of testing. Summarized below are the tests we have completed.

Table: Pre-clinical Tests

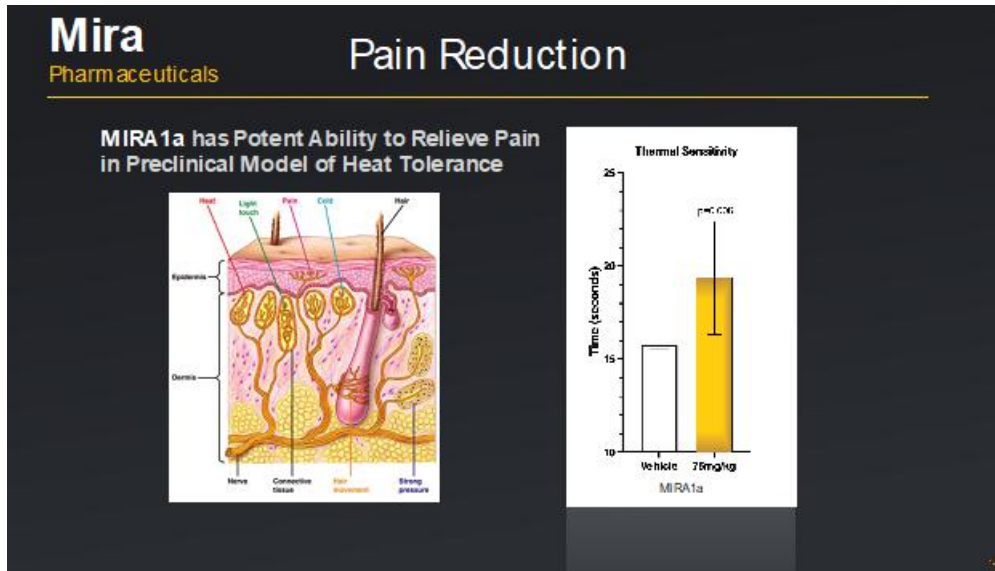
Status	Completed Tests
Group 1	<ul style="list-style-type: none"> ● Computational Mutagenicity Analysis ● Radioligand Binding ● EPM model of anxiety ● Thermal Sensitivity Model of Pain ● Trace Fear Conditioning Model of Cognition ● Rat Psychomotor Vigilance Test (“PVT”) of Cognition
Group 2	<ul style="list-style-type: none"> ● Insilico ICH7/M7 ● Micronucleus Assay ● AMES Test ● Metabolic Profiling ● Safety Screen 44

- EPM Model of Anxiety Test:
 - Method: We studied the effect of acute administration of MIRA1a on anxiety-related phenotypes in mice to model human conditions.
 - An intraperitoneal (i.p.) injection of Placebo (e.g. saline) or MIRA1a (e.g. 50mg/kg = Treatment) was administered to 8 -12-week-old C57Bl/6 mice (n=5/group)
 - 30 minutes following injection, mice were tested in anxiety related measures using EPM
 - Outcome: The following chart demonstrates MIRA1a’s anti-anxiety effects:



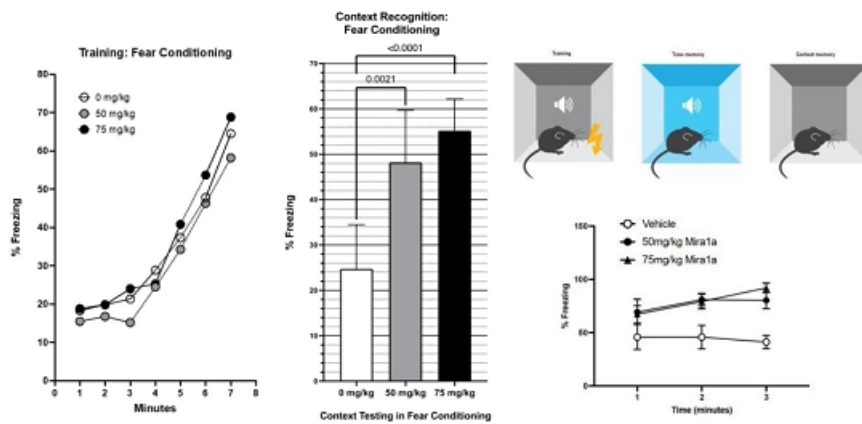
- Thermal Sensitivity Model of Pain:
 - Method: We studied the potential for pain reduction in pre-clinical models of heat tolerance using a hot plate methodology.

- **Outcome:** MIRA1a provided significantly delayed thermal sensitivity and enhanced pain tolerance.

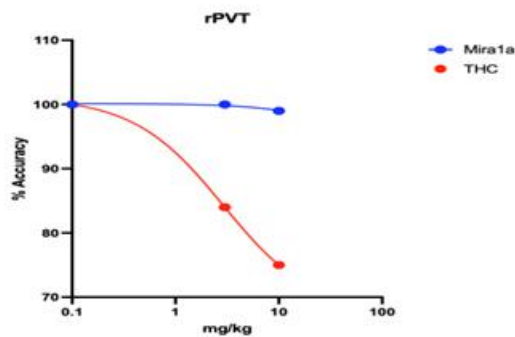


- Trace Fear Conditioning Model of Cognition:
 - **Method:** We studied the potential for improving recall in healthy mice using a fear conditioning model.
 - **Outcome:** MIRA1a sharply improves cognitive recall as dosage rises.

Cognition in Mouse Model of Fear Conditioning



- Rat PVT of Cognition
 - **Method:** We performed a PVT to evaluate simple reaction time.
 - **Outcome:** MIRA1a does not impair cognition. At 3 mg/kg and 10 mg/kg MIRA1a causes minimal impairment in rat PVT whereas THC has a clear negative effect even at these low doses.



In 2023, our pre-clinical work will include the conduct of several other pre-clinical studies and initiation of a 7-day maximum tolerated dose study of MIRA1a in rats and dogs.

Status	Planned Activity
Drug Substance Preparation	<ul style="list-style-type: none"> • Analytical Development • NonGMP Production Refinement • GMP Production Refinement

Testing	<ul style="list-style-type: none"> ● MTD/7D DRF Dog ● MTD/7D DRF Rat ● Dog 28-day Toxicology ● Rat 28-day Toxicology ● Cardiovascular Study Dog (Telemetry) ● Respiratory Study Rat ● hERG (Manual Patch-Clamp) ● Neurobehavioral Evaluation Rats ● Neurobehavioral Evaluation Mice
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We further plan on neurobehavioral evaluation of orally and intraperitoneally administered MIRA1a in rats and mice, respiratory evaluation of orally administered MIRA1a in rats, and in vitro testing for effects of MIRA1a on hERG (the human Ether-à-go-go-Related Gene) channel currents. The hERG is an early in vitro assay required by the FDA to alert companies of any potential cardiac abnormalities by the product before proceeding with dose studies in humans. hERG is a gene that codes for a protein known as the alpha subunit of a potassium ion channel. This ion channel (sometimes simply denoted as ‘hERG’) is best known for its contribution to the electrical activity of the heart: the hERG channel mediates the repolarizing current in the cardiac action potential, which helps coordinate the heart’s beating. When this channel’s ability to conduct electrical current across the cell membrane is inhibited or compromised, either by application of drugs or by rare mutations in some individuals, it can result in a potentially fatal disorder called long QT syndrome.

Testing is anticipated to conclude in the first quarter of 2024. Additionally, a 28-day toxicology analysis for dogs and rats is expected to begin at the end of the fourth quarter of 2023 and continue through the first quarter of 2024.

We have started the analytical development and manufacturing of MIRA1a as of January 2023. By the third quarter of 2023, we anticipate our suppliers will be developing MIRA1a at scale and manufactured under cGMP conditions, expanding on earlier non-GMP volumes of MIRA1a for use in our initial testing programs. We plan to work closely with our suppliers to generate sufficient volumes of cGMP-grade MIRA1a materials for the planned pre-clinical toxicity programs, expanded animal testing and human trials expected to be performed in 2024, subject to FDA approval.

Clinical Development Program

Following the pre-clinical development plan outlined above, we plan to submit to the FDA an Investigational New Drug application (“IND”) focused on investigating MIRA1a for the treatment of anxiety and cognitive decline in elderly patients.

Our first IND application submission investigating MIRA1a for the treatment of elderly patients suffering from anxiety with some cognitive decline is currently planned for the end of the second quarter of 2024, as we believe this is a patient population with unmet needs. If allowed to proceed by the FDA, a Phase I trial will be initiated 30 days post-IND submission. After the Phase I trial is complete, a Phase II trial in this same study subject population is planned to commence by the end of the fourth quarter of 2024. We believe that an overlapping (hybrid) Phase I and Phase II can be designed and allowed to proceed by the FDA, allowing us to accelerate the development of MIRA1a.

Our second IND application will focus on investigating MIRA1a for the treatment of chronic pain and is planned for submission during the third quarter of 2025. If allowed to proceed by the FDA, a Phase II trial will begin in the third quarter of 2026.

All development plans depend on FDA acceptance of our IND applications. As appropriate and pursuant to discussions with the FDA, we may periodically adjust the timeline for certain filings and associated clinical trials. It is important to note that the process for conducting clinical trials is uncertain and there is no assurance that our clinical development activities will meet the planned timelines set forth above.

Manufacture of Product for Clinical Development Activities

Curia Global (formerly AMRI), a leading global CDMO, is currently developing a large-scale synthesis protocol for us and will be supplying quantities of MIRA1a needed for our pre-clinical and clinical development activities. We are currently in discussions with other partners to have MIRA1a formulated into solid oral dosage forms for clinical trials.

Market Opportunity

MIRA1a, if approved, will compete in 3 key overlapping growth markets: the anxiety, cognitive decline (dementia), and chronic pain markets where multiple products with varying safety and efficacy profiles are already on the market. MIRA1a competes at the intersection of these three markets given the target patient profile previously outlined.

According to the IQVIA Report, the global market for medicines is expected to grow to \$1.9 trillion by 2027, driven by a variety of factors including the launch of new medicines, an expansion in specialized medicines and biosimilars. Our key competitive market, the US market, is expected to grow between one and two percent on a net price basis to \$763 billion by 2027 due to a variety of variables including the impact of loss of exclusivity, biosimilars, and discounting associated with the Inflation Reduction Act.

MIRA1a will compete primarily within the central nervous system (“CNS”) market that encapsulates anxiety, dementia, other pain, Alzheimer’s, migraines and related conditions. The IQVIA Report estimates that by 2027, the global CNS market will be worth \$81 billion, growing between two and five percent during the period from 2023 to 2027. Within that market opportunity, anxiety is worth between approximately \$20 billion and \$25 billion in annual sales.

Anxiety and pain are expected to grow approximately five percent over the same period, while Alzheimer is expected to grow approximately twelve percent. This is critical given MIRA1a’s focus on early-stage patients with dementia, as, according to the IQVIA Report, approximately 10 million new cases of dementia emerge globally each year, with Alzheimer’s disease as the leading cause. Thus, Alzheimer’s case directions are an important signal and gateway for MIRA1a-related opportunities.

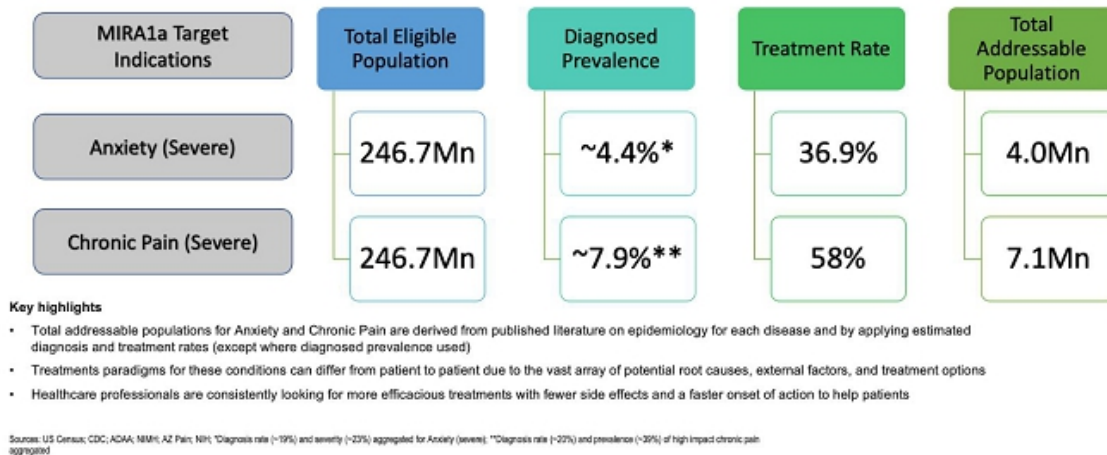
MIRA1a’s other key market will be the traditional pain market, which the IQVIA Report estimates will be worth \$42 billion in 2027 and grow between three and six percent during the forecast period. Note that this sizing is inclusive of chronic and acute pain, and MIRA1a is likely to only be used in the chronic segment of the market (approximately 40% to 50% of the market). Factors such as a rise in oncology related pain, diabetic neuropathy, and pain associated with aging (e.g. joint pain) are among the key drivers of patient and prescription growth. We believe that MIRA1a’s expected safety and toxicity profile should provide it with an edge over existing medicines categories such as opioids, allowing it to gain share in that market as well. Given the overlap across indications and the fact that the target patient is presenting across these markets, MIRA1a will be competing in a complex market valued by the IQVIA Report at over an estimated \$120 billion globally per annum.

Thus, our initial focus will be a dual path: potentially winning in traditional markets as well as the marijuana analog markets using a safe, effective and FDA-approved treatment option. Today, legal medical marijuana is a \$13.2 billion industry whereas legal recreational marijuana is a \$25.6 billion industry. Both are sub-sets of the traditional

pain and anxiety markets. However, in many patient populations, non-US legal, and cultural settings, marijuana may not be the first or a viable option for treatment of neurological disorders. As a result, these patients will typically use non-steroidal anti-inflammatory drugs (NSAIDs) or various mood management drugs, opening them up to a range of non-ideal outcomes. MIRA1a's objective is to offer physicians and patients an approved, viable synthetic option. Thus, if approved by the FDA, we believe that MIRA1a may potentially provide a preferred alternative in such patient populations, as it is not derived from the marijuana plant.

Summary of US Epidemiology

The eligible patient pool analysis for MIRA1a highlights a large patient pool looking for potential treatments to their conditions



Total addressable populations for anxiety and chronic pain are derived from published literature on epidemiology for each disease and by applying estimated diagnosis and treatment rates (except where diagnosed prevalence used). Treatments paradigms for these conditions may differ from patient to patient due to the vast array of potential root causes, external factors, and treatment options and healthcare professionals are consistently looking for more efficacious treatments with fewer side effects and a faster onset of action to help patients.

Our Market Advantage

MIRA1a is being developed as the first manufactured prescription drug to potentially target the CB1 and CB2 receptors for chronic pain and anxiety without the impurities of marijuana or its side effects, such as increased appetite and paranoia. MIRA1a is the first cannabinoid that has demonstrated the ability to improve cognitive performance in pre-clinical studies. MIRA1a is a novel synthetic cannabinoid analog directed at potentially treating patients with dementia associated cognitive decline and anxiety diagnoses. Unlike other cannabinoids in the market, MIRA1a is not derived from plants. Plants generate alkaloids as a defense mechanism, and it has been speculated that plant-derived cannabinoids have adverse side effects in humans.

Furthermore, in animal studies conducted by us, MIRA1a has preliminarily demonstrated more than 30-fold increased CB2 activation compared to CBD and more potent anti-inflammatory, anti-seizure, anti-cancer properties.

Unlike competitive products and product candidates that are scheduled, MIRA1a has been determined by the DEA not to be a controlled substance or listed chemical. As such, we believe that MIRA1a has a distinct competitive advantage by being poised to move through the regulatory approval process at a faster pace than that of competing scheduled product candidates.

Finally, with patent protection already in place in the United States, as well as in several of the largest pharmaceutical markets outside of the United States, the company is well positioned to enjoy market exclusivity in the United States for MIRA1a for several years upon receiving regulatory approval, and potentially in markets outside of the United States pending acquisition of foreign intellectual property rights.

Our Strategy

Our goal is to develop therapeutics targeting well-characterized CB1 and CB2 receptors with optimized pharmacological properties to transform the lives of patients with neurological and oncologic diseases. Key elements of our strategy to achieve this goal include:

- Advance our MIRA1a through clinical development and approval.** Our product candidate, MIRA1a, is in pre-clinical studies. Existing treatment options for neuropsychiatric disorders and neurological diseases have significant limitations, and, if approved, we believe MIRA1a would represent a major therapeutic advancement for patients.
- Continue pre-clinical development of MIRA1a across a range of CNS diseases associated with neurodegeneration and progress into clinical development.** MIRA1a is currently in IND-enabling studies for neurobehavioral disorders such as dementia, Post-Traumatic Stress Disorder (PTSD), chronic pain, as well as neurodegenerative diseases such as Alzheimer's and Parkinson's Disease. We believe MIRA1a may have potential in several diseases associated with neuroinflammation, including multiple sclerosis.
- Identify additional product candidates and expand current candidates into additional neurological diseases.** We see potential for our current product candidate to be evaluated in clinical trials outside of its initial indications and will evaluate additional indications to maximize the potential of our drug development program. Our current product focus is on targets that are well characterized in neurological diseases but for which there are limitations with currently available therapies. We also plan to continue to identify and develop additional novel product candidates that align with our focus.
- Explore strategic collaborations to maximize the value of our product candidates.** We plan to explore collaborations opportunistically to maximize the value of our product candidates. We intend to retain significant economic and commercial rights to our programs in key geographic areas that are core to our long-term strategy.

Competition

We are subject to competition from pharmaceutical and biotechnology companies and academic and research institutions. We believe our future success will depend,

in large part, on our ability to maintain a first mover advantage and competitive lead in our industry.

Competition arises mainly from two sources, traditional cell-based in vitro culture approaches and traditional in vivo animal models and testing. We also face future competition from companies developing cannabinoid therapies, as summarized in the table below:

FDA/EMCDA Approved Cannabinoid Therapies

Cannabis therapies currently authorized by regulators					
Brand Name	Originator	Description	Indications	Form	Location of Approvals
Sativex (nabiximols)	GW	Extract of cannabis: mix of delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD), 1:1 ratio	Multiple Sclerosis	Sublingual Spray	25 Countries in Europe, Latin America, North America and Australia. Not approved in the US
Marinol (dronabinol) Schedule 3	Unimed	Synthetic delta-9-THC	Loss of appetite, in people with AIDS and nausea and vomiting caused by chemotherapy	Capsules	US, Canada, Germany, Australia, and New Zealand
Syndros (dronabinol) Schedule 2	Insys	Synthetic delta-9-THC	Loss of appetite, in people with AIDS and nausea and vomiting caused by chemotherapy	Liquid	US
Cesamet (nabilone) Schedule 2	Lilly	Synthetic cannabinoid similar to THC	Nausea and vomiting caused by chemotherapy	Capsules	US, Canada, Europe, Australia
Epidolex Unscheduled	GW	Cannabidiol (CBD)	Dravet and Lennox-Gastaut syndrome (pediatric epilepsies)	Liquid	US

Source: European Monitoring Centre for Drugs and Addiction, FDA, drug labels, company reports

Sativex (delta-9-tetrahydrocannabinol and cannabidiol in the EU) is an oromucosal spray indicated as treatment for symptom improvement in adult patients with moderate to severe spasticity due to multiple sclerosis (MS) who have not responded adequately to other anti-spasticity medication and who demonstrate clinically significant improvement in spasticity related symptoms during an initial trial of therapy. Sativex is not assigned a schedule in the U.S. by the DEA as it is not approved but is a Class B controlled drug under the Misuse of Drugs Act 1971 and is placed in Schedule 4 to the Misuse of Drug Regulations 2001 in the United Kingdom.

Marinol (dronabinol) is an oral cannabinoid indicated in adults for the treatment of: Anorexia associated with weight loss in patients with AIDS and nausea and vomiting associated with cancer chemotherapy in patients who have failed to respond adequately to conventional antiemetic treatments. Marinol is a Schedule III controlled substance.

Cesamet (Nabilone) is a synthetic cannabinoid for oral administration that are indicated for the treatment of the nausea and vomiting associated with cancer chemotherapy in patients who have failed to respond adequately to conventional antiemetic treatments. Cesamet contains nabilone, which is a controlled in Schedule II of the Controlled Substances Act (CSA).

Intellectual Property

Our company owns U.S. Patent 10,787,675 B2, titled “Purified Synthetic Marijuana and Methods of Treatment by Administering Same,” which covers the MIRA1a compound *per se* as a racemic mixture, an isolated R-enantiomer, or an isolated S-enantiomer, as well as pharmaceutical formulations of the compound. This patent also covers MIRA1a in methods of treating Alzheimer’s disease, anxiety, depression, and addictions.

Foreign patents covering MIRA1a, and its therapeutic uses have issued in Australia, Belgium, Canada, Czech Republic, France, Germany, Greece, Netherlands, Hungary, Ireland, Israel, Italy, Malta, Poland, Portugal, Romania, South Korea, Spain, Sweden, and the United Kingdom, and corresponding applications are pending in China and Japan. MyMD Pharmaceuticals, Inc. (“MyMD”), a publicly traded New Jersey corporation, currently owns these foreign patents and patent applications. We may in the future seek an agreement under which we would acquire such patent rights through purchase or license, but we currently have no agreement with MyMD with respect to such patent rights. We have a perpetual license from MyMD allowing our company to use MyMD’s Supera-CBD as a synthetic intermediate in the manufacture of MIRA1a for research and development activities and have the right to commercial uses in the United States and in jurisdictions other than those mentioned above where MyMD holds foreign patent rights. Except for this license, we do not license any patent rights or other intellectual property for MIRA1a from third parties.

Besides relying on patents, we also rely on trade secrets, proprietary know-how and continuing innovation to develop and maintain our competitive position, especially when we do not believe that patent protection is appropriate or can be obtained. We seek protection of these trade secrets, proprietary know-how and any continuing innovation, in part, through confidentiality and proprietary information agreements. However, these agreements may not provide meaningful protection for, or adequate remedies to protect, our technology in the event of unauthorized use or disclosure of information. Furthermore, our trade secrets may otherwise become known to, or be independently developed by, our competitors. We intend to seek appropriate patent protection for technology in our research and development programs, where applicable, and their uses by filing patent applications in the United States and other selected countries. We intend for these patent applications to cover, where possible, claims for compositions of matter, medical uses, processes for preparation and formulations.

Regulation

The U.S. Food and Drug Administration (FDA) and comparable regulatory authorities in state and local jurisdictions impose substantial and burdensome requirements upon companies involved in the clinical development, manufacture, marketing, and distribution of drugs. These agencies and other federal, state, and local entities regulate, among other things, the research and development, testing, manufacture, quality control, safety, effectiveness, labeling, storage, record keeping, approval, advertising and promotion, distribution, post-approval monitoring and reporting, sampling and export and import of our drug candidates.

U.S. Government Regulation

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or FDCA, and its implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may

subject an applicant to a variety of administrative or judicial sanctions, such as the FDA's refusal to approve pending New Drug Applications (NDAs), withdrawal of an approval, imposition of a clinical hold, issuance of warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties.

The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- completion of pre-clinical laboratory tests, animal studies and formulation studies in compliance with the FDA's good laboratory practice ("GLP") regulations;
- submission to the FDA of an Investigational New Drug ("IND") application, which must become effective before human clinical trials may begin;
- approval by an independent Institutional Review Board ("IRB"), at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practices ("GCP") requirements to establish the safety and efficacy of the proposed drug product for each indication;
- demonstration that the API and finished product are manufactured under cGMP conditions and meet all applicable standards of identity, strength, quality, and purity;
- submission to the FDA of an NDA;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with cGMP requirements and to assure that the facilities, methods, and controls are adequate to preserve the drug's identity, strength, quality, and purity;
- FDA review and approval of the NDA, including consideration of the views of any FDA advisory committee, prior to commercial marketing or sale of the drug in the United States; and
- compliance with any post-approval requirements, including the potential requirement to implement a Risk Evaluation and Mitigation Strategy ("REMS") or to conduct a post-approval study.

Pre-clinical studies

Before testing any drug or biological product candidate in humans, the product candidate must undergo rigorous pre-clinical testing. The pre-clinical developmental stage generally involves laboratory evaluations of drug chemistry, formulation, and stability, as well as studies to evaluate toxicity in animals, to assess the potential for adverse events ("AEs") and, in some cases, to establish a rationale for therapeutic use. The conduct of pre-clinical studies is subject to federal regulations and requirements, including GLP regulations for safety/toxicology studies. An IND sponsor must submit the results of the pre-clinical studies, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND.

An IND is a request for authorization from the FDA to ship an investigation product and then administer it to humans and must be allowed to proceed by the FDA before human clinical trials may begin. Some long-term pre-clinical testing, such as animal tests of reproductive AEs and carcinogenicity, may continue after the IND is submitted. An IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions before that time related to one or more proposed clinical trials and places the trial on clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence.

Clinical trials

The clinical stage of development involves the administration of the investigational product to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by, or under control of, the trial sponsor, in accordance with GCPs, which include the requirement that all research patients provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria and the parameters to be used to monitor subject safety and assess efficacy. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Furthermore, each clinical trial must be reviewed and approved by an IRB for each institution at which the clinical trial will be conducted to ensure that the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. There also are requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries. Information about most clinical trials must be submitted within specific timeframes for publication on the www.clinicaltrials.gov website. Information related to the product, patient population, phase of investigation, study sites and investigators and other aspects of the clinical trial is made public as part of the registration of the clinical trial. Sponsors are also obligated to disclose the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed in some cases for up to two years after the date of completion of the trial. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs.

Human clinical trials are typically conducted in three sequential phases, which may overlap or be combined:

- Phase I clinical trials generally involve a small number of healthy volunteers or disease-affected patients who are initially exposed to a single dose and then multiple doses of the product candidate. The primary purpose of these clinical trials is to assess the metabolism, pharmacologic action, side effect tolerability and safety of the drug.
- Phase II clinical trials involve studies in disease-affected patients to determine the dose required to produce the desired benefits. At the same time, safety and further pharmacokinetic and pharmacodynamic information is collected, possible adverse effects and safety risks are identified, and a preliminary evaluation of efficacy is conducted.
- Phase III clinical trials generally involve a larger number of patients at multiple sites and are designed to provide the data necessary to demonstrate the effectiveness of the product for its intended use, its safety in use and to establish the overall benefit/risk relationship of the product and provide an adequate basis for product approval. These trials may include comparisons with placebo and/or other comparator treatments. The duration of treatment is often extended to mimic the actual use of a product during marketing.

Post-approval trials, sometimes referred to as Phase IV clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow up. In certain instances, the FDA may mandate the performance of Phase IV clinical trials as a condition of approval of an NDA or a Biologics License Application ("BLA").

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if significant adverse events ("SAEs") occur. The FDA or the sponsor may suspend or terminate a clinical trial at any time, or the FDA may impose other sanctions on various grounds, including a finding that the research patients are being exposed to an unacceptable health risk. Similarly, an IRB can refuse, suspend, or terminate approval of a clinical trial at its institution if the clinical

trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients.

Concurrently with clinical trials, companies usually complete additional pre-clinical studies and must also develop additional information about the physical characteristics of the drug or biological product as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the sponsor must develop methods for testing the identity, strength, quality, potency, and purity of the final biological product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the biological product candidate does not undergo unacceptable deterioration over its shelf life.

Marketing Approval

Assuming successful completion of the required clinical testing, the results of the pre-clinical studies and clinical trials, together with detailed information relating to the product's chemistry, manufacture, controls, and proposed labeling, among other things, are submitted to the FDA as part of an NDA requesting approval to market the product for one or more indications. In most cases, the submission of an NDA is subject to a substantial application user fee.

The review process typically takes twelve months from the date the NDA is submitted to the FDA. The FDA conducts a preliminary review of all NDAs within the first 60 days after submission to determine whether they are sufficiently complete to permit substantive review before accepting them for "filing." The FDA may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information and may be subject to an additional application user fee. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA reviews an NDA to determine, among other things, whether the drug is safe and effective and whether the facility in which it is manufactured, processed, packaged, or held meets standards designed to assure the product's continued safety, quality and purity. Under the current guidelines in effect in the Prescription Drug User Fee Act (PDUFA), the FDA has a goal to review and act on the submission within ten months from the completion of the preliminary review of a standard NDA for a new molecular entity.

The FDA also may require submission of a REMS plan to ensure that the benefits of the drug outweigh its risks. The REMS plan could include medication guides, physician communication plans, assessment plans, and/or elements to assure safe use, such as restricted distribution methods, patient registries, or other risk minimization tools.

The FDA may refer an application for a novel drug to an advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA may inspect one or more clinical trial sites to assure compliance with GCP requirements.

After evaluating the NDA and all related information, including the advisory committee recommendation, if any, and inspection reports regarding the manufacturing facilities and clinical trial sites, the FDA may issue an approval letter, or, in some cases, a complete response letter. A complete response letter generally contains a statement of specific conditions that must be met in order to secure final approval of the NDA and may require additional clinical trials or pre-clinical studies in order for FDA to reconsider the application. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

Post-approval requirements

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims are subject to prior FDA review and approval. There also are continuing, annual user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data.

Properties

Our administrative and accounting office is located in Tampa, Florida. We currently lease approximately 2,279 square feet of office space under a lease that is due to expire on March 31, 2024. We share the office and costs in Tampa with two other companies. Our corporate headquarters and executive offices are in Baltimore, Maryland. Our Baltimore location, which comprises approximately 150 square feet, is under a lease that us due to expire on November 30, 2023. We believe that this facility will be sufficient for our current and planned operations, although we may require additional office and laboratory space in Baltimore for our planned operations as we progress our programs.

Employees

As of May __, 2023, we had __ full-time employees and __ part-time employees. As of such date, we were also utilizing the services of one employee of an affiliate of our founder on an outsourced basis, who renders services to us on a part-time basis. We anticipate that the outsourced employee of such affiliated company who currently works for us on a part-time basis will become a part-time employee of our company upon the completion of this offering. None of our employees are represented by a labor union or are covered by a collective bargaining agreement. We consider our relationship with our employees to be satisfactory. In addition, we utilize the services of part-time outside consultants and contractors to perform several tasks for us.

Legal Proceedings

From time to time, we may be named in claims arising in the ordinary course of business. Currently, no legal proceedings, government actions, administrative actions, investigations, or claims are pending against us or involve us that, in the opinion of our management, could reasonably be expected to have a material adverse effect on our business and financial condition.

We anticipate that we will expend significant financial and managerial resources in the defense of our intellectual property rights in the future if we believe that our rights have been violated. We also anticipate that we will expend significant financial and managerial resources to defend against claims that our products and services infringe upon the intellectual property rights of third parties.

Corporation Information

MIRA Pharmaceuticals, Inc. is the registrant and the issuer of the common stock being sold in this offering. Our corporate headquarters is located at 855 N Wolfe

Our principal website address is www.mirapharmaceuticals.com. The information contained on, or that can be accessed through, our website is deemed not to be incorporated in this prospectus or to be part of this prospectus. You should not consider information contained on our website to be part of this prospectus.

MANAGEMENT

Executive Officers and Directors

The following table sets forth information about our current executive officers and directors, including their ages as of April 28, 2023. With respect to our directors, each biography includes information regarding the experience, qualifications, attributes, or skills that caused our board of directors to determine that such person should serve as a director of our company.

Name	Age	Position
Erez Aminov	45	Chief Executive Officer and Director
Michelle Yanez	51	Chief Financial Officer, Secretary and Treasurer
Adam Kaplin, MD, PhD	56	President and Chief Scientific Officer
Chris Chapman, MD	70	Executive Chairman and Director
Christos Nicholoudis, Esq.	33	Director and General Counsel
Dave Vorhoff	67	Director
Brad Kroenig	44	Director
Talhia Tuck	45	Director
Hugh McColl III	62	Director

The following is a brief biography of each of our current executive officers and directors:

Executive Officers and Directors

Erez Aminov has served as a director and our Chief Executive Officer since April 2023. From April 2022 to March 2023, Mr. Aminov was a consultant to MIRA providing support on fundraising and investor relations matters. Mr. Aminov is an experienced biotechnology investor and adviser with over 18 years of experience. Since September 2021, Mr. Aminov was the founder of Locate Venture Corp, a strategy and investment consulting firm which has advised multiple, early-stage life sciences companies including MYMD Pharmaceuticals (Nasdaq: MYMD), Telomir Pharmaceuticals and Tyna Pharmaceuticals on fund raising and strategic partnerships. Mr. Aminov's work has generally focused on assisting clients with structuring private investment opportunities, designing new clinical partnerships, and negotiating access to new markets. From February 2015 to September 2020, Mr. Aminov served as the President of Finds4less Inc., a global distributor of electronics and gaming products. In this role, Mr. Aminov provided strategic oversight and direction for all aspects of the company's operations, while also spearheading new business development initiatives to capitalize on emerging market opportunities. Mr. Aminov received his B.A. in accounting in 2004 from Touro University in New York. We believe that Mr. Aminov is qualified to serve as one of our directors based on his finance and investment experience, particularly with early stage life sciences companies.

Michelle Yanez has served as our Chief Financial Officer since April 2023, prior to which she served as our Corporate Controller since May 2022. Ms. Yanez is a senior financial executive with over 25 years of experience in public and privately held biotech, pharmaceuticals, and life science companies. Ms. Yanez' experience includes a broad range of responsibilities in a highly complex and regulated market. She also brings deep corporate governance experience through her work with corporate boards, including audit and finance committees. Since May 2022, Ms. Yanez has served as the Corporate Controller at our company (until being named Chief Financial Officer in April 2023) and Telomir Pharmaceuticals, Inc., a privately held biotech companies, where she was and is responsible for all aspects of the Controller's function, including accounting, budgeting, investor relations and financial reporting. From May 2002 to April 2022, Ms. Yanez held various positions, including the Director of Financial Reporting, of BioDelivery Sciences International, Inc. (NASDAQ:BDSI). In her role, she led financial offerings, managed due diligence for product acquisitions and financings and managed finance documents and filings for the tender offer, leading to the acquisition of BioDelivery Sciences in April 2022. Mr. Yanez has also served as a non-employee director of Inhibitor Therapeutics, Inc. (OTCQB: INTI), a publicly traded pharmaceutical development company focused on therapeutics for certain cancers and certain non-cancerous proliferation disorders, since December 2022. Ms. Yanez is a member of the Institute of Management Accountants and a member of the SEC Professionals Group. Ms. Yanez received her MBA degree *cum laude* from Rutgers Business School.

Adam Kaplin, MD, PhD has served as our President and Chief Scientific Officer since May 2022. He currently serves as the Chief Scientific Officer of MyMD Pharmaceuticals, Inc. (Nasdaq: MYMD), a publicly traded Delaware corporation focused on the development and commercialization of an immunometabolic regulator, and previously served as the Chief Scientific Officer of MyMD's predecessor company, MyMD Pharmaceuticals, Inc., a Florida corporation ("MyMD Florida"), since December 18, 2020. Since 2002, Dr. Kaplin has served in a number of positions at Johns Hopkins University, including Principal Neuro-Psychiatric Consultant to the Johns Hopkins Multiple Sclerosis Center of Excellence, Director of the Johns Hopkins Ketamine Clinic and the Departments of Psychiatry & Neurology at Johns Hopkins University School of Medicine, positions he has held at various times from 2002 to present. In addition, since 2019, Dr. Kaplin has served as Adjunct Faculty at the George Mason University Department of Global and Community Health. Dr. Kaplin has also served as Co-Founder of numerous healthcare related startups, including, from 2018 to present, REWARD Pathways Inc., a company devoted to addiction treatment development focused on a combined eHealth and medicine approach to curing addiction, and from 2016 to present, Hollinger Kaplin Benjamin & Bond, an eHealth software development company. Dr. Kaplin's research focuses on the investigation of the biological basis of immune mediated depression and cognitive impairment by using multiple sclerosis as the model. Dr. Kaplin has also been active for over a decade in the development and application of health information technology to mental health, combining this work with providing neuropsychiatric consultation and ongoing care of patients with multiple sclerosis spectrum disorders. Dr. Kaplin's original research has been published over 40 times in several different publications, and he has authored or co-authored numerous review articles and textbooks. Dr. Kaplin received his B.S. in Biology from Yale University, graduating *cum laude* in 1988, and received his M.D. and Ph.D. degrees from the Johns Hopkins University School of Medicine in 1996. Because of his research and scholastic accomplishments, as well as his executive experience in the pharmaceutical industry, we believe Dr. Kaplin is qualified to serve as one of our directors.

Chris Chapman, MD was appointed to serve as our Executive Chairman in April 2023. As Executive Chairman, Dr. Chapman's duties include those that are customarily associated with the position of Chairman of the Board, as well as oversight of the regulatory affairs and drug development activities of the Company. Dr. Chapman has also served as one of our directors since November 1, 2021, and served as a consultant with respect to regulatory affairs and drug development from November 1, 2021 until he began serving as our Executive Chairman in April 2023. Dr. Chapman also serves as the President, Chief Medical Officer, and a director of MyMD. Dr. Chapman previously served as President and Chief Medical Officer of MyMD Florida effective as of November 1, 2020. Prior to joining MyMD Florida and since 1999, Dr. Chapman has also served as the Chief Executive Officer of Chapman Pharmaceutical Consulting, Inc., a consulting organization that provides support to pharmaceutical and biotechnology companies in North America, Europe, Japan, India and Africa on issues such as product safety, pharmacovigilance, medical devices, clinical trials and regulatory issues. In addition, from 2003-2004, Dr. Chapman served as the Associate Director of Drug Safety, Pharmacovigilance, and Clinical Operations for Organon Pharmaceuticals, where he was responsible for the supervision of four fellow M.D.s and 10 drug safety specialists. Prior to his time at Organon, Dr. Chapman served as Director, Medical Affairs, Drug Safety and Medical Writing Departments at Quintiles (currently known as IQVIA), from 1995 to 2003, where he grew the division from no employees to forty employees, including eight board certified physicians, four RNs, two pharmacists, eight medical writers and supporting staff. Dr. Chapman has also served on the board of directors of

Rock Creek Pharmaceuticals, Inc. (f/k/a Star Scientific, Inc.) from 2007 to 2016, including as a member of the Audit Committee from 2007 to 2014, chairperson of the Compensation Committee from 2007 to 2014, and chairperson of the Executive Search Committee from 2007 to 2014. Dr. Chapman is an experienced executive and global medical expert and has extensive experience in providing monitoring and oversight for ongoing clinical trials including both adult and pediatric subjects. Dr. Chapman is also the founder of the Chapman Pharmaceutical Health Foundation, an IRS Section 501(c)(3) nonprofit organization established to solicit public funds and to support healthcare needs such as AIDS, diabetes, hypertension, lupus, sickle cell anemia, malaria and tuberculosis, which was organized in 2006. Dr. Chapman is a graduate of the Harvard Kennedy School of Cambridge, Massachusetts for financial management in 2020. Dr. Chapman received his M.D. degree from Georgetown University in Washington, D.C. in 1987, and completed his internship in Internal Medicine, a residency in Anesthesiology and a fellowship in Cardiovascular and Obstetric Anesthesiology at Georgetown. We believe Dr. Chapman is qualified to serve as one of our directors due to his executive experience in the pharmaceutical and biotechnology industries, as well as his medical expertise.

Christos Nicholoudis joined our company as a director in April 2023, and he was initially appointed under an agreement between our company and our largest stockholder, the Bay Shore Trust, to serve as the designated representative of the Bay Shore Trust on our board of directors. Mr. Nicholoudis was also named our General Counsel in April 2023, although he is not deemed to be an executive officer of our company. Mr. Nicholoudis is a Florida-licensed attorney who has practiced with his own firm, The Law firm of Christos Nicholoudis PLLC, since February, 2022, where he handles a wide range of legal matters including contract work, personal injury, real estate, wills trusts and estates and criminal law. Prior to that, from July of 2019 to February of 2022, Mr. Nicholoudis was employed by the State of Florida as a Public Defender for the 12th Judicial Circuit and from July 2012 to February of 2020, Mr. Nicholoudis owned and operated a restaurant franchise under Cortez Roadhouse, LLC. Mr. Nicholoudis is a 2012 graduate of Cornell University's School of Hotel Administration where he received a B.S. in hospitality and a 2017 graduate of Stetson College of Law where he received his J.D. He is admitted to the bar in New York, Florida, Texas, and Washington D.C. We believe that Mr. Nicholoudis is qualified to serve as one of our directors based on his legal experience and training and his diverse business management experience.

David Vorhoff has served as one of our directors since May 3, 2022. Since August of 2021, Mr. Vorhoff has served as Chief Executive Officer and Co-founder of Creo Valo, a financial services company, and a Partner of Texas Atlantic Group, a Family Office and Advisory firm, since May of 2019. He is also the Co-founder and Chairman of the Board of directors for Fintag Holdings, Inc., a financial technology company since April of 2021. Previously, from August 2015 to March 2019, Mr. Vorhoff served as Senior Vice President of Corporate Development and Strategy for Premier Inc. (NASDAQ: PINC), a healthcare improvement company, and as Managing Director, Co-Head Healthcare and Life Sciences at Deloitte, a professional services company, from 2013 to August 2015. He also previously served as a director of Star Scientific, Inc. Mr. Vorhoff has a B.A. in Interdisciplinary Studies from University of North Carolina at Chapel Hill, and his MBA from UNC Kenan-Flagler Business School. We believe Mr. Vorhoff is qualified to serve on our board of directors because of his experience in the healthcare and life sciences sectors, as well as his executive experience in the finance and investment banking industries.

Brad Kroenig has served as one of our directors since November 1, 2021. Since 2000, Mr. Kroenig's principal occupation has been serving as one of the world's leading fashion models. Mr. Kroenig was the face of Ralph Lauren, Gap, Tommy Hilfiger, Chanel, Fendi, Peter Millar, and many other top brands. Models.com ranked him the #1 male model in the world from 2004 to 2006, and Vogue magazine ranked him the #3 male model of all time. Mr. Kroenig also serves as a business and strategy consultant for many private firms and early-stage companies, where as a part of his consulting business he advises companies regarding building management teams and managing relationships with investors. Mr. Kroenig is an experienced investor and business executive with significant experience in collaborating with executive-level and cross-functional teams, analyzing business situations, and developing and implementing practical investor strategies. Mr. Kroenig attended Florida International University on a NCAA Division I soccer scholarship. We believe that Mr. Kroenig's business experience in the modeling industry as a business executive qualifies him to serve as one of our directors.

Talhia Tuck has served as one of our directors since November 1, 2021. Since 2019, Ms. Tuck has served as a Project Director with Georgetown Law School's Center for Innovations in Community Safety, formerly the Innovative Policing Program, which identifies new approaches to long-standing issues in policing such as determining what role police should have in a diverse and democratic society; ensuring that policing reduces insecurity and injustice in an inclusive manner instead of reinforcing inequality; and figuring out how communities and police departments can work together to address the toxic legacy of racial discrimination that continues to distort law and policy in the United States. From 2016 to 2019, Ms. Tuck served as an Associate Director of Admissions at Georgetown University, where she evaluated applications for the undergraduate schools and chaired several admissions committees. Prior to 2016, Ms. Tuck worked in the investment relations and communications field as Vice President for Communications and Investor Relations at Star Scientific, Inc. (OTC: STSC) where she was responsible for coordinating communications with shareholders, the financial community, and the media. She also has experience in the legal industry, as she participated in the Ropes & Gray New Alternatives Program as a Fellow at the Office of the State's Attorney for Montgomery County, Maryland, and subsequently worked in the Corporate Department at Ropes & Gray in Washington, D.C. Prior to attending law school, Ms. Tuck was a journalist with MSNBC, NBC News, ABC News, and the CBS affiliate, WINK-TV, and worked as an admissions officer for Harvard College at Harvard University. She also served as a financial analyst at Goldman Sachs in the Investment Management Division from July 2000 until April 2001. We believe that Ms. Tuck's experience in public policy and investment relations qualifies her to serve as one of our directors. She received her A.B. degree from Harvard College, *cum laude*, and received her J.D. degree from Harvard Law School.

Hugh McColl III has served as one of our directors since November 1, 2021. Mr. McColl has served as Co-Managing Member of Collwick Capital LLC, a fund of funds, since 2010 and Managing Member of McColl Brothers Lockwood, a family investment office, since 2006. Since June 2015, he has served as a Senior Advisor at Brown Brothers Harriman Capital Partners where he assists in sourcing, investment evaluation, transaction execution, and providing post-investment value-added oversight to portfolio companies. Before co-founding Collwick Capital, LLC, Mr. McColl spent 14 years in the hedge fund industry, where he was a private investments portfolio manager for Round Table Investment Management and McColl Brothers Lockwood LLC, served as the Chief Operating Officer for M&M Partners LLC and was the Chief Executive Officer for McColl Partners LLC. Mr. McColl has served on the boards of directors of Heritage Brands Inc. since 2019 and Fintag Holdings Inc. since 2022. Mr. McColl received a B.S. in Business Administration from the University of North Carolina at Chapel Hill in 1982 and an MBA from the University of Virginia Darden School of Business in 1987. We believe that Mr. McColl's investment management and executive experience qualifies him to serve as a member of our board of directors. We believe that Mr. McColl's investment management and executive experience qualifies him to serve as a member of our board of directors.

Board Composition

Our business and affairs are managed under the direction of our board of directors, which currently consists of seven members. The number of directors is determined by our board of directors, subject to the terms of our amended and restated certificate of incorporation and bylaws that will become effective upon the completion of this offering. Upon the completion of this offering, our board of directors will continue to consist of seven members, and our directors will be elected for one-year terms.

Family Relationships

There are no family relationships among any of our directors and executive officers. Erez Aminov, our Chief Executive Officer, is the fiancé of the daughter of our company's founder, Jonnie R. Williams, Sr.

Director Independence

Our board of directors has undertaken a review of the independence of each director. Based on information provided by each director concerning his or her background, employment, and affiliations, our board of directors has determined that Dave Vorhoff, Brad Kroenig, Talhia Tuck, and Hugh McColl III do not have any

relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and are independent directors under the Nasdaq Listing Rules.

In making these determinations, our board of directors considered the current and prior relationships that each non-employee director has with our company and all other facts and circumstances our board of directors deemed relevant in determining their independence, including the transactions described in the section of this prospectus titled "Certain Relationships and Related Party Transactions."

Committees of the Board of Directors

Our board of directors will establish an audit committee, a compensation committee, and a nominating and corporate governance committee prior to the completion of this offering. The functions of these committees are described below. Members will serve on these committees until their resignation or until otherwise determined by our board of directors. Our board of directors may establish other committees as it deems necessary or appropriate from time to time.

Audit Committee

Our board of directors will establish an audit committee, and we anticipate that the members of this committee will be: Dave Vorhoff, Brad Kroenig and Hugh McColl III, with Dave Vorhoff serving as the chair of the Audit Committee. Each member of the committee will meet the requirements for independence under the listing standards of Nasdaq and SEC rules and regulations, including Rule 10A-3(b)(1) under the Exchange Act. Each member of our audit committee will also meet the financial literacy requirements of the listing standards of Nasdaq. In addition, our board of directors has determined that Dave Vorhoff is an audit committee financial expert within the meaning of Item 407(d) of Regulation S-K under the Securities Act.

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The audit committee's main purpose is to oversee our corporate accounting and financial reporting process. Our audit committee will be responsible for, among other things:

- selecting a qualified firm to serve as the independent registered public accounting firm to audit our financial statements;
- helping to ensure the independence and performance of the independent registered public accounting firm;
- discussing the scope and results of the audit with the independent registered public accounting firm, and reviewing, with management and the independent registered public accounting firm, our interim and year-end results of operations;
- developing procedures for employees to submit concerns anonymously about questionable accounting or audit matters;
- reviewing our policies on risk assessment and risk management;
- reviewing related party transactions;
- reviewing and pre-approving, as required, all audit and all permissible non-audit services to be performed by the independent registered public accounting firm; and
- assisting our board of directors in monitoring the performance of our internal audit function.

Our audit committee will operate under a written charter that satisfies the applicable rules and regulations of the SEC and the listing standards of Nasdaq, a copy of which will be available on our website at www.mirapharmaceuticals.com.

Compensation Committee

Our board of directors will establish a compensation committee and we anticipate that the members of this committee will be: Talhia Tuck, Brad Kroenig, and Hugh McColl III, with Talhia Tuck serving as the chair of the compensation committee. Each member of the committee will meet the requirements for independence under the listing standards of Nasdaq and SEC rules and regulations. Each member of our compensation committee will also be a non-employee director, as defined pursuant to Rule 16b-3 promulgated under the Exchange Act, or Rule 16b-3. In arriving at these determinations, our board of directors will examine all factors relevant to determining whether any compensation committee member has a relationship to us that is material to that member's ability to be independent from management in connection with carrying out such member's duties as a compensation committee member.

The compensation committee's main purpose is to review and recommend policies relating to compensation and benefits of our officers and employees. Our compensation committee will be responsible for, among other things:

- reviewing, approving, and determining, or making recommendations to our board of directors regarding, the compensation and compensation arrangements of our executive officers;
- administering our equity compensation plans;
- reviewing and approving, or making recommendations to our board of directors regarding, incentive compensation and equity compensation plans; and
- establishing and reviewing general policies relating to compensation and benefits of our employees.

Our compensation committee will operate under a written charter that satisfies the applicable rules and regulations of the SEC and the listing standards of Nasdaq, a copy of which will be available on our website.

Nominating and Corporate Governance Committee

Our board of directors will establish a nominating and corporate governance committee, and we anticipate that the members of this committee will be: Talhia Tuck, Brad Kroenig and Hugh McColl III, with Talhia Tuck serving as the chair of the nominating and corporate governance committee. Each member of the committee will meet the requirements for independence under the listing standards of Nasdaq and SEC rules and regulations.

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Our nominating and corporate governance committee will be responsible for, among other things:

- identifying, evaluating, and selecting, or making recommendations to our board of directors regarding, nominees for election to our board of directors and its committees;
- developing and overseeing the annual evaluation of our board of directors and of its committees;
- considering and making recommendations to our board of directors regarding the composition of our board of directors and its committees;
- overseeing our corporate governance practices; and
- making recommendations to our board of directors regarding corporate governance guidelines.

Our nominating and corporate governance committee will operate under a written charter that satisfies the applicable listing standards of Nasdaq, a copy of which will be available on our website.

Compensation Committee Interlocks and Insider Participation

None of the members of our compensation committee is a current or former executive officer or employee of our company. None of our executive officers serves as a member of the compensation committee of any entity that has one or more executive officers serving on our compensation committee.

Risk Oversight

One of the key functions of our board of directors is informed oversight of our risk management process. Our board of directors administers this oversight function directly through our board of directors as a whole, and through various standing committees of our board of directors that address risks inherent in their respective areas of oversight. In particular, our board of directors is responsible for monitoring and assessing strategic risk exposure, including risks associated with cybersecurity and data protection, and our audit committee has the responsibility to consider our major financial risk exposures and the steps our management has taken to monitor and control these exposures, including guidelines and policies to govern the process by which risk assessment and management is undertaken. Our audit committee will review legal, regulatory, and compliance matters that could have a significant impact on our financial statements. Our nominating and corporate governance committee will monitor the effectiveness of our corporate governance practices, including whether they are successful in preventing illegal or improper liability-creating conduct. Our compensation committee will assess and monitor whether any of our compensation policies and programs has the potential to encourage excessive risk taking. While each committee is responsible for evaluating certain risks and overseeing the management of such risks, our entire board of directors will be regularly informed through committee reports about such risks.

Board Diversity

Our nominating and corporate governance committee will be responsible for reviewing with the board of directors, on an annual basis, the appropriate characteristics, skills, and experience required for the board of directors as a whole and its individual members. Although our board of directors does not have a formal written diversity policy with respect to the evaluation of director candidates, in its evaluation of director candidates, our nominating and corporate governance committee will consider factors including, without limitation, issues of character, integrity, judgment, potential conflicts of interest, other commitments, and diversity, and with respect to diversity, such factors as gender, race, ethnicity, experience, and area of expertise, as well as other individual qualities and attributes that contribute to the total diversity of viewpoints and experience represented on the board of directors. The nominating and corporate governance committee will ensure compliance with the new rule by Nasdaq for board diversity (the “Nasdaq Diversity Rule”), on or before the date required under the Nasdaq Diversity Rule. The Nasdaq Diversity Rule requires, assuming our shares of common stock are listed on the Nasdaq Capital Market and that we are a smaller reporting company, that we will have at least two directors serving on our board of directors, at least one of which identifies as female and the second of which identifies as female, underrepresented minority or LGBTQ+, by December 31, 2026, unless our board of directors is comprised of five or less directors.

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Code of Business Conduct and Ethics

Prior to the completion of this offering, our board of directors will adopt a code of business conduct and ethics applicable to all of our directors, officers (including our principal executive officer, principal financial officer, and principal accounting officer) and all global employees in accordance with applicable federal securities laws and corporate governance rules of the Nasdaq Capital Market. Our code of business conduct and ethics will be available on our website. Any amendments to the code of business conduct and ethics, or waivers of its requirements, will, if required, be disclosed on our website.

Corporate Governance Guidelines

Prior to the completion of this offering, our board of directors will adopt corporate governance guidelines, a copy of which will be available on our website.

Director Compensation

We did not provide any cash compensation to any of our directors during the year ended December 31, 2022 in their capacity as directors. However, on June 15, 2022, each of our non-employee directors was granted an option to purchase up to 100,000 shares of our common stock under our 2022 Omnibus Plan at an exercise price of \$1.00 per share, and on April 28, 2023, each non-employee director was granted an additional option to purchase up to 50,000 shares of our common stock under the 2022 Omnibus Plan. Each such option was immediately vested in full upon grant and has a 10-year term.

Certain of our directors have received option grants as a result of their service to our company in a non-director capacity. Prior to his appointment as Executive Chairman, Dr. Chapman was a party to a consulting agreement with our company entered into in April 2022 and was granted additional options in his capacity as a consultant on June 15, 2022. Mr. Kroenig previously provided consulting services to our company in 2022 and received an additional option grant on June 15, 2022 under which he has the right to purchase up to 50,000 shares of our common stock. Upon his appointment as the company’s General Counsel in April 2023, Mr. Nicholoudis was granted an option to purchase 75,000 shares of our common stock.

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EXECUTIVE COMPENSATION

This section discusses the material components of the executive compensation program for the following persons: (i) all persons serving as our principal executive officers during 2022 and (ii) the most highly compensated of our other executive officers who received compensation during 2022 of at least \$100,000 and who were executive officers on December 31, 2022. We refer to these persons as our “named executive officers” elsewhere in this prospectus. Our “named executive officers” and their positions are as follows:

- Jude Uzonwanne, Former Chief Executive Officer and President;
- James A. McNulty, CPA, Former Chief Financial Officer; and

- Adam Kaplin, MD, PhD, President and Chief Scientific Officer.

In April 2023, Mr. Aminov succeeded Mr. Uzonwanne as our Chief Executive Officer and President, and Ms. Yanez succeeded Mr. McNulty as our Chief Financial Officer.

Summary Compensation Table

The following table shows the compensation paid by us during the 2022 and 2021 fiscal years to our named executive officers.

Name and principal position	Year	Salary	Bonus	Stock Awards	Option Awards (5)	All Other Compensation	Total (\$)
Jude Uzonwanne, Former Chief Executive Officer and President	2022	\$ 125,000	50,000(1)	-	739,000	8,385(2)	\$ 922,385
	2021	\$ -	-	-	-	-	\$ -
James A. McNulty, CPA, Former Chief Financial Officer	2022	\$ 266,868	100,000(3)	-	-	-	\$ 366,868
	2021	\$ 43,000	-	-	-	-	\$ 43,000
Adam Kaplin, MD, PhD President and Chief Scientific Officer	2022	\$ -	50,000(4)	-	739,000	-	\$ 789,000
	2021	\$ -	-	-	-	-	\$ -

- (1) The bonus represents a paid sign-on amount.
- (2) Amount represents health insurance premiums paid.
- (3) The bonus represents a milestone payment pursuant to Mr. McNulty's employment agreement.
- (4) The bonus represents a milestone payment pursuant to Dr. Kaplin's employment agreement.
- (5) The reported amounts represent the aggregate grant date fair value of the awards computed in accordance with Financial Accounting Standards Board Account Standards Codification Topic 718, Stock Compensation, as modified or supplemented, or FASB ASC Topic 718. The assumptions used in calculating the grant date fair value of the stock options reported in this column are set forth in Note 8 to our Consolidated Financial Statements for the year ended December 31, 2022 included in this Report.

Executive Compensation Arrangements

Below is a more detailed summary of the elements of our current executive compensation program as it relates to our continuing named executive officers, as well as our current executive officers who were not executive officers as of the end of 2022, including our Executive Chairman.

Employment Agreements

Erez Aminov

On April 28, 2023, we entered into an employment agreement with Mr. Aminov pursuant to which Mr. Aminov will serve as our Chief Executive Officer on a full-time basis. Mr. Aminov's employment agreement provides that his employment will be on an at-will basis and can be terminated by either Mr. Aminov or our company at any time and for any reason. Under the agreement, Mr. Aminov will receive an initial base salary of \$110,000 per year. In the event that Mr. Aminov's employment is terminated by our company without "Cause" or is terminated by Mr. Aminov for "Good Reason", Mr. Aminov will be entitled to severance compensation in the form of salary continuation for a period of three months (subject to Mr. Aminov executing and delivering a customary general release in favor of the company). "Cause" is defined in the agreement to include dishonesty, misappropriation, willful misconduct, breach of the agreement, and other customary matters. "Good Reason" is defined to include a material adverse change in Mr. Aminov's compensation or duties and level of responsibility. The employment agreement also contains customary confidentiality and invention-assignment covenants to which Mr. Aminov is subject.

Michelle Yanez

On April 28, 2023, we entered into an employment agreement with Ms. Yanez pursuant to which Ms. Yanez will serve as our Chief Financial Officer on a full-time basis. Ms. Yanez's employment agreement provides that her employment will be on an at-will basis and can be terminated by either Ms. Yanez or our company at any time and for any reason. Under the agreement, Ms. Yanez will receive an initial base salary of \$165,000 per year. In the event that her employment is terminated by our company without "Cause" or is terminated by Ms. Yanez for "Good Reason", Ms. Yanez will be entitled to severance compensation in the form of salary continuation for a period of three months (subject to Ms. Yanez executing and delivering a customary general release in favor of the company). "Cause" is defined in the agreement to include dishonesty, misappropriation, willful misconduct, breach of the agreement, and other customary matters. "Good Reason" is defined to include a material adverse change in Ms. Yanez's compensation or duties and level of responsibility. The employment agreement also contains customary confidentiality and invention-assignment covenants to which Ms. Yanez is subject.

Adam Kaplin

On April 28, 2023, we entered into an employment agreement with Dr. Kaplin pursuant to which Dr. Kaplin will serve as our President and Chief Scientific Officer. Dr. Kaplin's employment agreement provides that his employment will be on a part-time basis whereby Dr. Kaplin will devote 50% of his full business time and effort to the business and affairs of the company, and it further provides that such employment will be on an at-will basis and can be terminated by either Dr. Kaplin or our company at any time and for any reason. Under the agreement, Dr. Kaplin will receive an initial base salary of \$110,000 per year. In the event that Dr. Kaplin's employment is terminated by our company without "Cause" or is terminated by Dr. Kaplin for "Good Reason", Dr. Kaplin will be entitled to severance compensation in the form of salary continuation for a period of three months (subject to Dr. Kaplin executing and delivering a customary general release in favor of the company). "Cause" is defined in the agreement to include dishonesty, misappropriation, willful misconduct, breach of the agreement, and other customary matters. "Good Reason" is defined to include a material adverse change in Dr. Kaplin's compensation or duties and level of responsibility. The employment agreement also contains customary confidentiality and invention-assignment covenants to which Dr. Kaplin is subject.

Chris Chapman

On April 28, 2023, we entered into an employment agreement with Dr. Chapman pursuant to which Dr. Chapman will serve as our Executive Chairman. Dr. Chapman's employment agreement provides that his employment will be on a part-time basis whereby Dr. Chapman will devote 50% of his full business time and effort to the business and affairs of the company, and it further provides that such employment will be on an at-will basis and can be terminated by either Dr. Chapman or our company at any time and for any reason. Under the agreement, Dr. Chapman will receive an initial base salary of \$150,000 per year. In the event that Dr. Chapman's employment is terminated by our company without "Cause" or is terminated by Dr. Chapman for "Good Reason", Dr. Chapman will be entitled to severance compensation in the form of salary continuation for a period of three months (subject to Dr. Chapman executing and delivering a customary general release in favor of the company). "Cause" is defined in the agreement to include dishonesty, misappropriation, willful misconduct, breach of the agreement, and other customary matters. "Good Reason" is defined to include a

Base Salaries

Our executive officers' base salaries are specified in their respective employment agreements, as summarized above.

Bonuses

We paid bonuses to three named executive officers in 2022. See Summary Compensation Table for details.

Equity Compensation

In June 2022, Dr. Kaplin was granted an option to purchase 1,000,000 shares of our common stock. In June 2022, prior to becoming our Chief Financial Officer, Ms. Yanez was granted an option to purchase 50,000 shares of our common stock. In June 2022, Dr. Chapman was granted an option to purchase 1,100,000 shares of our common stock.

In April 2023, we granted additional options to the following current executive officers for the following number shares of our common stock: Mr. Aminov, 750,000 shares; Ms. Yanez, 233,334 shares; Dr. Kaplin, 200,000 shares; and Dr. Chapman, 300,000 shares.

The foregoing options were granted under our 2022 Omnibus Plan and have an exercise price of \$1.00 per share. These options vest as to one-third of the option shares on the date of option grant and will vest as to one-third of the option shares on the succeeding two anniversaries of the date of option grant. Any unvested portion of the option will vest in full upon a "change of control" of our company within the meaning of the 2022 Omnibus Plan. The options have a term of 10-years, subject to earlier termination upon termination of employment.

Retirement Plans

We do not currently maintain any retirement plans for our employees.

Outstanding Equity Awards at Fiscal Year-End

There were a cumulative 3,750,000 stock options granted and outstanding as of December 31, 2022. Of the aforementioned amount, 1,400,000 stock options were vested at December 31, 2022.

2022 Omnibus Incentive Plan

Our board of directors has adopted, and our stockholders have approved, our 2022 Omnibus Incentive Plan, or the 2022 Omnibus Plan. The 2022 Omnibus Plan will authorize the grant of incentive stock options, within the meaning of Section 422 of the Internal Revenue Code, to our employees and any of our parent and subsidiary corporations' employees, and for the grant of nonstatutory stock options, restricted stock, restricted stock units, stock appreciation rights, performance units and performance shares to our employees, directors, and consultants and any of our future subsidiary corporations' employees and consultants. The following is a summary of certain terms and conditions of the 2022 Omnibus Plan. This summary is qualified in its entirety by reference to the 2022 Omnibus Plan attached as an exhibit to the registration statement of which this prospectus forms a part. You are encouraged to read the full text of the 2022 Omnibus Plan.

As of April 28, 2023, there are a cumulative 5,000,000 stock options outstanding under the 2022 Omnibus Plan.

Administration

The 2022 Omnibus Plan will be administered by our board of directors or our compensation committee, or any other committee or subcommittee or one or more of our officers to whom authority has been delegated (collectively, the "Administrator"). The Administrator will have the authority to interpret the 2022 Omnibus Plan and award agreements entered into with respect to the 2022 Omnibus Plan; to make, change and rescind rules and regulations relating to the 2022 Omnibus Plan; to make changes to, or reconcile any inconsistency in, the 2022 Omnibus Plan or any award agreement covering an award; and to take any other actions needed to administer the 2022 Omnibus Plan.

Eligibility

The Administrator may designate any of the following as a participant under the 2022 Omnibus Plan: any officer or employee, or individuals engaged to become an officer or employee, of our company or our affiliates; and consultants of our company or our affiliates, and our directors, including our non-employee directors.

Types of Awards

The 2022 Omnibus Plan will permit the Administrator to grant stock options, stock appreciation rights ("SARs"), performance shares, performance units, shares of common stock, restricted stock, restricted stock units ("RSUs"), cash incentive awards, dividend equivalent units, or any other type of award permitted under the 2022 Omnibus Plan. The Administrator may grant any type of award to any participant it selects, but only our employees or our subsidiaries' employees may receive grants of incentive stock options within the meaning of Section 422 of the Internal Revenue Code. Awards may be granted alone or in addition to, in tandem with, or (subject to the repricing prohibition described below) in substitution for any other award (or any other award granted under another plan of our company or any affiliate, including the plan of an acquired entity).

Shares Reserved Under the 2022 Omnibus Incentive Plan

The 2022 Omnibus Plan provides that 5,000,000 shares of our common stock are reserved for issuance under the 2022 Omnibus Plan, all of which may be issued pursuant to the exercise of incentive stock options. The number of shares available for issuance under our 2022 Omnibus Plan will also include an annual increase on the first day of each fiscal year after the completion of this offering equal to the lesser of:

- 1,000,000 shares;
- 1.0% of the outstanding shares of all class of our common stock as of the last day of the immediately preceding fiscal year; or
- such other amount as our board of directors may determine.

The number of shares reserved for issuance under the 2022 Omnibus Plan will be reduced on the date of the grant of any award by the maximum number of shares, if any, with respect to which such award is granted. However, an award that may be settled solely in cash will not deplete the 2022 Omnibus Plan's share reserve at the time the award is granted. If (a) an award expires, is canceled, or terminates without issuance of shares or is settled in cash, (b) the Administrator determines that the shares granted under an award will not be issuable because the conditions for issuance will not be satisfied, (c) shares are forfeited under an award, (d) shares are issued under any award and we reacquire them pursuant to our reserved rights upon the issuance of the shares, (e) shares are tendered or withheld in payment of the exercise price of an option or as a result of the net settlement of outstanding stock appreciation rights or (f) shares are tendered or withheld to satisfy federal, state or local tax withholding obligations, then those shares are added back to the reserve and may again be used for new awards under the 2022 Omnibus Plan. However, shares added back to the reserve pursuant to clauses (d), (e) or (f) in the preceding sentence may not be issued pursuant to incentive stock options.

Options

The Administrator may grant stock options and determine all terms and conditions of each stock option, which include the number of stock options granted, whether a stock option is to be an incentive stock option or non-qualified stock option, and the grant date for the stock option. However, the exercise price per share of common stock may never be less than the fair market value of a share of common stock on the date of grant and the expiration date may not be later than 10 years after the date of grant. Stock options will be exercisable and vest at such times and be subject to such restrictions and conditions as are determined by the Administrator, including with respect to the manner of payment of the exercise price of such stock options.

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Stock Appreciation Rights

The Administrator may grant SARs, which represent the right of a participant to receive cash in an amount, or common stock with a fair market value, equal to the appreciation of the fair market value of a share of common stock during a specified period of time. The 2022 Omnibus Plan provides that the Administrator will determine all terms and conditions of each SAR, including, among other things: (a) whether the SAR is granted independently of a stock option or relates to a stock option, (b) the grant price, which may never be less than the fair market value of our common stock as determined on the date of grant, (c) a term that must be no later than 10 years after the date of grant, and (d) whether the SAR will settle in cash, common stock or a combination of the two.

Performance and Stock Awards

The Administrator may grant awards of shares of common stock, restricted stock, RSUs, performance shares or performance units. Restricted stock means shares of common stock that are subject to a risk of forfeiture or restrictions on transfer, which may lapse upon the achievement or partial achievement of performance goals (as described below) or upon the completion of a period of service. An RSU grants the participant the right to receive cash or shares of common stock the value of which is equal to the fair market value of one share of common stock, to the extent performance goals are achieved or upon the completion of a period of service. Performance shares give the participant the right to receive shares of common stock to the extent performance goals are achieved. Performance units give the participant the right to receive cash or shares of common stock valued in relation to a unit that has a designated dollar value or the value of which is equal to the fair market value of one or more shares of common stock, to the extent performance goals are achieved.

The Administrator will determine all terms and conditions of the awards including (a) whether performance goals must be achieved for the participant to realize any portion of the benefit provided under the award, (b) the length of the vesting or performance period and, if different, the date that payment of the benefit will be made, (c) with respect to performance units, whether to measure the value of each unit in relation to a designated dollar value or the fair market value of one or more shares of common stock, and (d) with respect to performance shares, performance units, and RSUs, whether the awards will settle in cash, in shares of common stock (including restricted stock), or in a combination of the two.

Cash Incentive Awards

The Administrator may grant cash incentive awards. An incentive award is the right to receive a cash payment to the extent one or more performance goals are achieved. The Administrator will determine all terms and conditions of a cash incentive award, including, but not limited to, the performance goals (described below), the performance period, the potential amount payable, and the timing of payment. While the 2022 Omnibus Plan permits cash incentive awards to be granted under the 2022 Omnibus Plan, we may also make cash incentive awards outside of the 2022 Omnibus Plan.

Performance Goals

For purposes of the 2022 Omnibus Plan, the Administrator may establish objective or subjective performance goals which may apply to any performance award. Such performance goals may include, but are not limited to, one or more of the following measures with respect to our company or any one or more of our subsidiaries, affiliates, or other business units: net sales; cost of sales; gross income; gross revenue; revenue; operating income; earnings before taxes; earnings before interest and taxes; earnings before interest, taxes, depreciation and amortization; earnings before interest, taxes, depreciation, amortization and exception items; income from continuing operations; net income; earnings per share; diluted earnings per share; total stockholder return; fair market value of a share of common stock; cash flow; net cash provided by operating activities; net cash provided by operating activities less net cash used in investing activities; ratio of debt to debt plus equity; return on stockholder equity; return on invested capital; return on average total capital employed; return on net capital employed; return on assets; return on net assets employed before interest and taxes; operating working capital; average accounts receivable (calculated by taking the average of accounts receivable at the end of each month); average inventories (calculated by taking the average of inventories at the end of each month); economic value added; succession planning; manufacturing return on assets; manufacturing margin; and customer satisfaction. Performance goals may also relate to a participant's individual performance. The Administrator reserves the right to adjust any performance goals or modify the manner of measuring or evaluating a performance goal.

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Dividend Equivalent Units

The Administrator may grant dividend equivalent units. A dividend equivalent unit gives the participant the right to receive a payment, in cash or shares of common stock, equal to the cash dividends or other distributions that we pay with respect to a share of common stock. We determine all terms and conditions of a dividend equivalent unit award, except that dividend equivalent units may not be granted in connection with a stock option or SAR, and dividend equivalent unit awards granted in connection with another award cannot provide for payment until the date such award vests or is earned, as applicable.

Other Stock-Based Awards

The Administrator may grant to any participant shares of unrestricted stock as a replacement for other compensation to which such participant is entitled, such as in payment of director fees, in lieu of cash compensation, in exchange for cancellation of a compensation right or as a bonus.

Transferability

Awards are not transferable, including to any financial institution, other than by will or the laws of descent and distribution, unless the Administrator allows a

participant to (a) designate in writing a beneficiary to exercise the award or receive payment under the award after the participant's death, (b) transfer an award to a former spouse as required by a domestic relations order incident to a divorce, or (c) transfer an award without receiving any consideration.

Adjustments

If (a) we are involved in a merger or other transaction in which our shares of common stock are changed or exchanged; (b) we subdivide or combine shares of common stock or declare a dividend payable in shares of common stock, other securities, or other property (other than stock purchase rights issued pursuant to a stockholder rights agreement); (c) we effect a cash dividend that exceeds 10% of the fair market value of a share of common stock or any other dividend or distribution in the form of cash or a repurchase of shares of common stock that our board of directors determines is special or extraordinary, or that is in connection with a recapitalization or reorganization; or (d) any other event occurs that in the Administrator's judgment requires an adjustment to prevent dilution or enlargement of the benefits intended to be made available under the 2022 Omnibus Plan, then the Administrator will, in a manner it deems equitable, adjust any or all of (1) the number and type of shares subject to the 2022 Omnibus Plan and which may, after the event, be made the subject of awards; (2) the number and type of shares of common stock subject to outstanding awards; (3) the grant, purchase, or exercise price with respect to any award; and (4) the performance goals of an award. In any such case, the Administrator may also provide for a cash payment to the holder of an outstanding award in exchange for the cancellation of all or a portion of the award, subject to the terms of the 2022 Omnibus Plan.

The Administrator may, in connection with any merger, consolidation, acquisition of property or stock, or reorganization, authorize the issuance or assumption of awards upon terms and conditions we deem appropriate without affecting the number of shares of common stock otherwise reserved or available under the 2022 Omnibus Plan.

Change of Control

Upon a change of control (as defined in the 2022 Omnibus Plan), the successor or surviving corporation may agree to assume some or all outstanding awards or replace them with the same type of award with similar terms and conditions, without the consent of any participant, subject to the following requirements:

- Each award that is assumed must be appropriately adjusted, immediately after such change of control, to apply to the number and class of securities that would have been issuable to a participant upon the consummation of such change of control had the award been exercised, vested, or earned immediately prior to such change of control, and other appropriate adjustment to the terms and conditions of the award may be made.
- If the securities to which the awards relate after the change of control are not listed and traded on a national securities exchange, then (a) each participant must be provided the option to elect to receive, in lieu of the issuance of such securities, cash in an amount equal to the fair value of the securities that would have otherwise been issued, and (b) no reduction may be taken to reflect a discount for lack of marketability, minority, or any similar consideration, for purposes of determining the fair value of such securities.

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- If a participant is terminated from employment without cause, or due to death or disability, or the participant resigns employment for good reason (as defined in any award or other agreement between the participant and our company or an affiliate) within two years following the change of control, then upon such termination, all of the participant's awards in effect on the date of such termination will vest in full or be deemed earned in full.

If the purchaser, successor, or surviving entity does not assume the awards or issue replacement awards, then immediately prior to the change of control date, unless the Administrator otherwise determines:

- Each stock option or SAR then held by a participant will become immediately and fully vested, and all stock options and SARs will be cancelled on the change of control date in exchange for a cash payment equal to the excess of the change of control price of the shares of common stock over the purchase or grant price of such shares under the award.
- Unvested restricted stock and RSUs (that are not performance awards) will vest in full.
- All performance shares, performance units and cash incentive awards for which the performance period has expired will be paid based on actual performance, and all such awards for which the performance period has not expired will be cancelled in exchange for a cash payment equal to the amount that would have been due under such awards, valued assuming achievement of target performance goals at the time of the change of control, prorated based on the number of full months elapsed in the performance period.
- All unvested dividend equivalent units will vest (to the same extent as the award granted in tandem with such units) and be paid.
- All other unvested awards will vest and any amounts payable will be paid in cash.

Term of Plan

Unless earlier terminated by our board of directors, the 2022 Omnibus Plan will terminate on, and no further awards may be granted, after the 10th anniversary of its effective date.

Termination and Amendment of Plan

Our board of directors or the Administrator may amend, alter, suspend, discontinue, or terminate the 2022 Omnibus Plan at any time, subject to the following limitations:

- Our board of directors must approve any amendment to the 2022 Omnibus Plan if we determine such approval is required by prior action of our board of directors, applicable corporate law, or any other applicable law;
- Stockholders must approve any amendment to the 2022 Omnibus Plan, which may include an amendment to materially increase the number of shares reserved under the 2022 Omnibus Plan, if we determine that such approval is required by Section 16 of the Exchange Act, the Code, the listing requirements of any principal securities exchange or market on which the shares are then traded, or any other applicable law; and
- Stockholders must approve any amendment to the 2022 Omnibus Plan that would diminish the protections afforded by the participant award limits or repricing and backdating prohibitions.

Amendment, Modification, Cancellation and Disgorgement of Awards

Subject to the requirements of the 2022 Omnibus Plan, the Administrator may modify or amend any award or waive any restrictions or conditions applicable to any award or the exercise of the award, or amend, modify, or cancel any terms and conditions applicable to any award, in each case, by mutual agreement of the Administrator and the participant or any other person that may have an interest in the award, so long as any such action does not increase the number of shares of common stock issuable under the 2022 Omnibus Plan.

We do not need to obtain participant (or other interested party) consent for any such action (a) that is permitted pursuant to the adjustment provisions of the 2022 Omnibus Plan; (b) to the extent we deem the action necessary to comply with any applicable law or the listing requirements of any principal securities exchange or market on which our common stock is then traded; (c) to the extent we deem the action is necessary to preserve favorable accounting or tax treatment of any award for us; or (d) to the extent we determine that such action does not materially and adversely affect the value of an award or that such action is in the best interest of the affected participant or any other person as may then have an interest in the award.

The Administrator can cause a participant to forfeit any award, and require the participant to disgorge any gains attributable to the award, if the participant engages in any action constituting, as determined by the Administrator in its discretion, cause for termination, or a breach of a material company policy, any award agreement or any other agreement between the participant and us or one of our affiliates concerning noncompetition, nonsolicitation, confidentiality, trade secrets, intellectual property, nondisparagement or similar obligations.

Any awards granted under the 2022 Omnibus Plan, and any shares of common stock issued or cash paid under an award, will be subject to any recoupment or clawback policy that we adopt, or any recoupment or similar requirement otherwise made applicable by law, regulation or listing standards to us.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The following is a description of transactions within the last three years to which we have been a party, in which the amount involved exceeded or will exceed \$120,000, and in which any of our executive officers, directors or holders of more than 5% of our voting securities, or an immediate family member thereof, had or will have a direct or indirect material interest. We believe the terms obtained or consideration that we paid or received, as applicable, in connection with the transactions described below were comparable to terms available or amounts that would be paid or received, as applicable, in arm's-length transactions with unrelated third parties.

Confirmatory Patent Assignment and Royalty Agreement

On November 1, 2021, we entered into a Confirmatory Patent Assignment and Royalty Agreement with SRQ Patent Holdings II, LLC ("Patent Assignor"), and the founder of our company, Jonnie R. Williams, Sr., pursuant to which we granted a royalty of 8% of any net sales, royalties, or other revenue received by us with respect to the sale, commercialization, or disposition of MIRA1a, with such royalty being paid to Patent Assignor in consideration for Patent Assignor's assignment to us of U.S. Patent 10,787,675 B2, which is the patent for MIRA1a.

Line of Credit and Promissory Note with the Bay Shore Trust

On April 28, 2023, we entered into a Promissory Note and Loan Agreement with the Bay Shore Trust, a trust established by our founder, Jonnie R. Williams, Sr., and under which various of his family members are beneficiaries. Under the this Promissory Note and Loan Agreement (the "Bay Shore Note"), we have the right to borrow up to an aggregate of \$5,000,000 from the Bay Shore Trust at any time up to the second anniversary of the issuance of the Bay Shore Note or, if earlier, upon the completion of our initial public offering. Our right to borrow funds under the Bay Shore Note is subject to the absence of a material adverse change in our assets, operations, or prospects. The Bay Share Note, together with accrued interest, will become due and payable on the second anniversary of the issuance of the note, provided that it may be prepaid at any time without penalty. The Bay Shore Note will accrue interest at a rate equal 7% per annum, simple interest, during the first year that the note is outstanding and 10% per annum, simple interest, thereafter. The Bay Shore Note is unsecured. As of April 28, 2023, we have borrowed an aggregate of \$0.2 million under the Bay Shore Note.

In consideration of the loan facility provided by the Bay Shore Trust, on April 28, 2023, we issued to the Bay Shore Trust a common stock purchase warrant giving the Bay Shore Trust the right to purchase up to 5,000,000 shares of common stock at an exercise price of \$1.00 per share, which warrant will expire five years after the date of grant. Pursuant to a registration rights agreement, we have granted to Bay Shore Trust the right to require us, at any time after one year following our initial public offering, to register for resale the shares issuable upon the exercise of the warrant, with such registration rights being in the form of demand and "piggyback" registration rights that are subject to customary limitations and restrictions.

Amended and Restated Limited License Agreement with MyMD Pharmaceuticals

On June 27, 2022, we entered into an Amended and Restated Limited License Agreement with MyMD, having an effective date of April 26, 2022. The license, as amended on April 20, 2023, grants our company a perpetual right to use MyMD's Supera-CBD as a synthetic intermediate in the manufacture of MIRA1a for research and development activities as well as for commercial uses in the United States and in jurisdictions outside of those in which MyMD holds foreign patent rights to MIRA1a. In consideration of this license, we agreed to share with MyMD technical information and know-how that pertains to the synthetic manufacture and/or formulation of our MIRA1a product candidate and granted a license to MyMD to use improvements to MIRA1a made under the agreement.

Consulting and Employment Agreements with Dr. Chapman

On April 1, 2022, we entered into a Consulting Agreement with Dr. Chapman pursuant to which he provided regulatory and drug development consulting services to the Company on an as-requested basis. Pursuant to the Consulting Agreement, he was to be paid a one-time fee of \$100,000 upon the completion of this offering (of which \$50,000 was prepaid in in the first quarter of 2022) plus a monthly fee of \$20,000 thereafter. The monthly fee was to begin upon the completion of this offering. He was also reimbursed for reasonable out-of-pocket expenses incurred in connection with his duties under the Consulting Agreement. The agreement had a term of one year with an automatic one-year extension, provided that either party could terminate the agreement without cause upon 30-days prior written notice.

In his capacity as a consultant, Dr. Chapman was also granted on June 15, 2022, an option to purchase up to 1,000,000 shares of our common stock at an exercise price of \$1.00 per share. Upon Dr. Chapman becoming Executive Chairman, he has received or will receive additional compensation in that capacity, and his employment agreement will at such time replace his Consulting Agreement. See "Executive Compensation" above.

Consulting Relationship with Mr. Kroenig

In his capacity as a consultant, Mr. Kroenig was also granted on June 15, 2022, an option to purchase up to 50,000 shares of our common stock at an exercise price of \$1.00 per share. This option was granted under our 2022 Omnibus Plan and vested as to 25% of the option shares on the date of grant, with the balance vesting in one-third increments on each of the three successive anniversaries of the grant date. The option has a term of 10 years, subject to earlier termination upon certain terminations of Kroenig's position as a consultant to the Company and may be accelerated upon a change in control.

Consulting Agreement with Dr. Kaplin

Prior to Dr. Kaplin becoming our President and Chief Scientific Officer in May 2022, Dr. Kaplin was a party to a consulting agreement with our company pursuant to which Dr. Kaplin was paid \$100,000 in 2021.

Review and Approval of Related Party Transactions

Prior to the completion of this offering, our board of directors will adopt a written policy regarding the review and approval of related party transactions. Our audit committee charter provides that the audit committee shall review and approve or disapprove any related party transactions, which are transactions between us and related persons in which the aggregate amount involved exceeds or may be expected to exceed \$120,000 and in which a related person has or will have a direct or indirect material interest. Upon the completion of this offering, our policy regarding transactions between us and related persons will provide that a related person is defined as a director, executive officer, nominee for director or greater than 5% beneficial owner of our common stock, in each case since the beginning of the most recently completed year, and any of their immediate family members.

Certain of the foregoing disclosures are summaries of certain provisions of our related party agreements and are qualified in their entirety by reference to all of the provisions of such agreements. Because these descriptions are only summaries of the applicable agreements, they do not necessarily contain all of the information that you may find useful. Copies of certain of the agreements have been filed as exhibits to the registration statement of which this prospectus is a part and are available electronically on the website of the SEC at www.sec.gov.

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PRINCIPAL SHAREHOLDERS

The following table sets forth information as of April 28, 2023 (the “Beneficial Ownership Date”) with respect to the beneficial ownership of our common stock (i) immediately prior to this offering and (ii) as adjusted to reflect the sale of _____ shares of our common stock in this offering, in each case by:

- each of our named executive officers;
- each of our directors;
- all of our current directors and executive officers as a group; and
- each person known by us to be the beneficial owner of more than 5% of the outstanding shares of our common stock.

We have determined beneficial ownership in accordance with the rules of the SEC, and thus it represents sole or shared voting or investment power with respect to our securities. In computing the number of shares beneficially owned by a person and the percentage ownership of that person, shares of common stock subject to options or warrants held by that person that are currently exercisable or exercisable within 60 days of the Beneficial Ownership Date are deemed outstanding but are not deemed outstanding for computing the percentage ownership of any other person. Unless otherwise indicated below, to our knowledge, the persons and entities named in the table have sole voting and sole investment power with respect to all shares that they beneficially owned, subject to community property laws where applicable. The information does not necessarily indicate beneficial ownership for any other purpose, including for purposes of Sections 13(d) and 13(g) of the Securities Act.

In the table below, the applicable percentage ownership relating to shares beneficially owned prior to this offering is based on shares of our common stock outstanding as of the Beneficial Ownership Date. The applicable percentage ownership relating to shares beneficially owned after this offering is based on _____ shares of our common stock outstanding and assumes that the underwriters do not exercise their option to purchase additional shares of common stock from us. Unless otherwise indicated in the footnotes below, the address of each beneficial owner listed in the table below is 900 West Platt Street Suite 200, Tampa, Florida 33606.

Name of beneficial owner	Shares of Common Stock Beneficially Owned			
	Shares of Common Stock Beneficially Owned Before this Offering		Shares of Common Stock Beneficially Owned After this Offering	
	Number of Shares	Percentage	Number of Shares	Percentage
Directors and Executive Officers				
Erez Aminov	1,367,500	2.05%		
Michelle Yanez	111,112	*		
Adam Kaplin, MD, PhD	1,566,667	2.33%		
Chris Chapman, MD	1,600,000	2.38%		
Christos Nicholoudis, Esq.	25,000	*		
Dave Vorhoff	350,000	*		
Brad Koenig	433,334	*		
Talhia Tuck	250,000	*		
Hugh McColl III	350,000	*		
All current directors and officers as a group ⁽¹⁾	6,053,613	9.04%		
5% Stockholders				
George Cappy, Esq. ⁽²⁾	19,265,500	28.94%		
Brian McNulty ⁽³⁾	3,350,000	5.03%		
William J. Nellis ⁽⁴⁾	3,400,000	5.11%		
Samuel S. Duffey, Esq. ⁽⁵⁾	3,350,000	5.03%		

*Represents beneficial ownership of less than 1%

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(1) Includes shares subject to options granted under our 2022 Omnibus Plan that are exercisable within 60 days of the Beneficial Ownership Date held as follows: Mr. Aminov, 250,000 shares; Ms. Yanez, 111,112 shares; Dr. Kaplin, 566,667 shares; Dr. Chapman, 600,000 shares; Mr. Nicholoudis, 25,000 shares; Mr. Vorhoff, 150,000 shares; Mr. Koenig, 183,334 shares; Ms. Tuck, 150,000 shares; Mr. McColl, 150,000 shares; and all current officers and directors as a group, 3,867,500 shares. Excludes shares subject to options granted under our 2022 Omnibus Plan that are not exercisable within 60 days of the Beneficial Ownership Date.

(2) Consists of (i) 100,000 shares held directly by Mr. Cappy, and (ii) 14,165,500 shares held by the Bay Shore Trust, and (iii) 5,000,000 shares issuable pursuant to a warrant held by the Bay Shore Trust that is immediately exercisable. As trustee of the Bay Shore Trust, Mr. Cappy has sole voting and dispositive power over the shares held by the trust, and, as a result is deemed to have beneficial ownership (as determined under Section 13(d) of the Exchange Act) of the securities held by the trust.

- (3) Consists of (i) 50,000 shares held directly by Mr. McNulty and (iii) 3,300,000 shares held by the Celeste J. Williams Lifetime QTIP Trust. As trustee of the Celeste J. Williams Lifetime QTIP Trust, Mr. McNulty has sole voting and dispositive power over the shares held by the trust, and, as a result is deemed to have beneficial ownership (as determined under Section 13(d) of the Exchange Act) of the securities held by the trust.
- (4) Consists of (i) 100,000 shares held directly by Mr. Nellis and (ii) 3,300,000 shares held by the Jonnie Ray Williams, Jr. 2020 Irrevocable Trust. As trustee of the Jonnie Ray Williams, Jr. 2020 Irrevocable Trust, Mr. Nellis has sole voting and dispositive power over the shares held by the trust, and, as a result is deemed to have beneficial ownership (as determined under Section 13(d) of the Exchange Act) of the securities held by the trust.
- (5) Consists of (i) 50,000 shares held directly by Mr. Duffey and (ii) 3,300,000 shares held by the Rachel Jean Williams 2020 Irrevocable Trust. As trustee of the Rachel Jean Williams 2020 Irrevocable Trust, Mr. Duffey has sole voting and dispositive power over the shares held by the trust, and, as a result is deemed to have beneficial ownership (as determined under Section 13(d) of the Exchange Act) of the securities held by the trust.

DESCRIPTION OF CAPITAL STOCK

The following description of the material terms of our amended and restated articles of incorporation and our amended and restated bylaws is a summary, does not purport to be complete and is qualified in its entirety by reference to our amended and restated articles of incorporation and bylaws, which are filed as exhibits to the registration statement of which this prospectus is a part and are incorporated by reference into this prospectus.

The total number of shares of common stock our company is authorized to issue is presently 95,000,000, \$0.0001 par value. The total number of shares of preferred stock our company is authorized to issue is 5,000,000, \$0.0001 par value.

Upon completion of this offering, our authorized capital stock will consist of _____ shares of our common stock, par value \$0.0001 per share, and _____ shares of preferred stock, par value \$0.0001 per share. No shares of preferred stock will be issued or outstanding immediately after the completion of this offering. Unless our board of directors determines otherwise, we will issue all shares of our capital stock in an uncertificated form.

Corporate Governance

We are a corporation organized under the laws of the state of Florida and are governed by the Florida Business Corporation Act, which we sometimes refer to as the FBCA, our amended and restated articles of incorporation and our bylaws.

Common Stock

Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of shareholders. Accordingly, holders of a majority of the shares of our common stock entitled to vote in any election of directors may elect all of the directors standing for election. Holders of our common stock are entitled to receive proportionately any dividends if and when such dividends are declared by our board of directors, subject to any preferential dividend rights of outstanding preferred stock. Upon the liquidation, dissolution or winding up of the company, the holders of our common stock are entitled to receive ratably net assets available after the payment of all debts and other liabilities and subject to the prior rights of holders of any outstanding preferred stock. The rights, preferences, and privileges of holders of our common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future.

Preferred Stock

Our board of directors is authorized to provide for the issuance of shares of preferred stock in one more class series, to establish the number of shares to be included in each such class or series, and to fix the voting powers (if any), designations, powers, preferences, and relative, participating, optional or other rights, if any, of the shares of each such class or series, and any qualifications, limitations or restrictions of such preferences and rights, including, without limitation, dividend rights, conversion rights, voting rights (if any), redemption privileges and liquidation preferences, in each instance as the board of directors may determine in its sole discretion and without stockholder approval.

Dividends and Other Distributions

We currently intend to retain all available funds and any future earnings for general corporate purposes, including working capital, operating expenses, and capital expenditures, and do not anticipate declaring or paying any cash dividends on our common stock in the foreseeable future. See "Dividend Policy."

Number and Election of Directors

Our Board consists of seven members. The holders of common stock and any other class of stock of our company, to the extent they shall have the right to vote, shall retain the right to elect and remove all members of the board of directors.

Quorum/Voting

At all meetings of our board of directors, a majority of the total number of directors constitutes a quorum. If there is a quorum, a vote of the majority of the directors present at the meeting is considered an act of our board of directors.

Removal of Directors

Our articles provide that any director may be removed from office, but only for cause by the affirmative vote of not less than a majority of our shareholders entitled to vote in the election of directors. "Cause" is construed to exist only if the director whose removal is proposed has been convicted of a felony or has been adjudged to be liable for willful misconduct in the performance of his or her duties to us in a matter which has a material adverse effect on our business.

Vacancies on the Board of Directors

A vacancy on our board of directors may be filled by a vote of a majority of the remaining members of the board of directors, even if less than a quorum, at any meeting of the board of directors. A person so elected by the board of directors to fill a vacancy shall hold office for the remainder of the full term of the director for which the vacancy was created or occurred and until such director's successor shall have been duly elected and qualified.

Voting by Shareholders

Each holder of our common stock is entitled to one vote per share for the election of directors and for all other corporate purposes.

Amendment of Articles

Our amended and restated articles of incorporation provide that we may amend, alter, change, or repeal any provision in the manner now or hereafter prescribed by statute. The FBCA allows us to amend our articles at any time to add or change a provision that is required or permitted to be included in the articles of incorporation or to delete a provision that is not required to be included in the articles of incorporation.

Amendment of Bylaws

Our bylaws may be amended or repealed, and new bylaws may be adopted by our shareholders at any annual or special meetings at which a quorum is present. The bylaws may also be amended or repealed, and new bylaws may be adopted by our board of directors by affirmative vote of a majority of the number of directors present at any meeting at which a quorum is in attendance. Notwithstanding the foregoing, pursuant to our articles, the provisions of our bylaws that require a greater voting requirement than provided in the FBCA may only be amended by the same vote required to take action under that voting requirement.

Anti-Takeover Effects of Various Provisions of Florida Law, Our Amended and Restated Articles of Incorporation and Our Bylaws

Provisions of Florida law have certain anti-takeover effects. Our amended and restated articles of incorporation and bylaws also contain provisions that may have similar effects.

Florida Anti-Takeover Statutes

The control share acquisition statute, Section 607.0902 of the FBCA, generally provides that in the event a person acquires voting shares of the company in excess of 20% of the voting power of all of our issued and outstanding shares, such acquired shares will not have any voting rights unless such rights are restored by the holders of a majority of the votes of each class or series entitled to vote separately, excluding shares held by the person acquiring the control shares or any of our officers or employees who are also directors of the company. Certain acquisitions of shares are exempt from these rules, such as shares acquired pursuant to the laws of intestate succession or pursuant to a gift or testamentary transfer, pursuant to a merger or share exchange effected in compliance with the FBCA if we are a party to the agreement, or pursuant to an acquisition of our shares if the acquisition has been approved by our board of directors before the acquisition. The control share acquisition statute generally applies to any “issuing public corporation,” which means a Florida corporation which has:

- One hundred or more shareholders;
- Its principal place of business, its principal office, or substantial assets within Florida; and
- Either (i) more than 10% of its shareholders are resident in Florida; (ii) more than 10% of its shares are owned by residents of Florida; or (iii) one thousand shareholders are resident in Florida.

The affiliated transaction (or so-called “business combination”) statute, Section 607.0901 of the FBCA, provides that we may not engage in certain mergers, consolidations, sales of assets, issuances of stock, reclassifications, recapitalizations, and other affiliated transactions with any “interested shareholder” for a period of three years following the time that such shareholder became an interested shareholder, unless:

- Prior to the time that such shareholder became an interested shareholder, our board of directors approved either the affiliated transaction or the transaction which resulted in the shareholder becoming an interested shareholder; or
- Upon consummation of the transaction that resulted in the shareholder becoming an interested shareholder, the interested shareholder owned at least 85% of our voting shares outstanding at the time the transaction commenced; or
- At or subsequent to the time that such shareholder became an interested shareholder, the affiliated transaction is approved by our board of directors and authorized at an annual or special meeting of shareholders, and not by written consent, by the affirmative vote of at least two-thirds of the outstanding voting shares which are not owned by the interested shareholder.

An “interested shareholder” is generally defined as any person who is the beneficial owner of more than 15% of our outstanding voting shares.

The voting requirements set forth above do not apply to a particular affiliated transaction if one or more conditions are met, including, but not limited to, the following: if the affiliated transaction has been approved by a majority of our disinterested directors; if we have not had more than 300 shareholders of record at any time during the three years preceding the date the affiliated transaction is announced; if the interested shareholder has been the beneficial owner of at least 80% of our outstanding voting shares for at least three years preceding the date the affiliated transaction is announced; or if the consideration to be paid to the holders of each class or series of voting shares in the affiliated transaction meets certain requirements of the statute with respect to form and amount, among other things.

No Cumulative Voting

The FBCA provides that shareholders do not have the right to cumulate votes in the election of directors unless the articles of incorporation provide otherwise. Our articles do not provide for cumulative voting.

Calling a Special Meeting

Our bylaws provide those shareholders seeking to bring business before an annual meeting must provide timely notice of their proposal in writing to the corporate secretary. To be timely, a shareholder’s notice must have been received on or before December 31 of the year immediately preceding the annual meeting; provided, however, that in the event that the date of the annual meeting is on or after May 1 in any year, notice by the shareholder to be timely must be received not later than the close of business on the day which is determined by adding to December 31 of the year immediately preceding such annual meeting the number of days starting with May 1 and ending on the date of the annual meeting in such year. The bylaws also specify requirements as to the form and content of a shareholder’s notice. These provisions may impede shareholders’ ability to bring matters before an annual meeting of shareholders or make nominations for directors at an annual meeting of shareholders.

Our bylaws also provide that a special meeting of shareholders can only be called by our chairman of the board of directors, our chief executive officer, our president (in the absence of a chief executive officer), a majority of our board of directors or the holders of 10% or more of all of our votes entitled to be cast on any issue proposed to be considered at the special meeting of shareholders.

Authorized But Unissued Shares

Our authorized but unissued shares of common stock and preferred stock will be available for future issuance without shareholder approval.

Preemptive Rights

No holder of our common stock has any preemptive or subscription rights to acquire shares of our capital stock.

Liability and Indemnification of Officers and Directors

Our amended and restated articles of incorporation and bylaws provide that we shall indemnify any and all persons whom we shall have power to indemnify under the FBCA to the fullest extent permitted by law.

Section 607.0831 of the FBCA, provides that a director is not personally liable for monetary damages to the corporation or any other person for any statement, vote, decision to take or not to take action, or any failure to take any action, as a director, unless (1) the director breached or failed to perform his or her duties as a director and (2) the director's breach of, or failure to perform, those duties constitutes (a) a violation of the criminal law, unless the director had reasonable cause to believe his or her conduct was lawful or had no reasonable cause to believe his or her conduct was unlawful, (b) a transaction from which the director derived an improper personal benefit, either directly or indirectly, (c) a circumstance under which the liability provisions of Section 607.0834 of the FBCA are applicable, (d) in a proceeding by or in the right of the corporation to procure a judgment in its favor or by or in the right of a shareholder, conscious disregard for the best interest of the corporation, or willful or intentional misconduct, or (e) in a proceeding by or in the right of someone other than the corporation or a shareholder, recklessness or an act or omission which was committed in bad faith or with malicious purpose or in a manner exhibiting wanton and willful disregard of human rights, safety, or property. A judgment or other final adjudication against a director in any criminal proceeding for a violation of the criminal law estops that director from contesting the fact that his or her breach, or failure to perform, constitutes a violation of the criminal law; but does not estop the director from establishing that he or she had reasonable cause to believe that his or her conduct was lawful or had no reasonable cause to believe that his or her conduct was unlawful.

Under Section 607.0851 of the FBCA, a corporation has power to indemnify any person who is a party to any proceeding (other than an action by, or in the right of the corporation), because he or she is or was a director or officer of the corporation against liability incurred in connection with such proceeding, including any appeal thereof, if he or she acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, the best interests of the corporation and, with respect to any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful. The termination of any proceeding by judgment, order, settlement or conviction or upon a plea of nolo contendere or its equivalent shall not, of itself, create a presumption that the person did not act in good faith and in a manner which he or she reasonably believed to be in, or not opposed to, the best interests of the corporation or, with respect to any criminal action or proceeding, has reasonable cause to believe that his or her conduct was unlawful.

For purposes of the indemnification provisions of the FBCA, "director" or "officer" means an individual who is or was a director or officer, respectively, of a corporation or who, while a director or officer of the corporation, is or was serving at the corporation's request as a director or officer, manager, partner, trustee, employee, or agent of another domestic or foreign corporation, limited liability company, partnership, joint venture, trust, employee benefit plan, or another enterprise or entity and the terms include, unless the context otherwise requires, the estate, heirs, executors, administrators, and personal representatives of a director or officer.

In addition, under Section 607.0851 of the FBCA, a corporation has the power to indemnify any person, who was or is a party to any proceeding by or in the right of the corporation to procure a judgment in its favor by reason of the fact that the person is or was a director or officer, against expenses and amounts paid in settlement not exceeding, in the judgment of the board of directors, the estimated expense of litigating the proceeding to conclusion, actually and reasonably incurred in connection with the defense or settlement of such proceeding, including any appeal thereof. Such indemnification shall be authorized if such person acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, the best interests of the corporation, except that no indemnification shall be made under this subsection in respect of any claim, issue, or matter as to which such person shall have been adjudged to be liable unless, and only to the extent that, the court in which such proceeding was brought, or any other court of competent jurisdiction, shall determine upon application that, despite the adjudication of liability but in view of all circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which such court shall deem proper.

Section 607.0852 of the FBCA provides that a corporation must indemnify an individual who is or was a director or officer who was wholly successful, on the merits or otherwise, in the defense of any proceeding to which the individual was a party because he or she is or was a director or officer of the corporation against expenses incurred by the individual in connection with the proceeding.

Section 607.0853 of the FBCA provides that a corporation may, before final disposition of a proceeding, advance funds to pay for or reimburse expenses incurred in connection with the proceeding by an individual who is a party to the proceeding because that individual is or was a director or an officer if the director or officer delivers to the corporation a signed written undertaking of the director or officer to repay any funds advanced if (a) the director or officer is not entitled to mandatory indemnification under Section 607.0852; and (b) it is ultimately determined under Section 607.0854 or Section 607.0855 (as described below) that the director or officer has not met the relevant standard of conduct described in Section 607.0851 or the director or officer is not entitled to indemnification under Section 607.0859 (as described below).

Section 607.0854 of the FBCA provides that, unless the corporation's articles of incorporation provide otherwise, notwithstanding the failure of a corporation to provide indemnification, and despite any contrary determination of the board of directors or of the shareholders in the specific case, a director or officer of the corporation who is a party to a proceeding because he or she is or was a director or officer may apply for indemnification or an advance for expenses, or both, to a court having jurisdiction over the corporation which is conducting the proceeding, or to a circuit court of competent jurisdiction. Our amended and restated articles of incorporation do not provide any such exclusion. After receipt of an application and after giving any notice it considers necessary, the court may order indemnification or advancement of expenses upon certain determinations of the court.

Section 607.0855 of the FBCA provides that, unless ordered by a court under Section 607.0854, a corporation may not indemnify a director or officer under Section 607.0851 unless authorized for a specific proceeding after a determination has been made that indemnification is permissible because the director or officer has met the relevant standard of conduct set forth in Section 607.0851.

Section 607.0857 of the FBCA also provides that a corporation shall have the power to purchase and maintain insurance on behalf of and for the benefit of any person who is or was a director or officer of the corporation against any liability asserted against the person and incurred by him or her in any such capacity or arising out of his or her status as such, whether or not the corporation would have the power to indemnify or advance expenses to the individual against such liability under the provisions of Section 607.0857.

Section 607.0858 of the FBCA provides that the indemnification provided pursuant to Section 607.0851 and Section 607.0852, and the advancement of expenses provided pursuant to Section 607.0853, are not exclusive. A corporation may, by a provision in its articles of incorporation, bylaws, or any agreement, or by vote of shareholders or disinterested directors, or otherwise, obligate itself in advance of the act or omission giving rise to a proceeding to provide any other or further indemnification or advancement of expenses to any of its directors or officers.

Section 607.0859 of the FBCA provides that, unless ordered by a court under the provisions of Section 607.0854 of the FBCA, a corporation may not indemnify a director or officer under Section 607.0851 or Section 607.0858, or advance expenses to a director or officer under Section 607.0853 or Section 607.0858, if a judgment or other final adjudication establishes that his or her actions, or omissions to act, were material to the cause of action so adjudicated and constitute: (a) willful or intentional misconduct

or a conscious disregard for the best interests of the corporation in a proceeding by or in the right of the corporation to procure a judgment in its favor or in a proceeding by or in the right of a shareholder; (b) a transaction in which a director or officer derived an improper personal benefit; (c) a violation of the criminal law, unless the director or officer had reasonable cause to believe his or her conduct was lawful or had no reasonable cause to believe his or her conduct was unlawful; or (d) in the case of a director, a circumstance under which the liability provisions of Section 607.0834 are applicable (relating to unlawful distributions).

These provisions may have the practical effect in certain cases of eliminating the ability of shareholders to collect monetary damages from our directors and officers. We believe that these provisions are necessary to attract and retain qualified persons to serve as our directors and officers. There is currently no pending material litigation or proceeding involving any of our directors, officers or employees for which indemnification is sought.

Transfer Agent and Registrar

American Stock Transfer (also known as Equiniti) will be the transfer agent and registrar for our common stock.

Listing

We intend to apply to list our common stock on the Nasdaq Capital Market under the symbol "MIRA".

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SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there was no public market for our common stock, and there can be no assurance that a significant public market for our common stock will develop or be sustained after this offering. Future sales of substantial amounts of our common stock in the public market (including securities convertible into or redeemable, exchangeable, or exercisable for shares of common stock) or the perception that such sales may occur or the availability of such shares for sale in the public market, after this offering could adversely affect the prevailing market price of our common stock. Furthermore, because all of our common stock outstanding prior to the completion of this offering (including securities convertible into or redeemable, exchangeable, or exercisable for shares of our common stock) will be subject to the contractual and legal restrictions on resale described below, the sale of a substantial amount of common stock in the public market after these restrictions lapse could materially adversely affect the prevailing market price of our common stock and our ability to raise equity capital in the future.

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after the lock-up and other legal restrictions on resale discussed in this prospectus lapse, the trading price of our common stock could decline. Based on shares of common stock outstanding as of _____, 2023, upon the completion of this offering we will have outstanding a total of _____ shares of common stock. Of these shares, only the shares of common stock sold in this offering by us, plus any shares sold upon exercise of the underwriters' option to purchase additional shares, will be freely tradable without restriction in the public market immediately following this offering.

The lock-up agreements pertaining to this offering will expire _____ days from the date of this prospectus, subject to earlier release of all or a portion of the shares subject to such agreements by the representatives of the underwriters in this offering in their sole discretion. After the lock-up agreements expire, based upon the number of shares of common stock, on an as-converted basis, outstanding as of _____, 2023, up to an additional _____ shares of common stock will be eligible for sale in the public market. Approximately _____ % of these additional shares are beneficially held by directors, executive officers and their affiliates and will be subject to certain limitations of Rule 144 under the Securities Act of 1933, as amended, or the Securities Act.

In addition, shares of common stock that are either subject to outstanding options or reserved for future issuance under our existing equity compensation plans will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, the lock-up agreements and Rule 144 and Rule 701 under the Securities Act. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline. Additionally, the number of shares of our common stock reserved for issuance under the 2022 Omnibus Plan will automatically increase on January 1 of each year following our initial public offering by the least of 1.0 million shares, 1% of outstanding shares, or such lesser number as is determined by our board of directors.

All of the shares of common stock sold in this offering will be freely transferable without restriction or further registration under the Securities Act by persons other than "affiliates," as that term is defined in Rule 144 under the Securities Act.

Generally, the balance of our outstanding shares of common stock will be deemed "restricted securities" within the meaning of Rule 144 under the Securities Act, subject to the limitations and restrictions that are described below. Common stock purchased by our affiliates will be "restricted securities" under Rule 144. Restricted securities may be sold in the public market only if they are registered under the Securities Act or if they qualify for an exemption from registration under Rule 144 or Rule 701 under the Securities Act, which rules are summarized below.

As a result of the lock-up agreements described below and subject to the provisions of Rule 144 or Rule 701, shares of our common stock will be available for sale in the public market as follows:

- beginning on the date of this prospectus, all _____ shares of our common stock sold in this offering will be immediately available for sale in the public market;
- beginning _____ days after the date of this prospectus, _____ additional shares of common stock become eligible for sale in the public market, of which _____ shares would be held by affiliates and subject to the volume and other restrictions of Rule 144, as described below.

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Lock-up Agreements

In connection with this offering, we, our directors, our executive officers and stockholders holding 3% or more of our shares of common stock outstanding as of _____, 2023 have agreed, subject to certain exceptions, with the underwriters not to dispose of or hedge any shares of our common stock or securities convertible into or exchangeable for shares of common stock during the period from the date of the lock-up agreement continuing through the date 180 days after the closing date of this offering, except with the prior written consent of _____ as the representative of the underwriters and certain other exceptions. The representative of the underwriters has advised us that they have no current intent or arrangement to release any of the shares subject to the lock-up agreements prior to the expiration of the lock-up period. See the "Underwriting" section of this prospectus for additional information.

Following the lock-up periods set forth in the agreements described above, and assuming that the representative of the underwriters does not release any parties from these agreements, all of the shares of our common stock that are restricted securities or are held by our affiliates as of the date of this prospectus will be eligible for sale in the public market in compliance with Rule 144 under the Securities Act.

Rule 144

In general, under Rule 144 as in effect on the date of this prospectus, beginning 90 days after completion of this offering, a person (or persons whose common stock is

required to be aggregated) who is an affiliate and who has beneficially owned our common stock for at least six months is entitled to sell in any three-month period a number of shares that does not exceed the greater of:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately _____ shares immediately after completion of this offering; or
- the average weekly trading volume in our common stock on _____ during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such a sale.

Sales by our affiliates under Rule 144 are also subject to manner of sale provisions and notice requirements and to the availability of current public information about us. An “affiliate” is a person that directly, or indirectly through one or more intermediaries, controls or is controlled by, or is under common control with, an issuer.

Under Rule 144, a person (or persons whose shares are aggregated) who is not deemed to have been an affiliate of ours at any time during the 90 days preceding a sale, and who has beneficially owned the shares proposed to be sold for at least six months (including the holding period of any prior owner other than an affiliate), would be entitled to sell those shares subject only to availability of current public information about us, and after beneficially owning such shares for at least 12 months, would be entitled to sell an unlimited number of shares without restriction. To the extent that our affiliates sell their shares of common stock, other than pursuant to Rule 144 or a registration statement, the purchaser’s holding period for the purpose of effecting a sale under Rule 144 commences on the date of transfer from the affiliate.

Regulation S

Regulation S under the Securities Act provides that securities owned by any person may be sold without registration in the United States, provided that the sale is effected in an “offshore transaction” and no “directed selling efforts” are made in the United States (as these terms are defined in Regulation S) and subject to certain other conditions. In general, this means that our shares may be sold in some manner outside the United States without requiring registration in the United States.

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Rule 701

In general, under Rule 701 as in effect on the date of this prospectus, any of our employees, directors, officers, consultants, or advisors who purchased shares from us in reliance on Rule 701 in connection with a compensatory stock or option plan or other written agreement before the effective date of this offering, or who purchase shares from us after that date upon the exercise of options granted before that date, are eligible to resell such shares 90 days after the effective date of this offering in reliance upon Rule 144. If such person is not an affiliate, such sale may be made subject only to current public information provisions of Rule 144. If such a person is an affiliate, such sale may be made under Rule 144 without compliance with the holding period requirement, but subject to the other Rule 144 restrictions described above.

Equity Incentive Plans

Following the completion of this offering, we intend to file one or more registration statements on Form S-8 under the Securities Act to register all shares of common stock issued or issuable under the 2022 Omnibus Plan. Any such Form S-8 registration statements will automatically become effective upon filing. Accordingly, shares registered under such registration statements will be available for sale in the open market following the expiration of the lock-up period. We expect that the initial registration statements on Form S-8 will cover approximately _____ shares of our common stock. Shares issued under the 2022 Omnibus Plan after the effective date of the applicable Form S-8 registration statement will be eligible for resale in the public market without restriction, subject to Rule 144 limitations applicable to affiliates and the lock-up agreements described above. See “Executive Compensation — Executive Compensation Arrangements — Equity Compensation,” and “Executive Compensation Plan” for a description of the 2022 Omnibus Plan.

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MATERIAL U.S. FEDERAL INCOME TAX CONSIDERATIONS FOR NON-U.S. HOLDERS OF OUR COMMON STOCK

The following discussion is a summary of the material U.S. federal income tax consequences to non-U.S. holders (as defined below) of the ownership and disposition of our common stock issued pursuant to this offering but is not intended to be a complete analysis of all potential tax consequences. The effects of other U.S. federal tax laws, such as estate and gift tax laws, and any applicable state, local or non-U.S. tax laws are not discussed. This discussion is based on the U.S. Internal Revenue Code of 1986, as amended (the “Code”), final, temporary, and proposed Treasury Regulations, judicial decisions, and published rulings and administrative pronouncements of the U.S. Internal Revenue Service (the “IRS”), in each case as in effect as of the date of this prospectus. These authorities may change or be subject to differing interpretations, and any such change or differing interpretation may be applied retroactively in a manner that could adversely affect a non-U.S. holder of our common stock. We have not sought and will not seek any rulings from the IRS regarding the matters discussed below. There can be no assurance the IRS or a court will not take a contrary position to that discussed below regarding the tax consequences of the ownership and disposition of our common stock.

This discussion is limited to a non-U.S. holder that holds our common stock as a “capital asset” within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not address all U.S. federal income tax consequences relevant to a non-U.S. holder’s particular circumstance, including the impact of the alternative minimum tax, the special tax accounting rules in Section 451(b) of the Code or the Medicare contribution tax on net investment income. In addition, it does not address consequences relevant to Non-U.S. Holders subject to special rules, including, without limitation:

- U.S. expatriates and former citizens or long-term residents of the United States;
- persons holding our common stock as part of a straddle, or other risk reduction strategy or as part of a conversion transaction or other integrated investment;
- banks, insurance companies, and other financial institutions;
- brokers, dealers, or certain electing traders in securities that use a mark-to-market method of tax accounting for their securities positions;
- “controlled foreign corporations,” “passive foreign investment companies,” and corporations that accumulate earnings to avoid U.S. federal income tax;
- partnerships or other entities or arrangements treated as partnerships for U.S. federal income tax purposes and other pass-through entities (and investors in such entities);
- tax-exempt organizations or governmental organizations;
- persons deemed to sell our common stock under the constructive sale provisions of the Code;
- tax-qualified retirement plans; and

- “qualified foreign pension funds” as defined in Section 897(1)(2) of the Code and entities all of the interests of which are held by qualified foreign pension funds.

If an entity treated as a partnership for U.S. federal income tax purposes holds our common stock, the tax treatment of a partner in the partnership will depend on the status of the partner, the activities of the partnership, and certain determinations made at the partner level. Partnerships holding our common stock and the partners in such partnerships should consult their tax advisors regarding the U.S. federal income tax consequences to them.

THIS DISCUSSION IS FOR INFORMATIONAL PURPOSES ONLY AND IS NOT TAX ADVICE. INVESTORS SHOULD CONSULT THEIR TAX ADVISORS WITH RESPECT TO THE APPLICATION OF THE U.S. FEDERAL INCOME TAX LAWS TO THEIR PARTICULAR SITUATIONS AS WELL AS ANY TAX CONSEQUENCES OF THE PURCHASE, OWNERSHIP, AND DISPOSITION OF OUR COMMON STOCK ARISING UNDER THE U.S. FEDERAL ESTATE OR GIFT TAX LAWS OR UNDER THE LAWS OF ANY STATE, LOCAL, OR NON-U.S. TAXING JURISDICTION OR UNDER ANY APPLICABLE INCOME TAX TREATY.

Definition of a Non-U.S. Holder

For purposes of this discussion, a “non-U.S. holder” is any beneficial owner of our common stock that is an individual, corporation, estate or trust and is not a “U.S. person.” A U.S. person is any person that, for U.S. federal income tax purposes, is or is treated as any of the following:

- an individual who is a citizen or resident of the United States;
- a corporation created or organized under the laws of the United States, any state thereof, or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust that (1) is subject to the primary supervision of a U.S. court and the control of one or more “United States persons” (within the meaning of Section 7701(a)(30) of the Code), or (2) has a valid election in effect to be treated as a United States person for U.S. federal income tax purposes.

Distributions

As described in the section entitled “Dividend Policy,” we do not anticipate declaring or paying dividends to holders of our common stock in the foreseeable future. However, if we do make distributions of cash or property on our common stock, such distributions will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Amounts not treated as dividends for U.S. federal income tax purposes will constitute a nontaxable return of capital and first be applied against and reduce a Non-U.S. Holder’s adjusted tax basis in its common stock, but not below zero, and any excess will be treated as capital gain and will be treated as described below under “— Sale or Other Taxable Disposition.”

Subject to the discussion below on effectively connected income, dividends paid to a Non-U.S. Holder of our common stock will be subject to U.S. federal withholding tax at a rate of 30% of the gross amount of the dividends (or such lower rate specified by an applicable income tax treaty, provided the Non-U.S. Holder furnishes a valid IRS Form W-8BEN or W-8BEN-E (or other applicable documentation) certifying qualification for the lower treaty rate of withholding). A Non-U.S. Holder that does not timely furnish the required documentation, but that qualifies for a reduced treaty rate, may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS. Non-U.S. Holders should consult their tax advisors regarding their entitlement to benefits under any applicable income tax treaty.

If dividends paid to a Non-U.S. Holder are effectively connected with the Non-U.S. Holder’s conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the Non-U.S. Holder maintains a permanent establishment in the United States to which such dividends are attributable), the Non-U.S. Holder will be exempt from the U.S. federal withholding tax described above. To claim the exemption, the non-U.S. holder must furnish to the applicable withholding agent a valid IRS Form W-8ECI, certifying that the dividends are effectively connected with the Non-U.S. Holder’s conduct of a trade or business within the United States.

Any such effectively connected dividends will be subject to U.S. federal income tax on a net income basis at the rates applicable to U.S. persons. A Non-U.S. Holder that is a corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on such effectively connected dividends, as adjusted for certain items. Non-U.S. Holders should consult their tax advisors regarding any applicable tax treaties that may provide for different rules.

Sale or Other Taxable Disposition

Subject to the discussion below under “— Information Reporting and Backup Withholding” and “— Additional Withholding Tax Under FATCA”, a Non-U.S. Holder will not be subject to U.S. federal income tax on any gain realized upon the sale or other taxable disposition of our common stock unless:

- the gain is effectively connected with the Non-U.S. Holder’s conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the non-U.S. holder maintains a permanent establishment in the United States to which such gain is attributable);

- the non-U.S. holder is a nonresident alien individual present in the United States for 183 days or more during the taxable year of the disposition and certain other requirements are met; or
- our common stock constitutes a U.S. real property interest (a “USRPI”) by reason of our being treated as a U.S. real property holding corporation (a “USRPHC”) for U.S. federal income tax purposes at any applicable time within the shorter of the five-year period preceding the non-U.S. Holder’s disposition of, or the non-U.S. holder’s holding period for, our common stock.

Gain described in the first bullet point above generally will be subject to U.S. federal income tax on a net income basis at the rates applicable to U.S. persons. A non-U.S. Holder that is a corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on such effectively connected gain, as adjusted for certain items.

Gain described in the second bullet point above will be subject to U.S. federal income tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty), which may be offset by U.S. source capital losses of the non-U.S. Holder (even though the individual is not considered a resident of the United States), provided the Non-U.S. Holder has timely filed U.S. federal income tax returns with respect to such losses.

With respect to the third bullet point above, generally a corporation is a USRPHC if the fair market value of its USRPIs equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests and its other assets used or held for use in trades or businesses (all as determined for U.S. federal income tax purposes). We believe we currently are not, and we do not anticipate becoming, a USRPHC. Because the determination of whether we are a USRPHC depends, however, on the fair market

value of our USRPIs relative to the fair market value of all our real property interests and our other business assets, there can be no assurance that we currently are not a USRPHC or will not become one in the future. Even if we are or were to become a USRPHC, gain arising from the sale or other taxable disposition by a Non-U.S. Holder of our common stock will not be subject to U.S. federal income tax if our common stock is “regularly traded,” as defined by applicable Treasury Regulations, on an established securities market, and such Non-U.S. Holder owned, actually and constructively, 5% or less of our common stock throughout the shorter of the five-year period ending on the date of the sale or other taxable disposition or the Non-U.S. Holder’s holding period.

Non-U.S. Holders should consult their tax advisors regarding potentially applicable income tax treaties that may provide for different rules.

Information Reporting and Backup Withholding

Information returns are required to be filed with the IRS in connection with any dividends on our common stock paid to a non-U.S. holder whether or not withholding is required. Copies of the information returns reporting such interest, dividends, and withholding may also be made available to the tax authorities in the country in which a non-U.S. holder resides under the provisions of an applicable income tax treaty. Payments of dividends on our common stock will not be subject to backup withholding, provided the applicable withholding agent does not have actual knowledge or reason to know the beneficial owner is a United States person and the Non-U.S. Holder either certifies its non-U.S. status, such as by furnishing a valid IRS Form W-8BEN, W-8BEN-E or W-8ECI, or other applicable documentation, or otherwise establishes an exemption. Proceeds of the sale or other taxable disposition of our common stock within the United States or conducted through certain U.S.-related brokers generally will not be subject to backup withholding or information reporting, if the applicable withholding agent receives the certification described above and does not have actual knowledge or reason to know that such beneficial owner is a United States person, or otherwise establishes an exemption. Proceeds of a disposition of our common stock conducted through a non-U.S. office of a non-U.S. broker generally will not be subject to backup withholding or information reporting.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be allowed as a refund or a credit against a non-U.S. Holder’s U.S. federal income tax liability, provided the required information is timely furnished to the IRS.

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Additional Withholding Tax Under FATCA

Sections 1471 to 1474 of the Code (such sections commonly referred to as the Foreign Account Tax Compliance Act, or “FATCA”) and the Treasury Regulations and administrative guidance thereunder impose a 30% withholding tax on certain types of payments made to a “foreign financial institution” or a “non-financial foreign entity” (each as defined in the Code), including, in some cases, when such foreign financial institution or non-financial foreign entity acts as an intermediary, unless (1) the foreign financial institution has entered into an agreement with the U.S. government to withhold on certain payments and to undertake certain diligence and reporting obligations regarding U.S. account holders (including certain account holders that are non-U.S. entities with U.S. owners), (2) the non-financial foreign entity either certifies it does not have any “substantial United States owners” (as defined in the Code) or furnishes identifying information regarding each substantial United States owner, or (3) the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from these rules. Foreign financial institutions located in jurisdictions that have an intergovernmental agreement with the United States governing FATCA may be subject to different rules.

Under the applicable Treasury Regulations and administrative guidance, withholding under FATCA generally applies to payments of dividends on our common stock. While withholding under FATCA would have applied also to payments of gross proceeds from the sale or other disposition of stock on or after January 1, 2019, recently proposed Treasury Regulations eliminate FATCA withholding on payments of gross proceeds entirely. Taxpayers generally may rely on these proposed Treasury Regulations until final Treasury Regulations are issued.

Prospective investors should consult their tax advisors regarding the potential application of withholding under FATCA to their investment in our common stock.

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UNDERWRITING

Kingswood, division of Kingswood Capital Partners LLC is acting as representative of the underwriters of the offering. We have entered into an underwriting agreement (the “underwriting agreement”) with the Representative. Subject to the terms and conditions of the underwriting agreement, we have agreed to sell to the underwriters named below, and the underwriters have agreed, severally and not jointly, to purchase from us, the number of shares of common stock set forth opposite the underwriter’s name in the following table at the initial public offering price per share less underwriting discounts and commissions, as set forth on the cover page of this prospectus.

Underwriter	Number of Shares
Kingswood, division of Kingswood Capital Partners, LLC	
Total	

The underwriters are committed to purchase all of the shares offered by us other than those shares covered by the Over-Allotment Option described below, if they purchase any shares. The obligations of the underwriters may be terminated upon the occurrence of certain events specified in the underwriting agreement. Furthermore, pursuant to the underwriting agreement, the underwriters’ obligations are subject to customary conditions, representations and warranties contained in the underwriting agreement, such as receipt by the underwriters of officers’ certificates and legal opinions.

We have agreed to indemnify the underwriters against specified liabilities, including liabilities under the Securities Act, or to contribute to payments the underwriters may be required to make in respect of those liabilities.

The underwriters are offering the shares, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel and other conditions contained in the underwriting agreement. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

Over-Allotment Option

We have granted the underwriters an option to purchase from us up to an additional _____ shares of our common stock, solely to cover over-allotments, if any. The shares of our common stock to be purchased pursuant to the Over-Allotment Option will be acquired at the public offering price, less the underwriting discounts and commissions. The underwriters may exercise this option, in whole or in part, for our common stock, any time during the 45-day period from the date of this prospectus. If this option is exercised in full, the total price to the public will be \$_____ and the total net proceeds before expenses to us will be \$_____.

Underwriting Discount, Commissions and Expenses

The following table shows the per share of common stock and total underwriting discounts and commissions to be paid to the underwriters. Such amounts are shown assuming both no exercise and full exercise of the underwriters’ option to purchase additional shares, assuming an initial public offering price of \$___ per share, the midpoint of

the estimated price range set forth on the cover page of this prospectus.

	Per Share	Total Without Exercise of Over- Allotment Option	Total With Exercise in Full of Over- Allotment Option
Public offering price	\$	\$	\$
Underwriting discount and commissions	\$	\$	\$
Proceeds, before expenses, to us	\$	\$	\$

The Representative has advised us that they propose initially to offer the shares to the public at the public offering price set forth on the cover page of this prospectus and to dealers at that price less a concession not in excess of \$_____ per share. After the initial public offering, the public offering price, concession and discount may be changed.

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We have also agreed to pay all of the expenses relating to the offering, including, but not limited to, (a) all filing fees and communication expenses relating to the registration of the shares of common stock to be sold in this offering with the Securities and Exchange Commission; (b) all fees and expenses relating to the listing of the shares on the Nasdaq Capital Market and such other exchanges as the Company and Representative together determine, including any fees charged by DTC; (c) all fees, expenses and disbursements relating to the registration or qualification of the shares under “blue sky” or securities laws, of such states of the United States of America and other jurisdictions designated by the Representative, including the reasonable fees and expenses of the Representative’s blue sky counsel; (d) all fees, expenses and disbursements relating to the registration, qualification or exemption of the shares under the securities laws of such foreign jurisdictions designated by the Representative; (e) the costs of mailing and printing the underwriting documents (including the Underwriting Agreement, any Blue Sky Surveys and, if appropriate, any Agreement Among Underwriters, Selected Dealers’ Agreement, Underwriters’ Questionnaire and Power of Attorney), registration statements, prospectuses and all amendments, supplements and exhibits thereto and as many preliminary and final prospectuses as the Representative may reasonably deem necessary; (f) transfer and/or stamp taxes, if any, payable upon our transfer of the shares to the Underwriters; (g) the fees and expenses of the Company’s accountants; (h) all filing fees and communication expenses associated with the review of the offering by FINRA; (i) expenses incurred by the Underwriters for any roadshow for the offering up to \$10,000; (j) the costs associated with bound volumes of the offering materials in an aggregate amount not to exceed \$5,000; (k) the fees of counsel to the Underwriters in an amount not to exceed \$75,000; (l) fees and expenses of the transfer agent for our common stock; (m) the cost associated with the Representative’s use of Ipreo’s book building, prospectus tracking and compliance software for the offering up to \$29,500; (n) the costs of preparing, printing and delivering certificates representing the common stock issued in this offering.

We have paid a \$25,000 expense advance to the Representative, which shall be applied against actual out-of-pocket-accountable expenses, which will be returned to us to the extent such out-of-pocket accountable expenses are not actually incurred in accordance with FINRA Rule 5110(f)(2)(C). We have agreed to pay to the Representative 1% of the gross proceeds of the offering for non-accountable expenses, payable upon the closing of the offering.

We estimate that the total expenses of the offering payable by us, excluding the total underwriting discount, and including the above-referenced advance to the Representative, will be approximately \$_____.

Discretionary Accounts

The underwriters do not intend to confirm sales of the shares offered hereby to any accounts over which they have discretionary authority.

Representative’s Warrants

We have agreed to issue to the Representative or its designees at the closing of this offering warrants to purchase the number of common stock equal to 5.0% of the aggregate number of shares sold in this offering. The warrants will be exercisable at any time and from time to time, in whole or in part, during the four-and-a-half-year period commencing six months after the commencement of sales in this offering. The warrants will be exercisable at a per share price equal to 100% of the initial public offering price per share in the offering. The Warrants provide for registration rights (including a one-time demand registration right and unlimited piggyback rights) and customary anti-dilution provisions.

The warrants have been deemed compensation by FINRA and are therefore subject to a 180-day lock-up pursuant to Rule 5110(g)(1) of FINRA. The Representative (or permitted assignees under Rule 5110(g)(1)) will not sell, transfer, assign, pledge, or hypothecate these warrants or the securities underlying these warrants, nor will they engage in any hedging, short sale, derivative, put, or call transaction that would result in the effective economic disposition of the warrants or the underlying securities for a period of 180 days from the date of this prospectus. The warrants and the common stocks underlying the warrants are being registered as a part of the registration statement of which this prospectus forms a part and will be freely tradable upon the declaration of the effectiveness of such registration statement by the SEC.

The exercise price and number of shares of common stock issuable upon exercise of the warrants may be adjusted in certain circumstances including in the event of a stock dividend, extraordinary cash dividend or recapitalization, reorganization, merger or consolidation.

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Tail Period

The Representative shall be entitled to a cash fee equal to seven percent (7%) of the gross proceeds received by the Company from the sale of any equity, debt and/or equity derivative instruments to any investor actually introduced by the Representative to the Company during the period beginning on _____ 2023 and ending on the later of (i) _____, 2024 or (ii) the final closing, if any, of the Offering (the “Engagement Period”), in connection with any public or private financing or capital raise (each a “Tail Financing”), and such Tail Financing is consummated at any time during the Engagement Period or within the twelve (12) month period following the expiration or termination of the Engagement Period (the “Tail Period”), provided that such Tail Financing is by a party actually introduced to the Company first by the Representative during the Engagement Period.

Lock-Up Agreements

Our officers and directors, and certain of our stockholders have agreed not to, without the prior written consent of the Representative, directly or indirectly, offer to sell, sell, pledge or otherwise transfer or dispose of any shares of our common stock (or enter into any transaction or device that is designed to, or could be expected to, result in the transfer or disposition by any person at any time in the future of shares of our common stock, enter into any swap or other derivatives transaction that transfers to another, in whole or in part, any of the economic benefits or risks of ownership of shares of common stock, make any demand for or exercise any right or cause to be filed a registration statement, including any amendments thereto, with respect to the registration of any of the shares of common stock or securities convertible into or exercisable or exchangeable for shares of common stock or any other of our securities or publicly disclose the intention to do any of the foregoing, subject to customary exceptions, for periods of 180 days from the date of this prospectus.

No Sales of Similar Securities

We have agreed not to offer, pledge, announce the intention to sell, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase or otherwise transfer or dispose of, directly or indirectly, any shares of common stock or any securities convertible into or exercisable or exchangeable for shares of common stock or enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of shares of our common stock, whether any such transaction is to be settled by delivery of shares of common stock or such other securities, in cash or otherwise, without the prior written consent of the Representative, for a period of 180 days from the date of this prospectus.

Electronic Offer, Sale, and Distribution of Securities

A prospectus in electronic format may be made available on the websites maintained by one or more of the underwriters or selling group members. The Representative may agree to allocate a number of shares of common stock to underwriters and selling group members for sale to their online brokerage account holders. Internet distributions will be allocated by the underwriters and selling group members that will make internet distributions on the same basis as other allocations. Other than the prospectus in electronic format, the information on these websites is not part of, nor incorporated by reference into, this prospectus or the registration statement of which this prospectus forms a part, has not been approved or endorsed by us, and should not be relied upon by investors.

Listing

We have applied to have shares of our common stock listed on the Nasdaq Capital Market under the symbol "MIRA".

Determination of Offering Price

Before this offering, there has been no public market for our common stock. Accordingly, the public offering price will be negotiated between us and the underwriter. Among the factors to be considered in these negotiations are:

- the information set forth in this prospectus and otherwise available to the underwriter;
- the prospects for our Company and the industry in which we operate;
- an assessment of our management;
- our past and present financial and operating performance;
- our prospects for future earnings;
- financial and operating information and market valuations of publicly traded companies engaged in activities similar to ours;
- the prevailing conditions of United States securities markets at the time of this offering; and
- other factors deemed relevant.

Neither we nor the underwriter can assure investors that an active trading market will develop for shares of our common stock, or that the shares will trade in the public market at or above the initial public offering price.

Stabilization

In connection with this offering, the underwriter may engage in stabilizing transactions, over-allotment transactions, syndicate-covering transactions, penalty bids, and purchases to cover positions created by short sales.

- Stabilizing transactions permit bids to purchase securities so long as the stabilizing bids do not exceed a specified maximum and are engaged in for the purpose of preventing or retarding a decline in the market price of the securities while the offering is in progress.
- Over-allotment transactions involve sales by the underwriter of securities in excess of the number of securities the underwriter is obligated to purchase. This creates a syndicate short position which may be either a covered short position or a naked short position. In a covered short position, the number of securities over-allotted by the underwriter is not greater than the number of securities that they may purchase in the over-allotment option. In a naked short position, the number of securities involved is greater than the number of securities in the over-allotment option. The underwriter may close out any short position by exercising their over-allotment option and/or purchasing securities in the open market.
- Syndicate covering transactions involves purchases of securities in the open market after the distribution has been completed in order to cover syndicate short positions. In determining the source of securities to close out the short position, the underwriter will consider, among other things, the price of securities available for purchase in the open market as compared with the price at which they may purchase securities through exercise of the over-allotment option. If the underwriter sells more securities than could be covered by exercise of the over-allotment option and, therefore, have a naked short position, the position can be closed out only by buying securities in the open market. A naked short position is more likely to be created if the underwriter is concerned that after pricing there could be downward pressure on the price of the securities in the open market that could adversely affect investors who purchase in the offering.
- Penalty bids permit the underwriter to reclaim a selling concession from a syndicate member when the securities originally sold by that syndicate member are purchased in stabilizing or syndicate covering transactions to cover syndicate short positions.

These stabilizing transactions, over-allotment transactions, syndicate covering transactions, and penalty bids may have the effect of raising or maintaining the market price of our securities or preventing or retarding a decline in the market price of our securities. As a result, the price of our securities in the open market may be higher than it would otherwise be in the absence of these transactions. Neither we nor the underwriter make any representation or prediction as to the effect that the transactions described above may have on the price of our securities. These transactions may be affected on the Nasdaq Stock Market, in the over-the-counter market or otherwise and, if commenced, may be discontinued at any time.

Passive Market Making

In connection with this offering, underwriter, and selling group members may engage in passive market making transactions in our securities on the Nasdaq Stock Market in accordance with Rule 103 of Regulation M under the Exchange Act, during a period before the commencement of offers or sales of the shares and extending through the completion of the distribution. A passive market maker must display its bid at a price not in excess of the highest independent bid of that security. However, if all independent bids are lowered below the passive market maker's bid, then that bid must then be lowered when specified purchase limits are exceeded.

Other Relationships

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include sales and trading, commercial and investment banking, advisory, investment management, investment research, principal investment, hedging, market making, brokerage and other financial and non-financial activities and services. Certain of the underwriters and their respective affiliates have provided, and may in the future provide, a variety of these services to us and to persons and entities with relationships with us, for which they received or will receive customary fees and expenses.

SELLING RESTRICTIONS

Other than in the United States, no action has been taken by us or the underwriter that would permit a public offering of the securities offered by this prospectus in any jurisdiction where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

European Economic Area

In relation to each member state of the European Economic Area that has implemented the Prospectus Directive (each, a relevant member state), with effect from and including the date on which the Prospectus Directive is implemented in that relevant member state (the relevant implementation date), an offer of shares described in this prospectus may not be made to the public in that relevant member state other than:

- to any legal entity which is a qualified investor as defined in the Prospectus Directive;
- to fewer than 100 or, if the relevant member state has implemented the relevant provision of the 2010 PD Amending Directive, 150 natural or legal persons (other than qualified investors as defined in the Prospectus Directive), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the relevant Dealer or Dealers nominated by us for any such offer; or
- in any other circumstances falling within Article 3(2) of the Prospectus Directive,
- provided that no such offer of shares shall require us or any underwriter to publish a prospectus pursuant to Article 3 of the Prospectus Directive.

For purposes of this provision, the expression an “offer of securities to the public” in any relevant member state means the communication in any form and by any means of sufficient information on the terms of the offer and the shares to be offered so as to enable an investor to decide to purchase or subscribe for the shares, as the expression may be varied in that member state by any measure implementing the Prospectus Directive in that member state, and the expression “Prospectus Directive” means Directive 2003/71/EC (and amendments thereto, including the 2010 PD Amending Directive, to the extent implemented in the relevant member state) and includes any relevant implementing measure in the relevant member state. The expression 2010 PD Amending Directive means Directive 2010/73/EU.

The sellers of the shares have not authorized and do not authorize the making of any offer of shares through any financial intermediary on their behalf, other than offers made by the underwriters with a view to the final placement of the shares as contemplated in this prospectus. Accordingly, no purchaser of the shares, other than the underwriters, is authorized to make any further offer of the shares on behalf of the sellers or the underwriters.

United Kingdom

This prospectus is only being distributed to, and is only directed at, persons in the United Kingdom that are qualified investors within the meaning of Article 2(1)(e) of the Prospectus Directive that are also (i) investment professionals falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 (the “Order”) or (ii) high net worth entities, and other persons to whom it may lawfully be communicated, falling within Article 49(2)(a) to (d) of the Order (each such person being referred to as a “relevant person”). This prospectus and its contents are confidential and should not be distributed, published or reproduced (in whole or in part) or disclosed by recipients to any other persons in the United Kingdom. Any person in the United Kingdom that is not a relevant person should not act or rely on this document or any of its contents.

Canada

The securities may be sold in Canada only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligations. Any resale of the securities must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser’s province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser’s province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

LEGAL MATTERS

The validity of the shares of common stock offered hereby will be passed upon for us by Foley & Lardner LLP, Tampa, Florida. Lucosky Brookman LLP has acted as counsel for the underwriters with respect of this offering.

EXPERTS

The financial statements of MIRA Pharmaceuticals, Inc. as of and for the years ended December 31, 2022 and 2021 included in this prospectus have been audited by Cherry Bekaert LLP, an independent registered public accounting firm, appearing elsewhere herein, given on the authority of said firm as experts in auditing and accounting.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of common stock offered by this prospectus. This prospectus, which constitutes a part of the registration statement, does not contain all the information set forth in the registration statement. The rules and regulations of the

SEC allow us to omit certain information from this prospectus that is included in the registration statement. Statements made in this prospectus concerning the contents of any contract, agreement, or other document are summaries of all material information about the documents summarized but are not complete descriptions of all terms of these documents. If we filed any of these documents as an exhibit to the registration statement, you may read the document itself for a complete description of its terms.

You may read and copy the registration statement, including the related exhibits and schedules, and any document we file with the SEC without charge at the SEC's public reference room at 100 F Street, N.E., Room 1580, Washington, DC 20549. You may also obtain copies of the documents at prescribed rates by writing to the Public Reference Section of the SEC at 100 F Street, N.E., Room 1580, Washington, DC 20549. Please call the SEC at 1-800-SEC-0330 for further information on the public reference room. The SEC also maintains an Internet website that contains reports and other information regarding issuers that file electronically with the SEC. Our filings with the SEC are also available to the public through the SEC's website at <http://www.sec.gov>.

Upon completion of this offering, we will become subject to the information reporting requirements of the Exchange Act, and we will file periodic reports, proxy statements and other information with the SEC. These periodic reports, and other information are available for inspection and copying at the website of the SEC referred to above. You may access our annual reports on Form 10-K, quarterly reports on Form 10-Q, reports on Form 8-K and amendments to those reports filed pursuant to Section 13(a) or 15(d) of the Exchange Act with the SEC free of charge at our website as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC. The information contained in, or that can be accessed through, our website is not incorporated by reference in, and is not part of, this prospectus. A copy of the registration statement and the exhibits filed therewith may be inspected without charge at the public reference room maintained by the SEC, located at 100 F Street, NE, Washington, DC 20549, and copies of all or any part of the registration statement may be obtained from that office. Please call the SEC at 1-800-SEC-0330 for further information about the public reference room. The SEC also maintains a website that contains reports, proxy and information statements and other information regarding registrants that file electronically with the SEC. The address of the website is www.sec.gov.

We maintain a corporate website at www.mirapharmaceuticals.com. Information contained in, or that can be accessed through, our website does not constitute a part of this prospectus. We have included our website address in this prospectus solely as an inactive textual reference. We will post on our website any materials required to be so posted on such website under applicable corporate or securities laws and regulations.

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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders
MIRA Pharmaceuticals, Inc.
Tampa, Florida

Opinion on the Financial Statements

We have audited the accompanying balance sheets of MIRA Pharmaceuticals, Inc. (f/k/a MIRA1a Therapeutics, Inc.) (the "Company") as of December 31, 2022 and 2021, and the related statements of operations, stockholders' equity (deficit) and cash flows for the years then ended, 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, 2022 and 2021, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits. We are required to be independent with respect to the Company in accordance with the relevant ethical requirements relating to our audit.

We conducted our audits in accordance with the auditing standards of the Public Company Accounting Oversight Board (United States) and in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. 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.

Emphasis of Matter

As more fully described in Note 2 to the financial statements, the Company has incurred historical net losses and sustained substantial cash losses. Our opinion is not modified with respect to this matter.

/s/ Cherry Bekaert LLP

We have served as the Company's auditor since 2022.

Tampa, Florida
April 4, 2023

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MIRA Pharmaceuticals, Inc.
BALANCE SHEETS

DECEMBER 31, 2022 AND DECEMBER 31, 2021

	<u>December 31,</u> <u>2022</u>	<u>December 31,</u> <u>2021</u>
ASSETS		
Current assets:		
Cash	\$ 350,978	\$ 2,809,552
Deferred offering costs	143,427	100,000
Total current assets	<u>494,405</u>	<u>2,909,552</u>
Operating lease, right of use assets	164,910	-
Related party operating lease, right of use assets	198,759	-
Advances to affiliates	-	445,612
Total assets	<u>\$ 858,074</u>	<u>\$ 3,355,164</u>
LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY		
Current liabilities:		
Trade accounts payable and accrued liabilities	\$ 811,738	\$ 228,406
Related party accounts payable	116,350	547,600
Related party line of credit	133,062	293,062
Related party accrued interest	34,987	24,738
Current portion of operating lease liabilities	75,143	-
Related party current portion of operating lease liabilities	198,759	-
Total current liabilities	<u>1,370,039</u>	<u>1,093,806</u>
Non-current operating lease liabilities	<u>84,267</u>	<u>-</u>
Total liabilities	1,454,306	1,093,806
Stockholders' (Deficit) Equity		
Preferred Stock, \$0.0001 par value, 5,000,000 shares authorized and none issued or outstanding.	-	-
Common Stock, \$0.0001 par value; 95,000,000 shares authorized, 66,565,000 and 63,369,000 issued and outstanding at December 31, 2022 and December 31, 2021, respectively.	6,657	6,337
Additional paid-in capital	8,699,830	4,499,550
Accumulated deficit	<u>(9,302,719)</u>	<u>(2,244,529)</u>
Total stockholders' (deficit) equity	<u>(596,232)</u>	<u>2,261,358</u>
Total liabilities and stockholders' (deficit) equity	<u>\$ 858,074</u>	<u>\$ 3,355,164</u>

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

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MIRA Pharmaceuticals, Inc.
STATEMENTS OF OPERATIONS

YEAR ENDED DECEMBER 31, 2022 AND DECEMBER 31, 2021

	<u>Year ended December 31,</u>	
	<u>2022</u>	<u>2021</u>
Revenues	\$ -	\$ -
Operating costs:		
General and administrative expenses	2,992,125	770,115
Related party travel costs	1,704,350	697,600
Research and development expenses	2,351,465	684,447
Total operating costs	<u>7,047,940</u>	<u>2,152,162</u>
Interest expense	<u>(10,250)</u>	<u>(24,374)</u>
Net loss	<u>\$ (7,058,190)</u>	<u>\$ (2,176,536)</u>

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

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MIRA Pharmaceuticals, Inc.
STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)

YEAR ENDED DECEMBER 31, 2022 AND DECEMBER 31, 2021

	Common Stock		Additional Paid-In	Stock Subscription	Accumulated	Total Stockholders' Equity
	Shares	Amount	Capital	Receivable	Deficit	(Deficit)
Balances, January 1, 2021	58,869,000	5,887	-	(5,887)	(67,993)	(67,993)
Sale of common stock	4,500,000	450	4,499,550	-	-	4,500,000
Collection of stock subscription receivable	-	-	-	5,887	-	5,887
Net loss	-	-	-	-	(2,176,536)	(2,176,536)
Balances, December 31, 2021	63,369,000	\$ 6,337	\$ 4,499,550	\$ -	\$ (2,244,529)	\$ 2,261,358
Sale of common stock, net	3,196,000	320	2,903,680	-	-	2,904,000
Stock-based compensation	-	-	1,296,600	-	-	1,296,600
Net loss	-	-	-	-	(7,058,190)	(7,058,190)
Balances, December 31, 2022	66,565,000	\$ 6,657	\$ 8,699,830	\$ -	\$ (9,302,719)	\$ (596,232)

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

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MIRA Pharmaceuticals, Inc.
STATEMENTS OF CASH FLOWS

YEAR ENDED DECEMBER 31, 2022 AND DECEMBER 31, 2021

	Year Ended December 31,	
	2022	2021
Cash flows from Operating activities		
Net loss	\$ (7,058,190)	\$ (2,176,536)
Adjustments to reconcile net loss to net cash from operations		
Non-cash interest expense	10,250	24,374
Stock-based compensation expense	1,296,600	-
Change in operating assets and liabilities:		
Right of use lease, net	(5,500)	-
Accounts payable and accrued expenses	152,081	776,006
Net cash flows from operating activities	<u>(5,604,759)</u>	<u>(1,376,156)</u>
Financing activities:		
Advances to affiliates	445,612	(426,732)
Payment of deferred offering costs	(43,427)	(100,000)
Net (repayments) borrowings under related party line of credit	(160,000)	203,062
Collection of stock subscription receivable	-	5,887
Proceeds from sale of common stock, less offering costs	2,904,000	4,500,000
Net cash flows from financing activities	<u>3,146,185</u>	<u>4,182,217</u>
Net change in cash	(2,458,574)	2,806,061
Cash, beginning of year	2,809,552	3,491
Cash, end of year	<u>\$ 350,978</u>	<u>\$ 2,809,552</u>
Cash paid for interest	-	-

Non-cash Financing and Investing Activities:

The Company recorded a right of use asset and a corresponding liability in the amount of \$1.0 million in exchange for an operating lease liability as a result of the adoption of Accounting Standards Codification, ("ASC"), Topic 842, Leases, on January 1, 2022.

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

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MIRA Pharmaceuticals, Inc.
NOTES TO THE FINANCIAL STATEMENTS

DECEMBER 31, 2022, AND DECEMBER 31, 2021

Note 1. Description of business and summary of significant accounting policies:

Overview

MIRA Pharmaceuticals, Inc. ("MIRA" or the "Company" and formerly known as MIRA1a Therapeutics, Inc.) was formed in September 2020 and is a Florida-based clinical development stage biopharmaceutical company that is developing its product candidate, MIRA1a, as a synthetic cannabinoid analog for treating anxiety and chronic pain by targeting the cannabinoid type 1 and type 2 (CB1 and CB2) receptors.

Substantive operations began in late 2020 and the Company's Investigative New Drug application is anticipated to be filed with the U.S. Food and Drug Administration ("FDA") end of first quarter 2024. The Company owns U.S. Patent 10,787,675 B2, titled "Purified Synthetic Marijuana and Methods of Treatment by Administering Same," which covers the MIRA1a compound as a new molecular entity as well as pharmaceutical formulations of the compound and methods of treating Alzheimer's disease, anxiety, depression, and addictions. Foreign patent applications covering MIRA1a, and its therapeutic uses are pending in Australia, Canada, China, Europe, Israel, Japan, and South Korea.

The accounting and reporting policies of the Company conform to accounting principles generally accepted in the United States of America (“GAAP”).

As used herein, the Company’s Common Stock, par value \$0.0001 per share, is referred to as the “Common Stock” and the Company’s preferred stock, par value \$0.0001 per share, is referred to as the “Preferred Stock”.

Pending transactions

The Company is in the process of preparing for an initial public offering and expects to be listed under the NASDAQ symbol “MIRA.” The transaction is expected to be complete in second half of 2023. The Company incurred \$0.04 million and \$0.1 million of legal costs, during the years ended December 31, 2022 and December 31, 2021, respectively, associated with the offering, which have been recorded as deferred offering costs in the accompanying balance sheets. These deferred offering costs will be derecognized as a reduction in offering proceeds when the offering closes. However, there can be no guarantees that the Company will be successful in completing the proposed transaction and ultimately listing on the NASDAQ.

Income taxes

The Company is a C corporation. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amount of existing assets and liabilities and their respective tax bases. Deferred tax assets are recognized for temporary differences that will result in deductible amounts in future years and for loss carryovers. A valuation allowance is recognized regarding deferred tax assets, if any, if it is more likely than not that some portion of the deferred tax asset will not be realized.

Research and development expenses

Research and development costs are expensed in the period in which they are incurred and include the expenses paid to third parties, such as contract research organizations and consultants, who conduct research and development activities on behalf of the Company. Patent-related costs, including registration costs, documentation costs and other legal fees associated with the application, are expensed in the period in which they are incurred.

Use of estimates

The preparation of financial statements in accordance with generally accepted accounting principles in the United States of America requires the Company’s management to make estimates and assumptions that affect the reported amounts of assets and liabilities, and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Actual results may differ from such estimates and such differences could be material.

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MIRA Pharmaceuticals, Inc.

NOTES TO THE FINANCIAL STATEMENTS

DECEMBER 31, 2022, AND DECEMBER 31, 2021

Cash

The Company maintains cash balances with financial institutions that management believes are of high credit quality. The Company’s cash account at times may exceed federally insured limits. The Company has not experienced any losses in such accounts. The Company believes it is not exposed to any significant credit risk from its cash account.

Stock-based compensation

The Company accounts for stock-based compensation under the provisions of FASB ASC 718, “*Compensation - Stock Compensation*”, which requires the measurement and recognition of compensation expense for all stock-based awards made to employees, directors and consultants based on estimated fair values on the grant date. The Company estimates the fair value of stock-based awards on the date of grant using the Black-Scholes model. The value of the portion of the award that is ultimately expected to vest is recognized as expense over the requisite service periods using the straight-line method. The Company has elected to account for forfeiture of stock-based awards as they occur.

Change in Accounting Principle

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842), which supersedes existing guidance for accounting for leases under Topic 840, Leases. The FASB also subsequently issued additional ASUs which amend and clarify Topic 842. The most significant change in the new leasing guidance is the requirement to recognize right-to-use (ROU) assets and lease liabilities for operating leases on the balance sheet.

The Company adopted these ASUs effective January 1, 2022 using the modified retrospective approach. As a result of adopting these ASUs, the Company recorded ROU assets and lease liabilities of approximately \$1.0 million and \$0.4 million, respectively. Adoption of the new standard did not materially impact the Company’s net income and had no impact on cash flows.

Note 2. Liquidity and capital resources:

As of December 31, 2022, the Company had cash of approximately \$0.4 million. The Company used approximately \$5.6 million of cash in operations during the year ended December 31, 2022 and had stockholders’ (deficit) of approximately \$0.6 million, versus stockholders’ equity of approximately \$2.3 million at December 31, 2021. During the year ended December 31, 2022, the Company raised approximately \$3.2 million to finance its research and development and working capital needs, through a private placement of the Company’s common stock and collections on amounts previously advanced to affiliates of the Company.

Historically, the Company has been primarily engaged in developing MIRA1a. During these activities, the Company sustained substantial losses. The Company’s ability to fund ongoing operations and future clinical trials required for FDA approval is dependent on the Company’s ability to obtain significant additional external funding in the near term. Since inception, the Company financed its operations through the sale of Common Stock and related party financings. See Note 4 for details of a related party line of credit established in 2021. Additional sources of financing may be sought by the Company. However, there can be no assurance that any fundraising will be achieved on commercially reasonable terms, if at all.

The Company expects to be able to fund operations through the anticipated initial public offering, or through the first quarter of 2024, with available borrowings on the related party line of credit (Note 4). Should actual cash expenditures exceed management’s budget, the Company may be forced to curtail operations along with implementing other cost-saving measures, such as a reduction in staff, reducing the use of outside professional service providers, or significantly modifying or delaying the development of our product candidates.

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DECEMBER 31, 2022, AND DECEMBER 31, 2021

Note 3. License agreement, related party:

On April 28, 2022, and subsequently amended and restated on June 27, 2022 (the “Effective Date”), the Company and MyMD Pharmaceuticals, Inc. (“MYMD”) entered into a non-exclusive, royalty-free license (the “Agreement”) to use MYMD’s Supera-CBD as a synthetic intermediate in the manufacture of MIRA1a for research and development activities relating to our planned pre-clinical and clinical studies.

This Agreement was amended on April 17, 2023 to extend its original one-year term through December 31, 2024. The term of agreement may be extended by mutual agreement of the parties for an additional period that is reasonably necessary to complete the manufacture of quantities of MIRA1a needed for pre-clinical or clinical studies.

Either party may terminate this Agreement without cause upon forty-five (45) calendar days prior written notice to the other Party.

The Company and MYMD have similar members of the Board, as well as officers from the respective companies.

Note 4. Line of credit, related party:

In May 2021, the Company entered into a revolving credit facility which allows for borrowings of up to \$5,000,000 with a shareholder. The facility has an initial term of 24 months (extended to 36 months in March 2023), with a new maturity date of May 10, 2024, at which time all outstanding borrowings and accrued interest, if any, are due in full. Borrowings accrue interest at a rate of 5% per annum. The Company anticipates repaying the line of credit through proceeds from the anticipated initial public offering.

Note 5. Related party transactions:

Advances to affiliates – During the year ended December 31, 2022, and December 31, 2021, the Company made working capital advances to companies under common control. These advances were due on demand and were non-interest bearing. As of December 31, 2022, such advances were repaid in full.

Related party accounts payable – Amounts due to related parties as of December 31, 2022 and December 31, 2021, are recorded as Accounts payable related parties, in the accompanying balance sheets.

Travel expenses – In April 2021, the Company entered into an airplane lease with an entity under common control that the Company incurs approximately \$0.05 million of lease charges per month. The lease is renewable, at the Company’s discretion, for an additional one to three years, however, the Company intends to terminate the lease upon the date of its initial public offering, as allowed in the lease agreement. During the year ended December 31, 2022 and 2021, the Company incurred \$1.7 million and \$0.7 million, respectively, for travel-related expenses to the related party for monthly rental charges and airplane-related expenses.

License agreement - See Note 3.

Line of credit - See Note 4.

Lease and lease reimbursements - See Note 6.

Consulting and employment agreements – See Note 9.

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DECEMBER 31, 2022, AND DECEMBER 31, 2021

Note 6. Lease:

The Company leases certain office space and an airplane. The Company determines whether a contract contains a lease at inception by determining if the contract conveys the right to control the use of identified property, plant or equipment for a period of time in exchange for consideration. The Company has lease agreements with lease and non-lease components, which are generally accounted for separately with amounts allocated to the lease and non-lease components based on relative stand-alone prices.

Right-of-use (“ROU”) assets and lease liabilities are recognized at the commencement date based on the present value of the future minimum lease payments over the lease term. Renewal and termination clauses that are factored into the determination of the lease term if it is reasonably certain that these options would be exercised by the Company. Lease assets are amortized over the lease term unless there is a transfer of title or purchase option reasonably certain of exercise, in which case the asset life is used. Certain of our lease agreements include variable payments. Variable lease payments not dependent on an index or rate primarily consist of common area maintenance charges and are not included in the calculation of the ROU asset and lease liability and are expensed as incurred. In order to determine the present value of lease payments, the Company uses the implicit rate when it is readily determinable. As most of the Company’s leases do not provide an implicit rate, management uses the Company’s incremental borrowing rate based on the information available at lease commencement to determine the present value of lease payments.

Our lease agreements do not contain any material residual value guarantees or material restrictive covenants. The Company does not have leases where it is involved with the construction or design of an underlying asset. The Company has no material obligation for leases signed but not yet commenced as of December 31, 2022. The Company does not have any material sublease activities.

Practical Expedients Elected

- The Company elected the three transition practical expedients that permit an entity to (a) not reassess whether expired or existing contracts contain leases, (b) not reassess lease classification for existing or expired leases, and (c) not consider whether previously capitalized initial direct costs would be appropriate under the new standard.
- The Company has elected to account for lease and non-lease components as a single component.

Variable lease costs

Variable lease costs primarily include utilities, property taxes, and other operating costs that are passed on from the lessor. Variable lease costs related to the aircraft include usage expenses, which includes pilot expenses, jet fuel and general flight expenses.

The components of lease expense were as follows:

	<u>Year ended December 31,</u>	
	<u>2022</u>	<u>2021</u>
Lease Costs		
Operating Lease Cost		
Operating Lease	\$ 657,797	\$ -
Variable Lease Costs	1,112,913	-
Total Lease Cost	\$ 1,770,710	\$ -

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MIRA Pharmaceuticals, Inc.
NOTES TO THE FINANCIAL STATEMENTS

DECEMBER 31, 2022, AND DECEMBER 31, 2021

Supplemental cash flow information related to leases were as follows:

	<u>Year ended December 31,</u>	
	<u>2022</u>	<u>2021</u>
Other Lease Information		
Cash paid for amounts included in the measurement of lease liabilities		
Operating cash flows from operating leases	\$ 626,304	\$ -

	<u>Year ended</u> <u>December 31,</u>	
	<u>2022</u>	<u>2021</u>
Lease Term and Discount		
Weighted Average remaining lease term	0.53 years	-
Weighted Average discount rate	5.0%	-

Maturity of Lease Liabilities

Future minimum lease payments under non-cancellable leases as of December 31, 2022 were as follows:

	<u>December 31, 2022</u>
2023	281,050
2024	69,309
2025	17,444
Total Lease payments	367,803
Less: Interest	(9,634)
Present Value of Lease Liabilities	358,169

Note 7. Income taxes:

The significant components of the Company's net deferred tax assets are as follows as of December 31:

	<u>December 31,</u>	
	<u>2022</u>	<u>2021</u>
Deferred tax assets		
Net operating loss carry-forward	\$ 1,061,300	\$ 572,355
Section 174 Qualified Research Expenditures	388,230	-
Stock compensation	330,633	-
ROU liability	91,333	-
Other	6,120	-
	1,877,616	572,355
Less: valuation allowance	(1,784,880)	(572,355)
	92,736	-
Deferred tax liabilities		
ROU asset	(92,736)	-
Total net deferred tax asset	<u>\$ -</u>	<u>\$ -</u>

Beginning in 2022, in accordance with Internal Revenue Code Section 174, Qualified Research Expenditures are capitalized for tax purposes and amortized over a period of five years. Accordingly, for income tax purposes, the Company has recorded a deferred tax asset totaling approximately \$0.4 million related to the timing difference between GAAP and Tax recognition of these expenditures.

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MIRA Pharmaceuticals, Inc.
NOTES TO THE FINANCIAL STATEMENTS

DECEMBER 31, 2022, AND DECEMBER 31, 2021

The components of the provision for income taxes consist of the following:

	<u>2022</u>	<u>2021</u>
Deferred tax:		

Deferred	(1,212,525)	(555,017)
Change in valuation allowance	1,212,525	555,017
Total deferred	-	-
Total provision for income taxes	\$ -	\$ -

ASC Topic 740 requires that a deferred tax amount be reduced by a valuation allowance if, based on the weight of available evidence it is more likely than not (a likelihood of more than 50%) that some portion or all of the deferred tax assets will not be realized. The valuation allowance should be sufficient to reduce the deferred tax asset to the amount that is more likely than not to be realized. The Company has recorded a full valuation allowance against its deferred tax assets generated by net operating loss carryforwards as it has determined that such amounts may not be recognizable, given the historical losses of the Company to date. As of December 31, 2022, the Company has a cumulative federal net operating loss carryforward of approximately \$4.2 million. The net operating loss carryforwards have no expiry date.

Note 8. Stockholders' equity:

Capital stock

The Company has the authority to issue 100,000,000 shares of capital stock, consisting of 95,000,000 shares of Common Stock and 5,000,000 shares of undesignated preferred stock, whose rights and privileges will be defined by the Board of Directors when a series of preferred stock is designated.

Private placement

During the year ended December 31, 2022, the Company sold 3.2 million shares of Common Stock at \$1.00 per share, net of offering costs of \$0.3 million, resulting in net proceeds of \$2.9 million.

2022 Omnibus Incentive Plan

In June 2022, the Company's Board of Directors adopted, and its stockholders approved, the Company's 2022 Omnibus Incentive Plan, ("2022 Omnibus Plan"). The 2022 Omnibus Plan authorizes the grant of incentive stock options, within the meaning of Section 422 of the Internal Revenue Code, to the Company's employees and any of its parent and subsidiary corporations' employees, and for the grant of nonstatutory stock options, restricted stock, restricted stock units, stock appreciation rights, performance units and performance shares to the Company's employees, directors, and consultants and any of its future subsidiary corporations' employees and consultants.

The 2022 Omnibus Plan provides that 5,000,000 shares of the Company's Common Stock are reserved for issuance under the 2022 Omnibus Plan, all of which may be issued pursuant to the exercise of incentive stock options.

Stock-based compensation

During the year ended December 31, 2022, a total of 3,750,000 options to purchase Common Stock, with an aggregate fair market value of approximately \$2.7 million were granted to the Company's Board of Directors, executive officers and management, and a consultant of the Company. Options have a term of 10 years from the grant date. The Company's option vesting structure is the following: (i) Board of Director options vest 100% on date of grant, (ii) executive officer options vest 25% on date of grant and the remaining vest ratably over a three-year period, and (iii) management, employee and consultant options vest 33.3% on date of grant and the remaining vest ratably over a two-year period.

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MIRA Pharmaceuticals, Inc.

NOTES TO THE FINANCIAL STATEMENTS

DECEMBER 31, 2022, AND DECEMBER 31, 2021

The fair value of each option award is estimated on the grant date using the Black-Scholes valuation model that uses assumptions for expected volatility, expected dividends, expected term, and the risk-free interest rate.

Expected price volatility is based on the historical volatilities of a peer group as the Company does not have a trading history for its shares. Industry peers consist of several public companies in the biotech industry similar to the Company in size, stage of life cycle and product indications. The Company intends to continue to consistently apply this process using the same or similar public companies until a sufficient amount of historical information regarding the volatility of the Company's own stock price becomes available, or unless circumstances change such that the identified companies are no longer similar to the Company, in which case, more suitable companies whose share prices are publicly available would be utilized in the calculation.

Expected term of options granted is derived using the "simplified method" which computes expected term as the average of the sum of the vesting term plus contract term. The risk-free rate is based on the U.S. Treasury yield curve in effect at the time of grant for the period of the expected term.

The key assumptions used in determining the fair value of options granted during the year ended December 31, 2022 follows:

Expected price volatility	84.42%
Risk-free interest rate	3.38%
Fair value of common stock	\$ 1.00
Minimum and maximum average expected life in years	5-6.50 years
Dividend yield	-

Option activity during the year ended December 31, 2022 was as follows:

	<u>Number of shares</u>	<u>Weighted average exercise price per share</u>	<u>Aggregate intrinsic value</u>
Outstanding as January 1, 2022	-		
Options granted	3,750,000	\$ 1.00	
Outstanding as December 31, 2022	3,750,000	\$ 1.00	-

As of December 31, 2022, options exercisable totaled 1,400,000. There are approximately \$1.4 million of unrecognized compensation costs related to non-vested share-based compensation awards, which will be expensed through 2025.

Note 9 – Consulting and employment agreements:

On April 1, 2022, the Company entered into a Consulting Agreement with Dr. Chapman pursuant to which he provided regulatory and drug development consulting services to the Company on an as-requested basis. Pursuant to the Consulting Agreement, he was to be paid a one-time fee of \$0.1 million upon the completion of the anticipated offering (of which \$0.05 million was prepaid in the first quarter of 2022) plus a monthly fee of \$0.02 million thereafter. The monthly fee was to begin upon the completion of the offering. He was also reimbursed for reasonable out-of-pocket expenses incurred in connection with his duties under the Consulting Agreement. The agreement had a term of one year with an automatic one-year extension, provided that either party could terminate the agreement without cause upon 30-days prior written notice.

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MIRA Pharmaceuticals, Inc.
NOTES TO THE FINANCIAL STATEMENTS

DECEMBER 31, 2022, AND DECEMBER 31, 2021

In his capacity as a consultant, Dr. Chapman was also granted on June 15, 2022, an option to purchase up to 1,000,000 shares of the Company's common stock at an exercise price of \$1.00 per share. This option was granted under the Company's 2022 Omnibus Plan and vested as to 25% of the option shares on the date of grant, with the balance vesting in one-third increments on each of the three successive anniversaries of the grant date. Any unvested portion of the option will vest in full upon a "change of control" of our company within the meaning of the 2022 Omnibus Plan. The option has a term of 10-years, subject to earlier termination upon certain terminations of Dr. Chapman's position as a consultant to the Company. In his capacity as a Board Director, Dr. Chapman was also granted on June 15, 2022, an option to purchase up to 100,000 shares of the Company's common stock at an exercise price of \$1.00 per share. This option was granted under the Company's 2022 Omnibus Plan and vested as to 100% of the option shares on the date of grant. The option has a term of 10-years, subject to earlier termination upon certain terminations of Dr. Chapman's position as a director of the Company.

Note 10 – Subsequent events:

The Company has evaluated subsequent events through April 4, 2023, in connection with the preparation of these financial statements, which is the date the financial statements were available to be issued.

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Shares
Common Stock



MIRA Pharmaceuticals, Inc.

KINGSWOOD

division of Kingswood Capital Partners, LLC

PROSPECTUS

Until _____, 2023 (the 25th day after the date of this prospectus), all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

_____, 2023

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution

The following table sets forth all the costs and expenses, other than underwriting discounts and commissions, to be paid by us in connection with the sale of the shares of common stock being registered hereby. All amounts shown below are estimates, except the SEC registration fee, the FINRA filing fee and the stock exchange listing fee:

	Amount
SEC registration fee	\$ *
FINRA filing fee	*
Nasdaq listing fee	*
Printing expenses	*
Legal fees and expenses	*
Accounting fees and expenses	*
Transfer agent and registrar fees and expenses	*
Miscellaneous expenses	*
Total	\$ *

* To be filed by amendment.

Item 14. Indemnification of Directors and Officers

MIRA Pharmaceuticals, Inc. is incorporated under the laws of the state of Florida. Section 607.0831 of the Florida Business Corporation Act, as amended (the "FBCA"), provides that a director is not personally liable for monetary damages to the corporation or any other person for any statement, vote, decision to take or not to take action, or any failure to take any action, as a director, unless (1) the director breached or failed to perform his or her duties as a director and (2) the director's breach of, or failure to perform, those duties constitutes (a) a violation of the criminal law, unless the director had reasonable cause to believe his or her conduct was lawful or had no reasonable cause to believe his or her conduct was unlawful, (b) a transaction from which the director derived an improper personal benefit, either directly or indirectly, (c) a circumstance under which the liability provisions of Section 607.0834 of the FBCA are applicable, (d) in a proceeding by or in the right of the corporation to procure a judgment in its favor or by or in the right of a shareholder, conscious disregard for the best interest of the corporation, or willful or intentional misconduct, or (e) in a proceeding by or in the right of someone other than the corporation or a shareholder, recklessness or an act or omission which was committed in bad faith or with malicious purpose or in a manner exhibiting wanton and willful disregard of human rights, safety, or property. A judgment or other final adjudication against a director in any criminal proceeding for a violation of the criminal law estops that director from contesting the fact that his or her breach, or failure to perform, constitutes a violation of the criminal law; but does not estop the director from establishing that he or she had reasonable cause to believe that his or her conduct was lawful or had no reasonable cause to believe that his or her conduct was unlawful.

Under Section 607.0851 of the FBCA, a corporation has power to indemnify any person who is a party to any proceeding (other than an action by, or in the right of the corporation), because he or she is or was a director or officer of the corporation against liability incurred in connection with such proceeding, including any appeal thereof, if he or she acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, the best interests of the corporation and, with respect to any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful. The termination of any proceeding by judgment, order, settlement or conviction or upon a plea of nolo contendere or its equivalent shall not, of itself, create a presumption that the person did not act in good faith and in a manner which he or she reasonably believed to be in, or not opposed to, the best interests of the corporation or, with respect to any criminal action or proceeding, has reasonable cause to believe that his or her conduct was unlawful.

For purposes of the indemnification provisions of the FBCA, "director" or "officer" means an individual who is or was a director or officer, respectively, of a corporation or who, while a director or officer of the corporation, is or was serving at the corporation's request as a director or officer, manager, partner, trustee, employee, or agent of another domestic or foreign corporation, limited liability company, partnership, joint venture, trust, employee benefit plan, or another enterprise or entity and the terms include, unless the context otherwise requires, the estate, heirs, executors, administrators, and personal representatives of a director or officer.

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In addition, under Section 607.0851 of the FBCA, a corporation has the power to indemnify any person, who was or is a party to any proceeding by or in the right of the corporation to procure a judgment in its favor by reason of the fact that the person is or was a director or officer, against expenses and amounts paid in settlement not exceeding, in the judgment of the board of directors, the estimated expense of litigating the proceeding to conclusion, actually and reasonably incurred in connection with the defense or settlement of such proceeding, including any appeal thereof. Such indemnification shall be authorized if such person acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, the best interests of the corporation, except that no indemnification shall be made under this subsection in respect of any claim, issue, or matter as to which such person shall have been adjudged to be liable unless, and only to the extent that, the court in which such proceeding was brought, or any other court of competent jurisdiction, shall determine upon application that, despite the adjudication of liability but in view of all circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which such court shall deem proper.

Section 607.0852 of the FBCA provides that a corporation must indemnify an individual who is or was a director or officer who was wholly successful, on the merits or otherwise, in the defense of any proceeding to which the individual was a party because he or she is or was a director or officer of the corporation against expenses incurred by the individual in connection with the proceeding.

Section 607.0853 of the FBCA provides that a corporation may, before final disposition of a proceeding, advance funds to pay for or reimburse expenses incurred in connection with the proceeding by an individual who is a party to the proceeding because that individual is or was a director or an officer if the director or officer delivers to the corporation a signed written undertaking of the director or officer to repay any funds advanced if (a) the director or officer is not entitled to mandatory indemnification under Section 607.0852; and (b) it is ultimately determined under Section 607.0854 or Section 607.0855 (as described below) that the director or officer has not met the relevant standard of conduct described in Section 607.0851 or the director or officer is not entitled to indemnification under Section 607.0859 (as described below).

Section 607.0854 of the FBCA provides that, unless the corporation's articles of incorporation provide otherwise, notwithstanding the failure of a corporation to provide indemnification, and despite any contrary determination of the board of directors or of the shareholders in the specific case, a director or officer of the corporation who is a party to a proceeding because he or she is or was a director or officer may apply for indemnification or an advance for expenses, or both, to a court having jurisdiction over the corporation which is conducting the proceeding, or to a circuit court of competent jurisdiction. Our amended and restated articles of incorporation do not provide any such exclusion. After receipt of an application and after giving any notice it considers necessary, the court may order indemnification or advancement of expenses upon certain determinations of the court.

Section 607.0855 of the FBCA provides that, unless ordered by a court under Section 607.0854, a corporation may not indemnify a director or officer under Section 607.0851 unless authorized for a specific proceeding after a determination has been made that indemnification is permissible because the director or officer has met the relevant standard of conduct set forth in Section 607.0851.

Section 607.0857 of the FBCA also provides that a corporation shall have the power to purchase and maintain insurance on behalf of and for the benefit of any person who is or was a director or officer of the corporation against any liability asserted against the person and incurred by him or her in any such capacity or arising out of his or her status as such, whether or not the corporation would have the power to indemnify or advance expenses to the individual against such liability under the provisions of Section 607.0857.

Section 607.0858 of the FBCA provides that the indemnification provided pursuant to Section 607.0851 and Section 607.0852, and the advancement of expenses provided pursuant to Section 607.0853, are not exclusive. A corporation may, by a provision in its articles of incorporation, bylaws or any agreement, or by vote of shareholders or disinterested directors, or otherwise, obligate itself in advance of the act or omission giving rise to a proceeding to provide any other or further indemnification or advancement of expenses to any of its directors or officers.

Section 607.0859 of the FBCA provides that, unless ordered by a court under the provisions of Section 607.0854 of the FBCA, a corporation may not indemnify a director or officer under Section 607.0851 or Section 607.0858, or advance expenses to a director or officer under Section 607.0853 or Section 607.0858, if a judgment or other final adjudication establishes that his or her actions, or omissions to act, were material to the cause of action so adjudicated and constitute: (a) willful or intentional misconduct or a conscious disregard for the best interests of the corporation in a proceeding by or in the right of the corporation to procure a judgment in its favor or in a proceeding by or in the right of a shareholder; (b) a transaction in which a director or officer derived an improper personal benefit; (c) a violation of the criminal law, unless the director or officer had reasonable cause to believe his or her conduct was lawful or had no reasonable cause to believe his or her conduct was unlawful; or (d) in the case of a director, a circumstance under which the liability provisions of Section 607.0834 are applicable (relating to unlawful distributions).

Our amended and restated articles of incorporation and bylaws provide that we shall indemnify any and all persons whom it shall have power to indemnify under the FBCA to the fullest extent permitted by law.

The underwriting agreement for this offering will provide that the underwriters indemnify us against certain civil liabilities that may be incurred in connection with this offering, including certain liabilities under the Securities Act of 1933.

We also maintain director and officer liability insurance against certain claims and liabilities which may be made against our former, current or future directors and officers. In addition, we have individual indemnification agreements with our directors.

Item 15. Recent Sales of Unregistered Securities

In the preceding three years, we have issued and sold the following securities that were not registered under the Securities Act:

1. From November 2021 to December 2022, we undertook a private placement solely to accredited investors pursuant to which we issued and sold an aggregate of 7,696,000 shares of our common stock at a price of \$1.00 per share, for an aggregate purchase price of approximately \$7.7 million to 90 investors.

2. In June 2022 and April 2023, we granted to 16 directors, employees, or other service providers stock options to purchase an aggregate of 5,000,000 shares of our common stock at an exercise price of \$1.00 per share pursuant to our 2022 Omnibus Plan.

3. In April, 2023, we granted to Bay Shore Trust a warrant to purchase up to 5,000,000 shares of our common stock at an exercise price of \$1.00 per share in consideration of making a credit facility available to the Company.

We claimed exemption from registration under the Securities Act of 1933, as amended, or the Securities Act, for the sale and issuance of securities in the transaction described in paragraphs 1 and 3 above by virtue of Section 4(a)(2) and/or Regulation D promulgated thereunder as a transaction not involving any public offering. All the purchasers of unregistered securities for which we relied on Section 4(a)(2) and/or Regulation D represented that they were accredited investors as defined in Rule 501(a) under the Securities Act. We claimed such exemption on the basis that (a) the purchasers in each case represented that they intended to acquire the securities for investment only and not with a view to the distribution thereof and that they either received adequate information about the registrant or had access, through employment or other relationships, to such information and (b) appropriate legends were affixed to the stock certificates issued in such transactions.

We claimed exemption from registration under the Securities Act for the sales and issuances of securities in the transactions described in paragraph 2 above under Section 4(a)(2) of the Securities Act in that such sales and issuances did not involve a public offering or under Rule 701 promulgated under the Securities Act, in that they were offered and sold either pursuant to written compensatory plans or pursuant to a written contract relating to compensation, as provided by Rule 701.

Item 16. Exhibits and Financial Statement Schedules

(A) *Exhibits.*

INDEX TO EXHIBITS

Exhibit No.	Exhibit Description
1.1*	Form of Underwriting Agreement
3.1*	Amended and Restated Articles of Incorporation of MIRA Pharmaceuticals, Inc., to be in effect upon the completion of this offering
3.2*	Amended and Restated Bylaws of MIRA Pharmaceuticals, Inc., to be in effect upon the completion of this offering.
4.1*	Specimen certificate evidencing shares of common stock
5.1*	Opinion of Foley & Lardner LLP
10.1*+	2022 Omnibus Incentive Plan
10.2*+	Form of Stock Option Award under 2022 Omnibus Incentive Plan
10.3*	Form of Indemnification Agreement
10.4*	Confirmatory Patent Assignment and Royalty Agreement, dated November 1, 2021, between SRQ Patent Holdings II, LLC and MIRA Pharmaceuticals, Inc.
10.5*	Amended and Restated Limited License Agreement, dated June 27, 2022, between MIRA Pharmaceuticals, Inc. and MyMD Pharmaceuticals, Inc.
10.6*	Amendment No. 1, dated April 20, 2023, to Amended and Restated Limited License Agreement between MIRA Pharmaceuticals, Inc. and MyMD Pharmaceuticals, Inc.
10.7*+	Employment Agreement, dated April 28, 2023, between MIRA Pharmaceuticals, Inc. and Erez Aminov
10.8*+	Employment Agreement, dated April 28, 2023, between MIRA Pharmaceuticals, Inc. and Michele Yanez
10.9*+	Employment Agreement, dated April 28, 2023, between MIRA Pharmaceuticals, Inc. and Adam Kaplin
10.10*+	Employment Agreement between MIRA Pharmaceuticals, Inc. and Chris Chapman to become effective upon the completion of this offering
10.11*	Promissory Note and Loan Agreement, dated April 28, 2023, between MIRA Pharmaceuticals, Inc. and Bay Shore Trust
10.12*	Common Stock Purchase Warrant, dated April 28, 2023, between MIRA Pharmaceuticals, Inc. and Bay Shore Trust
10.13*	Registration Rights Agreement, dated April 28, 2023, between MIRA Pharmaceuticals, Inc. and Bay Shore Trust
14.1*	Code of Business Conduct and Ethics
21.1*	List of Subsidiaries of Registrant
23.1*	Consent of Cherry Bekaert LLP
23.2*	Consent of Foley & Lardner LLP (included in Exhibit 5.1)
24.1*	Power of Attorney (included on signature page)
99.1*	Audit Committee Charter
99.2*	Nominating and Corporate Governance Committee Charter
99.3*	Compensation Committee Charter

99.4*	Corporate Governance Guidelines
99.5*	Insider Trading Policy
107*	Filing Fee Table

* To be filed by amendment.

+ Denotes management contract or compensatory plan or arrangement.

(B) *Financial Statement Schedules*.

Not applicable.

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Item 17. Undertakings

The undersigned Registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933, as amended.

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement.

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

The undersigned registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this Registration Statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

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SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Tampa, Florida, on this _____ day of _____, 2023.

MIRA PHARMACEUTICALS, INC.

By: _____

Erez Aminov
Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints each of Erez Aminov and Michelle Yanez, and each of them individually, his or her true and lawful attorneys-in-fact and agents, with full powers of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any or all amendments (including post effective amendments) to this registration statement and any subsequent registration statement filed pursuant to Rule 462 under the Securities Act of 1933, as amended, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he or she might or could do in person, and hereby ratifying and confirming all that either of the said attorneys-in-fact and agents, or his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, as amended, this Registration Statement has been signed below by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
Erez Aminov	Chief Executive Officer (Principal Executive Officer)	, 2023
Michelle Yanez	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	, 2023
Chris Chapman	Executive Chairman and Director	, 2023
Christos Nicholoudis, Esq.	Director	
Dave Vorhoff	Director	, 2023
Brad Kroenig	Director	, 2023
Talhia Tuck	Director	, 2023
Hugh McColl III	Director	, 2023