As confidentially submitted to the Securities and Exchange Commission on June 29, 2022
This draft registration statement has not been publicly filed with the Securities and Exchange Commission and all information herein remains strictly confidential.

Registration No. 333-

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

FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

MIRA1A THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Florida	**2834**	**85-3354547**
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(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)

James McNulty, CPA, Chief Financial Officer
MIRA1a Therapeutics, Inc.
900 West Platt Street Suite 200
Tampa, Florida 33606-2173
813-864-2562
(Name, address, including zip code, and telephone number including area code, of agent for service)

Copies of all communications, including communications sent to agent for service, should be sent to:

Curt P. Creely
Neda Sharifi
Foley & Lardner LLP
100 North Tampa Street, Suite 2700
Tampa, Florida 33602
(813) 229-2300

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

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

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 June , 2022

PRELIMINARY PROSPECTUS

Shares

of Common Stock

This is an 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 list our common stock on the Nasdaq Capital Market ("Nasdaq") under the symbol "MIRA".

We are an "emerging growth company," as defined in Section 2(a) of the Securities Act of 1933, as amended (the "Securities Act"), and, as such, are subject to reduced public company reporting requirements. See "Prospectus Summary — Implications of Being an Emerging Growth Company."

Investing in our common stock involves risks. See "Risk Factors" beginning on page 10 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 MIRA1a Therapeutics, Inc.	$	$

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

The representative of the underwriters has the option for a period of 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 representative exercises the option in full, the total underwriting discounts and commissions payable by us will be $, and the total proceeds to us, before expenses, will be $.

Delivery of the shares of common stock will be made on or about , 2022.

The date of this prospectus is , 2022.

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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 ®, TM or 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.

GLOSSARY OF CERTAIN SCIENTIFIC TERMS

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

"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.

"cGMP" is the current GMP 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 safe for use and that it has the ingredients and strength it claims to have.

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

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

"GPCRs" form a large group of proteins that are expressed at the cell surface as cell surface receptors 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, "MIRA1a," "the company," "our company," "we," "our," "ours" and "us" refer to MIRA1a Therapeutics, Inc.

Business Summary

We are a preclinical-stage pharmaceutical development company focused on the development and commercialization of novel synthetic cannabinoid analogs for the treatment of adult patients with anxiety and chronic pain. Our lead drug candidate, MIRA1a, if approved by the FDA, may be a significant advancement in the treatment of neuropsychiatric, inflammatory, neurologic, and oncologic diseases and disorders. Based on preclinical and animal studies conducted by us, we believe that MIRA1a enhances the therapeutic potential for treating anxiety and chronic pain by potentially striking a balance between the beneficial effects of THC and CBD 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 including appetite, pain-sensation, mood, and memory. Relative 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. MIRA1a is being developed as the first prescription drug to 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. Unlike natural cannabinoids in the market, MIRA1a is not derived from plants and is a synthetic product. Plants generate alkaloids as a defense mechanism, and it has been speculated that plant-derived cannabinoids have adverse side effects in humans.

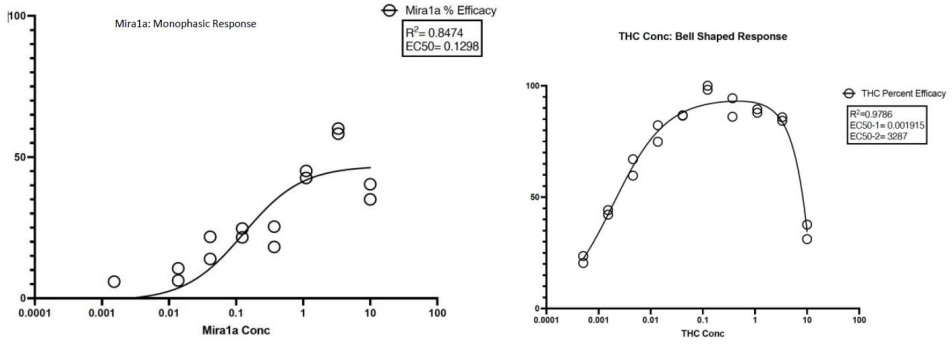
Our Lead Product Candidate in Development

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 brain and central nervous system, 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 lead product candidate, MIRA1a, has a strong selectivity for CB2 versus the 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 impact of MIRA1a at the Cannabinoid Receptors CB1 and CB2 is predicted to account for the majority of its 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 dramatically improved therapeutic profile.

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



Unlike CB1 receptors, that mediate 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 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.

Planned Pre-Clinical Developments

During the first quarter of 2022, we completed several pre-clinical studies, including but not limited to, computational mutagenicity analysis, radio-ligand binding assay, Elevated Plus Maze model of anxiety and hot plate model thermal sensitivity testing.

We plan to conduct several other preclinical studies from April thru August of 2022, including AMES test, Micronucleus Assay and Metabolic Profiling. Moving towards the end of the second quarter, we plan on initiating a 7-day maximum tolerated dose study of MIRA1a in rats and dogs. Additionally, we are planning to schedule a Pre-Investigational New Drug application or Pre-IND Meeting with the FDA to review MIRA1a and to address specific questions related to the initial first-in-human study for new drugs and other questions that could affect the IND application, including those related to our non-clinical program, manufacturing and product quality for the investigational product, and related regulatory considerations.

We further plan on neurobehavioral evaluation of orally administered MIRA1a in rats, 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 invitro 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 December of 2022. Additionally, a 28-day toxicology analysis for dogs and rats is expected to begin at the end of the fourth quarter and continue through the first quarter of 2023.

We plan to begin manufacturing and analytical development of MIRA1a in June of 2022; over the course of the last four months of 2022, Non-GMP development is planned to take place followed by GMP through the end of 2022. We plan to continue to provide GMP MIRA1a materials for the preclinical toxicity programs and plan to continue analytical analysis to provide GMP materials for long-term toxicity and human trials.

Planned Clinical Developments

Following the pre-clinical development plan outlined above, we plan to submit an Investigational New Drug application, or IND, for each of anxiety, chronic pain, and migraine headache indications.

Our first IND application for anxiety is currently planned for an April 2023 submission, followed by a planned Phase I trial in May 2023. After the Phase I trial is complete, a Phase II trial is planned to commence in September 2023 or thereafter.

The second IND application will focus on chronic pain and is planned for an October 2023 submission, followed by a Phase I trial in November 2023 or thereafter. After the phase I trial is complete, a Phase II trial will begin in the first quarter of 2024 or thereafter.

The third IND application will focus on migraine headaches and is currently planned for an April 2024 submission, followed by a Phase I trial in May 2024. After the Phase I trial is complete, a Phase II trial is planned for September of 2024 or thereafter.

The process for conducting clinical trials is uncertain, however, and there is no assurance that our clinical development activities will meet the planned timelines set out above.

Clinical Developments To-Date

We have studied the effects of acute administration of MIRA1a on anxiety-related phenotypes in mice to model human conditions. An intraperitoneal injection of vehicle (saline + 1%DMSO) or MIRA1a (0 mg/kg = Placebo [PBO] vs 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 the elevated plus maze (EPM). The EPM is a widely used preclinical behavioral assay for rodents and it has been validated to assess the anti-anxiety effects of pharmacological agents. We found that, at the doses tested, MIRA1a has potent anti-anxiety effects without any symptoms 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 or Post-Traumatic Stress Disorder. The model is based on the test 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 to treat pain, including opioids, have been demonstrated to delay the onset of heat sensitivity upon paw exposure of mice to heat. Thirty minutes after treatment with either a vehicle (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 significantly took longer to become bothered by the heat and to lift their paws. In comparison with treatment with the control, MIRA1a statistically significantly increased the time it took mice to lift their legs, indicating its potential effectiveness as a possible treatment for pain in this model.

CB2 agonism has been shown in preclinical 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 selective CB2 agonist to treat a range of neurodegenerative diseases. MIRA1a, through its selectivity for CB2 versus the CB1, was designed to minimize the risk of psychoactive adverse events associated with CB1 activation.

Manufacture of Product for Clinical Development Activities

BioVectra Inc. (Prince Edward Island, Canada) currently 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 working with potential Canadian partners to have MIRA1a formulated into solid oral dosage forms for clinical trials.

Market Opportunity

Our lead product, if approved, will potentially compete in 2 key growth markets: the pain and anxiety markets where multiple assets with varying safety and efficacy profiles are already on the market. According to IQVIA's *Global Spending on Medicines (2020)* publication, our first market, the pain market, was worth $63B - $65B in developed markets (US, EU, and OECD) in 2020, and another $19B - $20B in emerging markets. Our focus on severe pain is a sub-set of that market. Our targeted second indication, anxiety, is a sub-set of the mental health market which was worth $30B - $$32B in the developed world and $4B - $5B in emerging markets. Viewed as a whole, MIRA1a intends to compete in a global market worth ~$116B - $122B.

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 lead product MIRA1a through clinical development and approval.
- Continue preclinical development of MIRA1a across a range of CNS diseases associated with neurodegeneration and progress into clinical development.
- Identify additional product candidates and expand current candidates 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 and South Korea, and corresponding applications are pending in Canada, China, Europe, Israel, and Japan. The Canadian and Israeli applications have been allowed and are in the grant phase. 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 patent rights through purchase or license, but we currently have no agreement with MyMD Pharmaceuticals with respect to such patent rights, except that we have a limited license from MyMD Pharmaceuticals to such patent rights for research and development activities relating to our planned pre-clinical and clinical studies, whether carried out in the United States or outside of the United States. The limited license also grants the Company the right to use MyMD's Supera-CBD as a synthetic intermediate in the manufacture of MIRA1a for research and development activities. Except for this license, we do not license any patent rights or other intellectual property for MIRA1a from third parties.

Risk Factors

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 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. These factors raise substantial doubt about our ability to continue as a going concern.
- 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 preclinical 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.
- Other risks and factors listed under "Risk Factors," "Cautionary Note Regarding Forward-Looking Statements" and elsewhere in this prospectus.

Implications of Being an Emerging Growth Company

As a company with less than $1.07 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, as modified by the Jumpstart Our Business Startups Act of 2012 (the "JOBS 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 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 $1.07 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, Section 107 of the JOBS Act also provides that an emerging growth company can 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."

Corporate Information

MIRA1a Therapeutics, 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.mira1a.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 ®, TM, or 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 (or shares if the representative of the underwriters' exercises in full its option to purchase additional shares).
Representative's option to purchase additional shares of common stock	The representative of the underwriters has the option to purchase up to additional shares of common stock from us at the initial public offering price, less underwriting discounts and commissions. The representative can exercise this option at any time within days from the date of this prospectus.
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."
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. See "Dividend Policy."

Trading symbol	We intend to apply to list our common stock on The Nasdaq Capital Market under the symbol "MIRA".
Risk factors	Investing in our common stock involves a high degree of risk. See "Risk Factors" beginning on page 10 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 65,380,000 shares of our common stock outstanding as of June 15, 2022.

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

- 3,750,000 shares of our common stock issuable upon the exercise of stock options outstanding as of June 15, 2022, under our 2022 Omnibus Incentive Plan (the "2022 Omnibus Plan") at a weighted-average exercise price of $1.00 per share; and
- 1,250,000 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.

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, 2021 and 2020, and the balance sheet data as of December 31, 2021 and 2020, from our audited financial statements included elsewhere in this prospectus. We have derived the summary statements of operations data for the three months ended March 31, 2022 and 2021, and the balance sheet data as of March 31, 2022, from our unaudited 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 financial statements and related notes included elsewhere in this prospectus.

Statement of Operations:

	Three months ended March 31,		Year ended December 31,	
	2022	2021	2021	2020
	(Unaudited)	(Unaudited)		
Revenues	$ -	$ -	$ -	$ -
Operating costs:				
General and administrative expenses	617,234	18,347	770,115	52,982
Related party travel costs	374,900	-	697,600	-
Research and development expenses	479,050	33,707	684,447	14,647
Total operating costs	1,471,184	52,054	2,152,162	67,629
Interest expense	(3,862)	(4,921)	(24,374)	(364)
Net loss	**$ (1,475,046)**	**$ (56,975)**	**$ (2,176,536)**	**$ (67,993)**

Balance Sheets:

	March 31,	December 31,	
	2022	2021	2020
	(Unaudited)		
ASSETS			
Current assets:			
Cash	$ 2,122,761	$ 2,809,552	$ 3,491
Deferred offering costs	100,000	100,000	-
Total current assets	2,222,761	2,909,552	3,491
Operating lease, right of use assets	194,195	-	
Advances to affiliates	623,848	445,612	18,880
Total assets	**$ 3,040,804**	**$ 3,355,164**	**$ 22,371**
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)			
Current liabilities:			
Trade accounts payable and accrued liabilities	$ 145,137	$ 228,406	$ -
Related party accounts payable	65,000	547,600	-

Related party line of credit	243,062	293,062	90,000
Related party accrued interest	28,599	24,738	364
Current portion of operating lease liabilities	52,465	-	
Total current liabilities	534,263	1,093,806	90,364
Non-current operating lease liabilities	136,229	-	-
Total liabilities	670,492	1,093,806	90,364
Stockholders' Equity			
Preferred Stock, $0.0001 par value, 5,000,000 shares authorized and none issued or outstanding.	-	-	-
Common Stock, $0.0001 par value; 95,000,000 shares authorized, 65,380,000, 63,369,369 and 58,869,000 issued and outstanding at March 31, 2022, December 31, 2021, and December 31, 2020, respectively.	6,538	6,337	5,887
Additional paid-in capital	6,218,349	4,499,550	-
Stock subscription receivable	(135,000)	-	(5,887)
Accumulated deficit	(3,719,575)	(2,244,529)	(67,993)
Total stockholders' equity (deficit)	2,370,312	2,261,358	(67,993)
Total liabilities and stockholders' equity (deficit)	**$ 3,040,804**	**$ 3,355,164**	**$ 22,371**

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 a development stage company with no revenues, and there are doubts about our ability to continue as a going concern.

As a development-stage enterprise that is focused on the development of a preclinical pharmaceutical product, we have generated no revenue and have an accumulated deficit of $3.7 million through March 31, 2022 and $2.2 million through December 31, 2021. These factors raise substantial doubt about our ability to continue as a going concern. There can be no assurance that sufficient funds required during the next year or thereafter 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 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.

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 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 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.

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 preclinical stage of development. Our business depends almost entirely on the successful clinical development, regulatory approval, and commercialization of our product candidates, principally MIRA1a. Investors need to be aware that substantial additional investments including preclinical and clinical development and regulatory 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 preclinical 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 Food and Drug Administration (the "FDA") and similar foreign regulatory authorities;
- 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;
- 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 preclinical studies and earlier clinical trials are not necessarily predictive indicators of future results.

Any positive results from future preclinical testing of our product candidates and potential future clinical trials may not necessarily be predictive of the results from Phase 1, Phase 2 or Phase 3 clinical trials. In addition, our interpretation of results derived from clinical data or our conclusions based on our preclinical data may prove inaccurate. Frequently, pharmaceutical and biotechnology companies have suffered significant setbacks in clinical trials after achieving positive results in preclinical 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 preclinical and clinical data can be susceptible to varying interpretations and analyses. Furthermore, certain product candidates may perform satisfactorily in preclinical studies and clinical trials, but nonetheless fail to obtain FDA approval or appropriate approvals by the appropriate medicines 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. The success and acceptance of a product in one country may be negatively affected by our activities in another. If we fail to adapt our approach to clinical trials in the U.S. market to meet the needs of the regulatory authorities of other countries, or to generate the health economics and outcomes research data needed to support pricing and reimbursement negotiations in other countries, we may have difficulties obtaining marketing authorization for our products from regulatory authorities in other countries and may have difficulties obtaining pricing and reimbursement approval for our products at a national level. 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, whether foreign or domestic, or governmental or commercial, 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 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, including MIRA1a and our other product candidates. 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.

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 GMP 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 GMP, 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. or other countries, we must obtain FDA or other regulatory approval for the product, which requires a successful FDA or other regulatory 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. and in other countries, 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.

Our product candidates contain controlled substances, the use of which may generate public controversy.

To the extent our product candidates contain controlled substances, their regulatory approval may generate public controversy. Political and social pressures and adverse publicity could lead to delays in approval of, and increased expenses for, our product candidates. These pressures could also limit or restrict the introduction and marketing of our product candidates. Adverse publicity from cannabis misuse or adverse side effects from cannabis or other cannabinoid products, including synthetic cannabis-related products, may adversely affect the commercial success or market penetration achievable by our product candidates. The nature of our business attracts a high level of public and media interest, and in the event of any resultant adverse publicity, our reputation may be harmed.

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.

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

Our operations have consumed substantial amounts of cash since inception. For the three months ended March 31, 2022, we reported a net operating cash outflow of $2.0 million and a net cash inflow from investing activities of $1.3 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, and approvals in international markets of our product candidates, if at all;
- 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.

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 be in compliance 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. and foreign jurisdictions 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., European, and foreign governments, 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 both the U.S. and some foreign jurisdictions, 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.

In some foreign countries, including major markets in the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take six to 12 months or longer after the receipt of regulatory approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a pharmacoeconomic study that compares the cost effectiveness of our product candidates to other available therapies. Such pharmacoeconomic studies can be costly and the results uncertain. Our business could be harmed if reimbursement of our products is unavailable or limited in scope or amount or if pricing is set at unsatisfactory levels.

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.

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;
- DEA-related recordkeeping, reporting or security violations at a clinical site, leading the DEA or state authorities to suspend or revoke the site’s controlled substance license and causing a delay or termination of planned or ongoing trials;
- 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;
- 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 for controlled substances;
- 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 Medicinal Products (IMPs) can vary from one IMP 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 preclinical study or clinical trial will result in 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;
- 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 and foreign 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, and their foreign equivalents, when applicable. If we or our suppliers fail to comply with applicable regulations, including FDA pre-or post-approval cGMP requirements, then FDA or other foreign regulatory authorities 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. MIRA1a, 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 warning letters;
- impose civil or criminal penalties;
- suspend regulatory approval;
- suspend any of our ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications submitted by us;
- impose restrictions on our operations, including by requiring us to enter 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, our products are regulated by the DEA, under the Controlled Substances Act. DEA scheduling is a separate process that can delay when a drug may become available to patients beyond an NDA approval date, and the timing and outcome of such DEA process is uncertain. See also "Risks Related to Controlled Substances."

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, state and foreign healthcare laws and regulations and implementation of or changes to such healthcare laws and regulations could adversely affect our business and results of operations.

In both the U.S. and certain foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the healthcare system in ways that could impact our ability to sell our 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.

In addition, in many foreign countries, particularly the countries of the European Union, the pricing of prescription drugs is subject to government control. In some non-U.S. jurisdictions, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product, or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. We may face competition from lower-priced products in foreign countries that have placed price controls on pharmaceutical products. In addition, there may be importation of foreign products that compete products we may market, which could negatively impact our profitability.

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 and other comparable foreign regulatory authorities 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 preclinical studies and clinical trials. 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 (or any other country's medicine regulatory body);
- results of clinical trials that may not meet the level of statistical or clinical significance required by the FDA (or any other country's medicine regulatory body);
- disagreements with the FDA (or any other country's medicine regulatory body) with respect to the number, design, size, conduct or implementation of clinical trials;
- requirements by the FDA (or any other country's medicine regulatory body) to conduct additional clinical trials;
- disapproval by the FDA or other applicable foreign regulatory authorities of certain formulations, labeling or specifications of product candidates;
- findings by the FDA (or any other country's medicine regulatory body) that the data from preclinical studies and clinical trials are insufficient;

- the FDA (or any other country's medicine regulatory body) may disagree with the interpretation of data from preclinical studies and clinical trials; and
- the FDA, or other applicable foreign regulatory agencies 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 or other regulatory authorities may disagree with our interpretation of the data. In the event that we obtain negative results from clinical trials for product candidates or other problems related to potential chemistry, manufacturing and control issues or other hurdles occur and our 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 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. To date, we have only voluntarily suspended clinical trials when recruitment of the target patients has proven to be too difficult or, temporarily, to properly investigate suspected adverse events. 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 Controlled Substances

Our drug candidates may become subject to controlled substance laws and regulations in the U.S.

While cannabis and some cannabinoids are controlled substances under the CSA in the United States, we plan to initially focus our drug development projects using cannabinoid analogs and other molecules that are produced via chemical synthesis.

A number of cannabinoid-containing medicines, such as Marinol® or Syndros® (containing dronabinol), or Epidiolex (containing botanically-derived cannabidiol) or Cesamet® (containing nabilone) have been approved by the FDA for various indications.

Marinol®, a capsule formulation which contains synthetic tetrahydrocannabinol, or THC when formulated is a Schedule III medicine. Syndros® (which also contains synthetic THC, dronabinol) is a liquid formulation as is classified as Schedule II. Epidiolex® was initially a Schedule V medicine when it was introduced in 2018 but was descheduled by the DEA in 2020.

It is our intention to produce product candidates via synthetic means, which may produce complex extracts or purified drug substance as API.

Depending upon the content of our selected API(s), and their subsequent controlled drug status in the USA, and if the company conducts preclinical studies or clinical trials in the United States, we will become subject to the CSA laws and regulation in addition to FDA regulations. If the Company decides to proceed with APIs which are controlled drugs, it will evaluate where it is best to conduct its research and preclinical and clinical trials. This may or may not be the USA.

Nevertheless, our finished drug products may contain controlled substances as defined in the CSA. Product candidates which contain controlled substances are subject to a high degree of regulation under the CSA, which establishes, among other things, certain registration, manufacturing quotas, security, recordkeeping, reporting, import, export, and other requirements administered by the DEA. The DEA classifies controlled substances into five schedules: Schedule I, II, III, IV or V substances. Schedule I substances, by definition, have a high potential for abuse, have not currently "accepted medical use" in the United States, lack accepted safety for use under medical supervision, and may not be prescribed, marketed, or sold in the United States. Pharmaceutical products approved for use in the United States may be listed as Schedule II, III, IV or V, with Schedule II substances considered to present the highest potential for abuse or dependence and Schedule V substances the lowest relative risk of abuse among such substances. Schedule I and II drugs are subject to the strictest controls under the CSA, including manufacturing and procurement quotas, security requirements and criteria for importation. In addition, dispensing of Schedule II drugs is further restricted. For example, they may not be refilled without a new prescription.

While cannabis and certain of its derivatives and certain cannabinoids are Schedule I controlled substances, drugs approved for medical use in the United States that contain cannabis, cannabis extracts or certain cannabinoids must be placed in Schedules II - V, since approval by the FDA satisfies the "accepted medical use" requirement. If, and when any of our product candidates receive FDA approval, for those that are considered controlled substances under the CSA, the DEA will make a scheduling determination

and place it in a schedule other than Schedule I for it to be prescribed for patients in the United States. If approved by the FDA, depending upon the products potential for abuse amongst other factors, we expect the finished dosage forms of any of our product candidates to be listed by the DEA as a Schedule II-V controlled substance. Consequently, their manufacture, importation, exportation, domestic distribution, storage, sale and legitimate use will be subject to a significant degree of regulation by the DEA (in the USA) and the corresponding competent authorities around the world.

The scheduling process may take one or more years beyond FDA approval in the USA, thereby significantly delaying the launch of our drugs / medicines. However, the DEA must issue a temporary order scheduling the drug within 90 days after the FDA approves the drug and the DEA receives a scientific and medical evaluation and scheduling recommendation from the Department of Health and Human Services. Furthermore, if the FDA, DEA or any foreign regulatory authority determines that any of our drugs may have potential for abuse, it may require us to generate more clinical data than that which is currently anticipated, which could increase the cost and/or delay the launch of our drugs / medicines or APIs (or food or cosmetic ingredients outside of the USA).

DEA registration and inspection of facilities. Facilities conducting research, manufacturing, distributing, importing, or exporting, or dispensing controlled substances must be registered (licensed) to perform these activities and have the security, control, recordkeeping, reporting and inventory mechanisms required by DEA to prevent drug loss and diversion. All these facilities must renew their registrations annually, except dispensing facilities, which must renew every three years. DEA conducts periodic inspections of certain registered establishments that handle controlled substances. Obtaining and maintaining the necessary registrations may result in delay of the importation, manufacturing, or distribution of our products. Furthermore, failure to maintain compliance with the CSA, particularly non-compliance resulting in loss or diversion, can result in regulatory action that could have a material adverse effect on our business, financial condition, and results of operations. DEA may seek civil penalties, refuse to renew necessary registrations, or initiate proceedings to restrict, suspend or revoke those registrations. In certain circumstances, violations could lead to criminal proceedings.

State-controlled substances laws. Individual states have also established controlled substance laws and regulations. Though state-controlled substances laws often mirror federal law because the states are separate jurisdictions, they may separately schedule our product candidates as well. We or our partners must also obtain separate state registrations, permits or licenses to be able to obtain, handle, and distribute controlled substances for clinical trials or commercial sale, and failure to meet applicable regulatory requirements could lead to enforcement and sanctions by the states in addition to those from the DEA or otherwise arising under federal law.

Clinical trials. Because our product candidates are controlled substances in the U.S., to conduct clinical trials in the U.S., each of our research sites must submit a research protocol to the DEA and obtain and maintain a DEA researcher registration that will allow those sites to handle and dispense our products and to obtain product from our importer. If DEA delays or denies the grant of a research registration to one or more research sites, the clinical trial could be significantly delayed, and we could lose clinical trial sites. The importer for the clinical trials must also obtain an importer registration and an import permit for each import.

Importation. If one of our product candidates are approved and classified as a Schedule II or III substance, an importer can import for commercial purposes if it obtains an importer registration and files an application for an import permit for each import. DEA provides annual assessments/estimates to the International Narcotics Control Board which guides the DEA in the amounts of controlled substances that DEA authorizes to be imported. The failure to identify an importer or obtain the necessary import authority, including specific quantities, could affect product availability and have a material adverse effect on our business, results of operations and financial condition. In addition, an application for a Schedule II importer registration must be published in the Federal Register, and there is a waiting period for third party comments to be submitted. It is always possible that adverse comments may delay the grant of an importer registration.

If one of our product candidates are approved and classified as a Schedule II controlled substance, federal law may impose additional restrictions on importation for commercial purposes.

Manufacture in the U.S. If, because of a Schedule II classification or voluntarily, we were to conduct manufacturing or repackaging/relabeling in the U.S., our contract manufacturers would be subject to DEA's annual manufacturing and procurement quota requirements. Additionally, regardless of the scheduling of nabiximols, cannabis and the BDSs comprising the active ingredient in the final dosage form are currently Schedule I controlled substances and would be subject to such quotas as these substances could remain listed on Schedule I. The annual quota allocated to us or our contract manufacturers for the active ingredients in our products may not be sufficient to complete clinical trials or meet commercial demand. Consequently, any delay or refusal by the DEA in establishing our, or our contract manufacturers', procurement and/or production quota for controlled substances could delay or stop our clinical trials or product launches, which could have a material adverse effect on our business, financial position, and results of operations.

Distribution in the U.S. If any of our product candidates are scheduled as Schedule II or III, we would also need to identify wholesale distributors with the appropriate DEA and state registrations and authority to distribute the product to pharmacies and other health care providers. We would need to identify distributors to distribute the product to pharmacies; these distributors would need to obtain Schedule II or III distribution registrations. The failure to obtain, or delay in obtaining, or the loss any of those registrations could result in increased costs to us. If any of our product candidates are a Schedule II drug, pharmacies would have to maintain enhanced security with alarms and monitoring systems, and they must adhere to recordkeeping and inventory requirements. This may discourage some pharmacies from carrying either or both of these products. Furthermore, state, and federal enforcement actions, regulatory requirements, and legislation intended to reduce prescription drug abuse, such as the requirement that physicians consult a state prescription drug monitoring program may make physicians less willing to prescribe, and pharmacies to dispense, Schedule II products.

The legalization and use of medical and recreational marijuana in the U.S. and elsewhere may impact our business.

There is a substantial amount of change occurring in the U.S. regarding the use of medical and recreational marijuana products. While federal law prohibits the sale and distribution of most marijuana products not approved or authorized by the FDA, at least 36 jurisdictions and the District of Columbia have enacted state laws to enable possession and use of marijuana for medical purposes, and at least 15 jurisdictions for recreational purposes. Under the U.S. Farm Bill, enacted in late 2018, certain extracts and other material derived from cannabis are now descheduled from the CSA. Although the marketing of such products as a food, dietary supplement, or for medical purposes remains subject to FDA requirements and is not currently permitted, the FDA continues to evaluate regulatory pathways to permit CBD in conventional foods and dietary supplements. In addition, the House passed a legalization proposal in December 2020 though it was never considered in the Senate. Although our business is quite distinct from that of unapproved marijuana and dietary supplement companies, future legislation or FDA action authorizing the sale, distribution, use, and insurance reimbursement of non-FDA approved marijuana products could affect our business.

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.

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

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 currently are exploring pathways for the large-scale synthesis of MIRA1a that involve use of Supera-CBD as a synthetic intermediate. Rights to Supera-CBD are owned by MyMD. We have a limited license from MyMD to use Supera-CBD as a synthetic intermediate for the manufacture of MIRA1a for research and development activities relating to our planned pre-clinical and clinical studies. We do not currently have an express license from MyMD to use Supera-CBD as a synthetic intermediate in the manufacture of MIRA1a for commercial use. If we are unable to obtain such a commercial license, we may need to develop an alternative pathway for the synthesis of MIRA1a, which may be more costly, less efficient, or even infeasible.

We own the rights associated with our patents in the United States, however, we do not yet 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 and South Korea, and corresponding applications are pending in Canada, China, Europe, Israel, and Japan. The Canadian and Israeli applications have been allowed and are in the grant phase. 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 (other than a limited license to such patent rights for research and development activities, i.e., pre-clinical and clinical studies). 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, and MyMD potentially could develop a competing product for jurisdictions outside of the United States.

Risks Relating to our Common Stock

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.

We have never declared or paid any cash dividends or distributions on our capital stock. And 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.

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 preclinical 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.

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 for pre-clinical research and development expenses for MIRA1a;
- approximately $ to $ to for Phase 1 research and development expenses for MIRA1a; 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 March 31, 2022:

- on an actual basis;
- on a pro forma basis, into an aggregate of shares of common stock, which will occur immediately prior to the completion of this offering; and
- on a pro forma as adjusted basis, giving effect to the pro forma adjustments set forth above and the receipt of the estimated net proceeds from the sale and issuance by us of shares of our common stock in this offering (assuming no exercise of the underwriters' option to purchase additional shares of common stock from us) 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 March 31, 2022		
	Actual	**Pro Forma**	**Pro Forma As Adjusted[(1)]**
(in thousands)	(unaudited)	(unaudited)	(unaudited)
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 a pro forma 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 March 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 March 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 March 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 March 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
	Number	Percent	Amount	Percent	Per Share
			($ 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 a preclinical-stage pharmaceutical development company organized as a Florida corporation in September 2020 to focus on the development and commercialization of our initial product candidate, MIRA1a, which is a novel synthetic cannabinoid analog for the treatment of adult patients with chronic pain and anxiety. We began substantive operations in late 2020, at which time we commenced our development program for MIRA1a.

We had net losses of $1.5 million for the three months ended March 31, 2022 and $2.2 million and $68 thousand for years ended December 31, 2021 and 2020, respectively.

COVID-19 Business Update

Due to the ongoing 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. 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 initial 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 our initial product candidate 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 developing 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 three months ended March 31, 2022 and 2021

	Three months ended March 31,	
	2022	**2021**
	(Unaudited)	**(Unaudited)**
Revenues	$ -	$ -
Operating costs:		
General and administrative expenses	617,234	18,347
Related party travel costs	374,900	-
Research and development expenses	479,050	33,707
Total operating costs	1,471,184	52,054
Interest expense	(3,862)	(4,921)
Net loss	**$ (1,475,046)**	**$ (56,975)**

General and Administrative Expenses. We incurred $0.6 million in general and administrative expenses during the three months ended March 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 $0.02 million during the three months March 31, 2021, which consisted of legal fees and website development costs.

Related party travel costs. During the three months ended March 31, 2022, we incurred $0.4 million in related party travel costs, as compared to $0 during the three months ended March 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 $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.

Research and Development Expenses. We incurred $0.5 million of expense during the three months ended March 31, 2022, as compared to $0.03 thousand during the three months ended March 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	2,152,162	67,629
Interest expense	(24,374)	(364)
Net loss	**$ (2,176,536)**	**$ (67,993)**

Research and Development Expenses. We incurred $0.7 million of expense 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 first quarter of 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.

As of March 31, 2022 and December 31, 2021, we had cash of $2.1 million and $2.8 million, respectively. We raised $4.5 million during the year ended December 31, 2021, and an additional $2.01 million in early 2022. Substantially all of our equity capital has been raised at $1.00 per share. We used $1.4 million in operating activities during the year ended December 31, 2021, compared to approximately $0.1 million during the year ended December 31, 2020, which was provided by a related party line of credit. 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 2023.

While 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 in late 2022 or early 2023, 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.

Emerging Growth Company and Smaller Reporting Company Status

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, as amended, or the JOBS Act. Under the JOBS Act, companies have extended transition periods available for complying with new or revised accounting standards. We have elected this exemption to delay adopting new or revised accounting standards.

We will remain an emerging growth company until the earlier of (1) December 31, 2028, (2) the last day of the fiscal year in which we have total annual gross revenues of at least $1.07 billion, (3) the date on which we are deemed to be a "large accelerated filer" as defined in Rule 12b-2 under the Exchange Act, or (4) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period. An emerging growth company may take advantage of specified reduced reporting requirements and is relieved of certain other significant requirements that are otherwise generally applicable to public companies. As an emerging growth company,

- we may present only two years of audited financial statements, plus unaudited condensed financial statements for any interim period, and related Management's Discussion and Analysis of Financial Condition and Results of Operations in this prospectus;
- we may avail ourselves of the exemption from the requirement to obtain an attestation and report from our auditors on the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act;
- we may provide reduced disclosure about our executive compensation arrangements; and

- we may not require stockholder non-binding advisory votes on executive compensation or golden parachute arrangements.

We have elected to take advantage of certain of the reduced disclosure obligations in the registration statement of which this prospectus is a part and may elect to take advantage of other reduced reporting requirements in future filings. As a result, the information that we provide to our stockholders may be different than you might receive from other public reporting companies in which you hold equity interests.

We are also a "smaller reporting company," meaning that the market value of our stock held by non-affiliates plus the proposed aggregate amount of gross proceeds to us as a result of this offering is less than $700.0 million and our annual revenue is less than $100.0 million during the most recently completed fiscal year. We may continue to be a smaller reporting company after this offering if either (1) the market value of our stock held by nonaffiliates is less than $250.0 million or (2) our annual revenue is less than $100.0 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700.0 million. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

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.

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.

BUSINESS

Overview

We are a preclinical-stage pharmaceutical development company that was organized as a Florida corporation in September 2020 to focus on the development and commercialization of novel synthetic cannabinoid analogs for the treatment of adult patients with anxiety and chronic pain. We commenced substantive operations in late 2020, at which time we commenced our pharmaceutical development program.

Our lead drug candidate, MIRA1a, if approved by the FDA, may be a significant advancement in the treatment of neuropsychiatric, inflammatory, neurologic, and oncologic diseases and disorders. Based on preclinical and animal studies conducted by us, we believe that MIRA1a enhances the therapeutic potential for treating anxiety and chronic pain by striking a balance between the beneficial effects of THC and CBD 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 including appetite, pain-sensation, mood, and memory. Relative 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 $1.5 million for the three months ended March 31, 2022, and we had net losses of $2.2 million and $.07 million for years ended December 31, 2021, and 2020, respectively.

Our Lead Product Candidate in Development

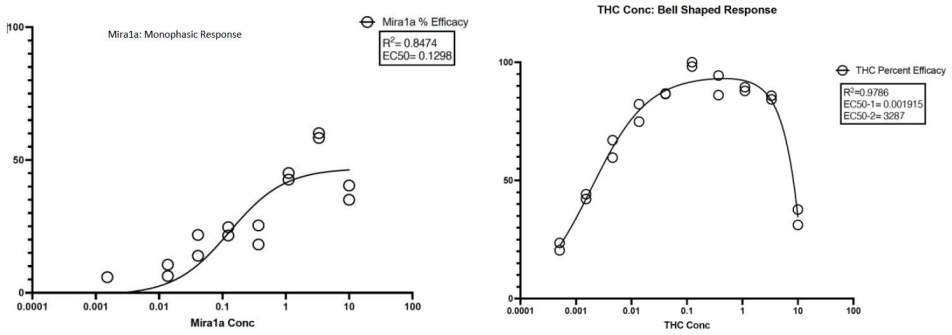
Our objective is to develop and commercialize new treatment options for neuropsychiatric, inflammatory, neurologic, and oncologic diseases and disorders. Cannabinoids are a class of chemical compounds that are naturally occurring and are primarily found in cannabis plant extracts. The two major cannabinoids 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 brain and central nervous system, 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 lead product candidate, MIRA1a, has a strong selectivity for CB2 versus the 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 impact 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 dramatically improved therapeutic profile.

THC is notorious for having biphasic effects, which have been described for over 40 years: at low levels THC has positive effects while high doses cause the opposite,

harmful symptoms. Examples of biphasic effects at low versus high levels of THC include the following: anti-anxiety versus pro-anxiety, cognitively enhancing versus cognitively impairing, mood elevating versus decreasing, respectively. We obtained the following dose-response effects for MIRA1a and THC as agonists at the CB1 receptor (see below). In contrast to THC that displays a biphasic stimulatory and then inhibitory response at CB1, MIRA1a appears to act as monophasic partial agonist where it is stimulatory throughout its dose response. We believe that this nicely accounts for the potential broad therapeutic efficacy of MIRA1a and the observed absence of negative symptoms even at maximal doses of the drug.



Unlike CB1 receptors, that mediate 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 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.

Planned Pre-Clinical Developments

During the first quarter of 2022, we completed several pre-clinical studies, including but not limited to, computational mutagenicity analysis, radio-ligand binding assay, Elevated Plus Maze model of anxiety and hot plate model thermal sensitivity testing.

We plan to conduct several other preclinical studies from April thru August of 2022, including AMES test, Micronucleus Assay and Metabolic Profiling. Moving towards the end of the second quarter, we plan on initiating a 7-day maximum tolerated dose study of MIRA1a in rats and dogs. Additionally, we are planning to schedule a Pre-IND Meeting with the FDA to review MIRA1a and to address specific questions related to the initial first-in-human study for new drugs and other questions that could affect the IND application, including those related to our non-clinical program, manufacturing and product quality for the investigational product, and related regulatory considerations.

We further plan on neurobehavioral evaluation of orally administered MIRA1a in rats, 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 invitro 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 December of 2022. Additionally, a 28-day toxicology analysis for dogs and rats is expected to begin at the end of the fourth quarter and continue through the first quarter of 2023.

We plan to begin manufacturing and analytical development of MIRA1a in June of 2022; over the course of the last four months of 2022, Non-GMP development is planned to take place followed by GMP through the end of 2022. We plan to continue to provide GMP MIRA1a materials for the preclinical toxicity programs and plan to continue analytical analysis to provide GMP materials for long-term toxicity and human trials.

Planned Clinical Developments

Following the pre-clinical development plan outlined above, we plan to submit an Investigational New Drug application, or IND, for each of anxiety, chronic pain, and migraine headache indications.

Our first IND application for anxiety is currently planned for an April 2023 submission, followed by a planned Phase I trial in May 2023. After the Phase I trial is complete, a Phase II trial is planned to commence in September 2023 or thereafter.

The second IND application will focus on chronic pain and is planned for an October 2023 submission, followed by a Phase I trial in November 2023 or thereafter. After the phase I trial is complete, a Phase II trial will begin in the first quarter of 2024 or thereafter.

The third IND application will focus on migraine headaches and is currently planned for an April 2024 submission, followed by a Phase I trial in May 2024. After the Phase I trial is complete, a Phase II trial is planned for September of 2024 or thereafter.

The process for conducting clinical trials is uncertain, however, and there is no assurance that our clinical development activities will meet the planned timelines set out above.

Clinical Developments To-Date

We have studied the effects of acute administration of MIRA1a on anxiety-related phenotypes in mice to model human conditions. An intraperitoneal injection of vehicle (saline + 1%DMSO) or MIRA1a (0 mg/kg = Placebo [PBO] vs 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 the elevated plus maze (EPM). The EPM is a widely used preclinical behavioral assay for rodents and it has been validated to assess the anti-anxiety effects of pharmacological agents. We found that, at the doses tested, MIRA1a has potent anti-anxiety effects without any

symptoms 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 or Post-Traumatic Stress Disorder. The model is based on the test 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 to treat pain, including opioids, have been demonstrated to delay the onset of heat sensitivity upon paw exposure of mice to heat. Thirty minutes after treatment with either a vehicle (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 significantly took longer to become bothered by the heat and to lift their paws. In comparison with treatment with the control, MIRA1a statistically significantly increased the time it took mice to lift their legs, indicating its potential effectiveness as a possible treatment for pain in this model.

MIRA1a is a CB2 agonist for neurodegenerative diseases associated with neuroinflammation caused by microglial activation. CB2 agonism has been shown in preclinical 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 selective CB2 agonist to treat a range of neurodegenerative diseases. MIRA1a, through its selectivity for CB2 versus the CB1, was designed to minimize the risk of psychoactive adverse events associated with CB1 activation.

Manufacture of Product for Clinical Development Activities

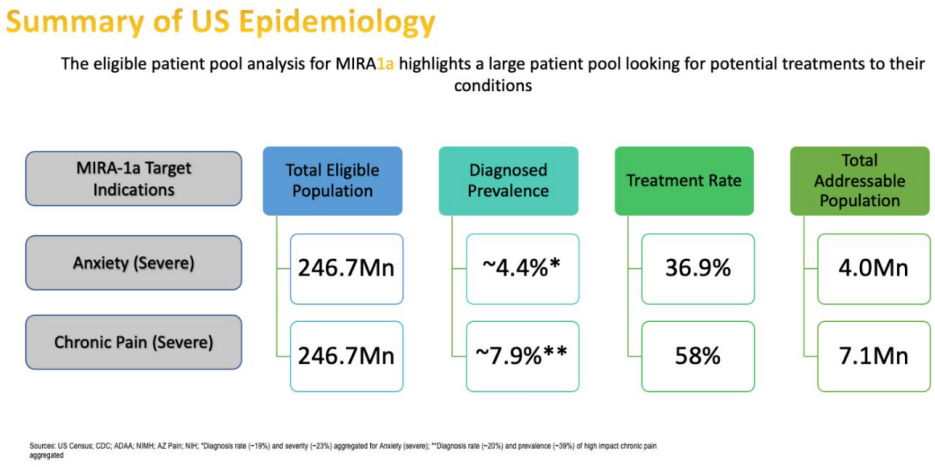
BioVectra Inc. (Prince Edward Island, Canada) is currently developing a large-scale synthesis protocol and will be supplying quantities of MIRA1a needed for our pre-clinical and clinical development activities. We are currently working with potential Canadian partners to have MIRA1a formulated into solid oral dosage forms for clinical trials.

Market Opportunity

Our lead Product, if approved, will potentially compete in 2 key growth markets: the pain and anxiety markets where multiple assets with varying safety and efficacy profiles are already on the market. According to IQVIA's Global Spending on Medicines (2020) publication, our first market, the pain market, was worth $63B - $65B in developed markets (US, EU, and OECD) in 2020, and another $19B - $20B in emerging markets. Our focus on severe pain is a sub-set of that market. Our targeted second indication, anxiety, is a sub-set of the mental health market which was worth $30B - $$32B in the developed world and $4B - $5B in emerging markets. Viewed as a whole, MIRA1a intends to compete in a global market worth ~$116B - $122B.

MIRA1a intends to utilize its synthetic cannabinoid analog to compete effectively with existing pain and anxiety focused assets. At a minimum, that strategy entails winning at the intersection of existing marijuana-based products as well as traditional pain and anxiety medications (small molecule or otherwise). That approach means initially viewing our market opportunity as the marijuana sub-segment of the pain and anxiety markets, and then moving deeper into traditional markets.

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 asset. Today, legal medical marijuana is a $10 billion industry whereas legal recreational marijuana is a $30 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 present 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.



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 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 a novel synthetic cannabinoid analog directed at potentially treating patients with chronic pain 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 1000-fold increased CB2 activation and more potent anti-inflammatory, anti-seizure, anti-cancer properties.

Our Strategy

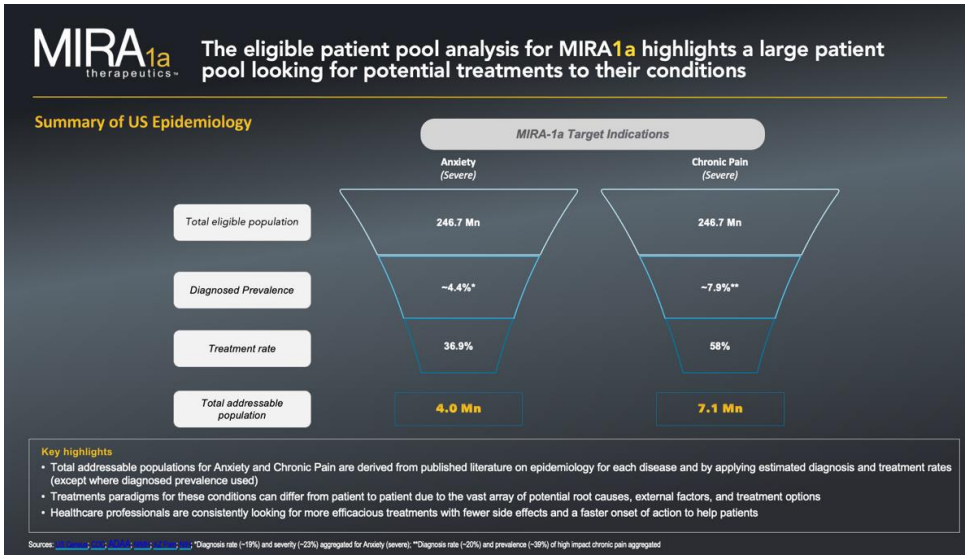
Our goal is to develop therapeutics targeting well-characterized CB1 and CB2 receptors with optimized pharmacological properties to transform the lives of patients with neurological and oncologic diseases. Key elements of our strategy to achieve this goal include:

- ***Advance our lead product MIRA1a through clinical development and approval.*** MIRA1a, our lead product, is in preclinical studies. Existing treatment options for neuropsychiatric disorders and neurological diseases have significant limitations, and, if approved, we believe MIRA1a would represent a therapeutic advancement for patients.

- ***Continue preclinical 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 Post-Traumatic Stress Disorder and chronic pain as well as neurodegenerative diseases such as Alzheimer's and Parkinson's Disease and we expect to submit an IND to the FDA in early 2023. 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; 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) Schedule 1	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 1	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 1	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 Schedule 5	GW	Cannabidiol (CBD)	Dravet and Lennos-Gastaut syndrome (pediatric epilepsies)	Liquid	US

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

Sativex (delta-9-tetrahydrocannibinol 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.

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 and South Korea, and corresponding applications are pending in Canada, China, Europe, Israel, and Japan. The Canadian and Israeli applications have been allowed and are in the grant phase. 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 patent rights through purchase or license, but we currently have no agreement with MyMD with respect to such patent rights, except that we have a limited license from MyMD to such patent rights for research and development activities relating to our planned pre-clinical and clinical studies, whether carried out in the United States or outside of the United States. This limited license also allows the Company to use MyMD's Supera-CBD as a synthetic intermediate in the manufacture of MIRA1a for research and development activities. This license is for a term of one year, subject to termination by either party without cause upon 45-days prior written notice, unless extended by the parties. 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 and in other countries 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;
- 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 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 administer an investigational product to humans and must become effective 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 1 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 2 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 3 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 4 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 4 clinical trials as a condition of approval of 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 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 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. 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 is in Baltimore, Maryland, and is used as an executive office. Our Baltimore location, which comprises approximately 150 square feet, is under a lease that us due to expire on November 30, 2022. 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 June 15, 2022, we had 4 part-time employees and 3 full-time employees. 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.

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

MIRA1a Therapeutics, 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.mira1a.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 executive officers and directors, including their ages as of June 15, 2022. 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
Jude Uzonwanne	48	Chief Executive Officer and Co-Chairman
James A. McNulty, CPA	71	Chief Financial Officer
Adam Kaplin, MD, PhD	55	President and Chief Scientific Officer
Paul M. Rivard, ESQ	51	Executive Vice President and General Counsel
Josh Silverman	52	Director, Co-Chairman of the Board
Chris Chapman, MD	69	Director and Consultant, Regulatory Affairs and Drug Development
Dave Vorhoff	66	Director
Brad Kroenig	43	Director
Talhia Tuck, JD	44	Director
Hugh McColl III	62	Director

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

Executive Officers and Directors

Jude Uzonwanne has served as our Chief Executive Officer and Co-Chairman of our Board of Directors since June 2022. Since April 2021, he has served as a member of MyMD's Board of Directors where he chairs the Nomination Committee. Prior to becoming our Chief Executive Officer and Co-Chairman, he served as Chief Business Officer at 54gene, Inc, a Washington DC-based venture-backed, clinical-stage biopharmaceutical, since March 2021. Prior to 54gene, he was a Principal with ZS Associates, Inc., a consulting and professional services firm focusing on consulting, software and technology that provides services for clients in the private equity, healthcare, and technology industries, a position he has held since January 2021. Prior to joining ZS Associates, Mr. Uzonwanne was a Principal at IQVIA, Inc. from 2018 to 2020, where he served as the head of the firm's US Financial Investors Consulting practice and as management consulting lead for IQVIA's service to a top-6 global pharmaceutical company

and select emerging biopharmaceutical companies. Prior to joining IQVIA, Mr. Uzonwanne served as Vice President (Associate Partner) at EY-Parthenon LLP from 2016 to 2018, where he managed teams advising corporate and private equity investors on a range of commercial due diligence targets in healthcare strategies and advised clients on growth accelerating strategies and investments. Prior to this role, Mr. Uzonwanne has worked for several other companies including Bain & Company, Dalberg Global Development Advisers, the Bill and Melinda Gates Foundation, and Monitor Group. He also served as an adviser and founding Managing Director for Nirsal Plc, a wholly-owned subsidiary of the Central Bank of Nigeria. Mr. Uzonwanne presently serves on the Board of Directors of a privately held African specialty food and snacks manufacturer, Bonita Foods. Mr. Uzonwanne graduated from Swarthmore College with a double Honors B.A. in Economics and Political Science.

James A. McNulty, CPA has served as our Chief Financial Officer since September 2020. He also served as one of our directors from September 2020 until November 2021. He currently serves as the Chief Financial Officer of Hopkins Capital Group, an affiliation of limited liability companies which engage in venture activities primarily in the development of pharmaceuticals, a position that he has held since 2000. From 2016 to 2020, Mr. McNulty also served as a member of the board of directors, including as the Lead Director and Chair of the Audit Committee, of CV Sciences, Inc. (OTC:CVSI). Mr. McNulty previously served as the Chief Executive Officer of MyMD Pharmaceuticals, Inc. from its inception in 2014 until it became public in early 2020. He served as the Chief Financial Officer of Star Scientific, Inc. (NASDAQ: STSI) from 1998 to 2001 and of BioDelivery Sciences International, Inc. (NASDAQ: BDSI) from 2000 until 2014, with each company operating within the biopharmaceutical industry. He has extensive experience in privately held companies, including five years as a Director of Quantum Technology Sciences, Inc. until its acquisition by a public company. Mr. McNulty has performed accounting and consulting services, including expert testimony as a Florida-licensed Certified Public Accountant, since 1975. He is also a partner in Perfect Golf Event, LLC, an online organizer of over 4,000 charity golf events. Mr. McNulty received his B.S. in accounting from the University of South Florida in 1972.

Adam Kaplin, MD, PhD was appointed as our President and Chief Scientific Officer in May 2022. He currently serves as the Chief Scientific Officer of MyMD and previously served as the Chief Scientific Officer of MyMD Florida effective as of December 18, 2020. Prior to joining MyMD Florida, Dr. Kaplin served in a number of positions at John 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. 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.

Paul M. Rivard, ESQ has served as our President from November 1, 2021 to February 15, 2022, and on the same day, was appointed to Executive Vice President and General Counsel. Mr. Rivard has also served as the Executive Vice President of Operations and General Counsel of MyMD Pharmaceuticals, Inc. ("MyMD"; NASDAQ: MYMD) since April 16, 2021. He previously served as Executive Vice President of Operations and General Counsel of MyMD Pharmaceuticals (Florida), Inc., a Florida corporation formerly known as MyMD Pharmaceuticals, Inc. ("MyMD Florida") effective as of September 21, 2020. Prior to joining MyMD Florida, Mr. Rivard was a principal shareholder of Banner Witcoff, a national law firm specializing in intellectual property law, from 2003 until 2020, and in that capacity also served as Chair of the firm's Prosecution Policies and Procedures Committee, developing, and refining internal procedures, workflow, and docketing practices to improve efficiencies and mitigate risk. Before becoming a principal shareholder, Mr. Rivard was an associate at Banner Witcoff from 1998 to 2002. In addition, prior to his time at Banner Witcoff, Mr. Rivard served as a patent examiner for the United States Patent and Trademark Office from 1992 until 1998. Mr. Rivard brings more than 20 years of experience as intellectual property counsel for clients ranging from startups to Fortune 100 companies in the life sciences, chemical and consumer product industries, including primary outside intellectual property counsel for MyMD Florida from 2014 to 2020. Mr. Rivard received his Juris Doctor from Catholic University of America's Columbus School of Law, graduating cum laude in 1998, and his B.S. in Chemical Engineering from Clarkson University in 1992.

Josh Silverman has served as the Co-Chairman of our Board of Directors since June 2022 and previously served as the Chairman of our Board of Directors since November 1, 2021. Mr. Silverman currently serves as the managing member of Parkfield Funding LLC. He was the co-founder, and a principal and managing partner of Iroquois Capital Management, LLC ("Iroquois"), an investment advisory firm. Since its inception in 2003 until July 2016, Mr. Silverman served as co-chief investment officer of Iroquois. While at Iroquois, he designed and executed complex transactions, structuring and negotiating investments in both public and private companies and has often been called upon by the companies to solve inefficiencies as they relate to corporate structure, cash flow, and management. From 2000 to 2003, Mr. Silverman served as co-chief investment officer of Vertical Ventures, LLC, a merchant bank. Prior to forming Iroquois, Mr. Silverman was a director of Joele Frank, a boutique consulting firm specializing in mergers and acquisitions. Previously, Mr. Silverman served as assistant press secretary to the president of the United States. Mr. Silverman also currently serves as a director of MyMD, as the Chairman and as a member of the Audit Committee; Ayro Inc. (NASDAQ: AYRO), as the Chairman and as a member of the Audit Committee; Protagenic Therapeutics (NASDAQ: PTIX), as a member of the Audit Committee; Synaptogenix, Inc. (NASDAQ: SNPX), as the Chairman; and Petros Pharmaceutical, Inc. (NASDAQ: PTPI), as the Vice Chairman and member of the Audit Committee, all of which are public companies. He previously served as a director of National Holdings Corporation (NASDAQ: NHLD) from July 2014 through August 2016 and as a director of Marker Therapeutics, Inc. (NASDAQ: MRKR) from August 2016 until October 2018. Mr. Silverman received his B.A. from Lehigh University in 1992. Due to his extensive experience with public companies in the pharmaceutical industry, we believe Mr. Silverman is qualified to serve as one of our directors.

Chris Chapman, MD has served as one of our directors and Consultant Regulatory Affairs and Drug Development since November 1, 2021. He 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.

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 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, JD 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.

Hugh McColl III has served as one of our directors since November 1, 2021. 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, a providing post-investment value-added oversight to portfolio companies. He has also served as a Partner at Collwick Capital, LLC, a boutique alternative investment firm that he founded in 2010. Before 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 received his B.S. in business administration from the University of North Carolina at Chapel Hill in 1982 and his 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.

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.

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 Josh Silverman, Dave Vorhoff, 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.

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.mira1a.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.

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.

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 compensation to any of our directors during the year ended December 31, 2021 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, with each option being immediately vested in full upon grant and having a 10-year term. In addition, Dr. Chapman is 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. See "Certain Relationships and Related Party Transactions-Consulting Agreement with Dr. Chapman." Also, Mr. Kroenig provides consulting services to our company 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. See "Certain Relationships and Related Party Transactions-Consulting Relationship with Mr. Kroenig."

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 2021 and (ii) the two most highly compensated of our other executive officers who received compensation during 2021 of at least $100,000 and who were executive officers on December 31, 2021. We refer to these persons as our "named executive officers" elsewhere in this prospectus. Our "named executive officers" and their positions were as follows:

- Paul M. Rivard, President (as of December 31, 2021); and
- James A. McNulty, CPA, Chief Financial Officer.

In June 2022, Mr. Jude Uzonwanne became our Chief Executive Officer, but he was not an executive officer as of December 31, 2022. In May 2022, Dr Adam Kaplin became our President and Chief Scientific Officer, whereunder Mr. Rivard ceased to hold the office of President.

Summary Compensation Table

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

Name and principal position	Year (1)	Salary	Bonus	Stock Awards	All Other Compensation	Total ($)
Paul M. Rivard *Former President; Executive Vice President and General Counsel*	2021	$ 13,750	-	-	-	$ 13,750
James A. McNulty, CPA *Chief Financial Officer*	2021	$ 43,000	-	-	-	$ 43,000

(1) Compensation in 2021 began November 1, 2021.
(2) See Employment Agreement for changes in position.

Executive Compensation Arrangements

Below is a more detailed summary of the elements of our current executive compensation program as it relates to our named executive officers and our current executive officers.

Employment Agreements

Jude Uzonwanne

On June 15, 2022, we entered into an employment agreement with Jude Uzonwanne pursuant to which Mr. Uzonwanne will serve as our Co-Chairman and Chief Executive Officer until his employment is terminated in accordance with the agreement. Mr. Uzonwanne will receive a $50,000 cash sign-on bonus payable immediately, and his annual base salary of $300,000 will commence upon the listing of our common stock on the Nasdaq or another public securities market. Mr. Uzonwanne is also entitled to receive reimbursement for all reasonable pre-approved travel and out of pocket expenses incurred in providing services to us. Mr. Uzonwanne's employment agreement provides that we or Mr. Uzonwanne may terminate the Uzonwanne Agreement for any reason at any time.

Paul Rivard

On November 1, 2021, we entered into an employment agreement with Mr. Rivard. Pursuant to the agreement, Mr. Rivard began serving as our President on November 1, 2021 on a part-time basis at an annual base salary of $82,500. The agreement provides that Mr. Rivard is also entitled to receive reimbursement for all reasonable pre-approved travel and out of pocket expenses incurred in providing services to us. Mr. Rivard's employment agreement provides that we or Mr. Rivard may terminate the agreement for any reason at any time. In the event that we terminate Mr. Rivard's employment agreement for any reason, the agreement provides that we will pay to Mr. Rivard

his monthly base salary for the three months following such notice of termination.

On February 15, 2022, we and Mr. Rivard entered into an amendment to Mr. Rivard's employment agreement. Under such amendment, Mr. Rivard was named our President and General Counsel, and the amendment provides for a base salary in the amount of $240,000 per year plus a cash bonus of $100,000 upon the listing of our common stock on the Nasdaq or another public securities market.

On May 10, 2022, we and Mr. Rivard entered a second amendment to change Mr. Rivard's title and role to Executive Vice President and General Counsel, whereupon he ceased to serve as President.

James McNulty

On November 1, 2021, we entered an employment agreement with Mr. McNulty. Pursuant to the agreement, Mr. McNulty will continue to serve as our Chief Financial Officer on a full-time basis until his employment is terminated in accordance with the agreement. Mr. McNulty's annual base salary is $264,000. Mr. McNulty is also entitled to receive reimbursement for all reasonable pre-approved travel and out of pocket expenses incurred in providing services to us. Mr. McNulty's employment agreement provides that we or Mr. McNulty may terminate the employment for any reason at any time. In the event that we terminate the agreement for any reason, the agreement provides that we will pay to Mr. McNulty his monthly base salary for the three months following such notice of termination.

On January 1, 2022, we entered into an amendment to Mr. McNulty's employment agreement with Mr. McNulty to provide that he is eligible to receive a cash bonus of $100,000 upon the substantial completion of an initial capital raise of $6.5 million. McNulty earned and was paid this cash bonus in February 2022.

Adam Kaplin

On May 10, 2022, we entered an employment with Dr. Kaplin pursuant to which Dr. Kaplin will serve as our President and Chief Scientific Officer until his employment is terminated in accordance with the agreement. Dr. Kaplin's annual base salary of $240,000 will commence upon the listing of our common stock on the Nasdaq or another public securities market. Also at the same time, Dr. Kaplin will be entitled to a cash bonus of $100,000. During the first quarter of 2022, Dr. Kaplin was paid $50,000 in consulting fees, which will be credited toward any $100,000 that would become due upon the listing of our common stock. Dr. Kaplin is also entitled to receive reimbursement for all reasonable pre-approved travel and out of pocket expenses incurred in providing services to us. Dr. Kaplin's employment agreement provides that we or Dr. Kaplin may terminate his agreement for any reason at any time. In the event that we terminate the agreement for any reason, we will pay to Dr. Kaplin his monthly base salary for the three months following such notice of termination.

Base Salaries

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

Bonuses

No bonuses were paid to any of our named executive officers in 2021.

Equity Compensation

Our executive officers did not receive any equity compensation grants in 2021. In June 2022, Mr. Uzonwanne and Dr. Kaplin were each granted an option to purchase 1,000,000 shares of common stock. These options, which were granted under our 2022 Omnibus Plan, have an exercise price of $1.00 per share. These options vested as to 25% of the option shares on the date of option grant and will vest as to one-third of the option shares on the succeeding three 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 2020 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 no equity awards granted or outstanding as of December 31, 2021.

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 June 15, 2022, there are a cumulative 3,750,000 of stock options granted to members of the board of directors, management of the company and a consultant.

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.

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.

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.

- 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.

Repricing and Backdating Prohibited

Except for the adjustments provided for in the 2022 Omnibus Plan, neither the Administrator nor any other person may amend the terms of outstanding stock options or SARs to reduce their exercise or grant price, cancel outstanding stock options or SARs in exchange for stock options or SARs with an exercise or grant price that is less than the exercise or grant price of the awards being cancelled, or cancel outstanding stock options or SARs with an exercise or grant price above the current fair market value of a share in exchange for cash or other securities. In addition, the Administrator may not grant a stock option or SAR with a grant date that is effective prior to the date the Administrator takes action to approve such award.

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 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, which 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.

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 Pharmaceuticals, Inc., or MyMD, having an effective date of April 26, 2022, under which we were granted a royalty-free license under MyMD's foreign patent rights relating to MIRA1a for the limited purpose of undertaking research and development activities relating to our pre-clinical and clinical studies, whether carried out in the United States or outside of the United States. The license also grants our company the right to use MyMD's Supera-CBD as a synthetic intermediate in the manufacture of MIRA1a for research and development activities relating to such trials. This agreement has a term of one year, subject to the right of either party to terminate the agreement upon 45-days prior notice without cause, unless the parties mutually agree to extend the agreement for an additional period necessary for our company to complete the manufacture of quantities of MIRA1a needed for pre-clinical or clinical studies. 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 MyMD's Supera-CBD product and our MIRA1a product candidate. Our Chairman of the Board, Josh Silverman, is the Chairman of the Board of MyMD, and our Executive Vice President and General Counsel, Paul Rivard, is the Executive Vice President and General Counsel of MyMD.

Consulting Agreement with Dr. Chapman

On April 1, 2022, we entered into a Consulting Agreement with Dr. Chapman pursuant to which he provides regulatory and drug development consulting services to the Company on an as-requested basis. Under the agreement, he will 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 will begin once we have completed this offering. He will also be reimbursed for reasonable out-of-pocket expenses incurred in connection with his duties under the Consulting Agreement. The agreement has a term of one year with an automatic one-year extension, provided that either party can 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. 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. Any unvested portion of the option will vest in full upon a "change of control" of our company within the meaning of the 2020 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.

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*.

PRINCIPAL SHAREHOLDERS

The following table sets forth information as of , 2022 (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 , 2022. 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.

	Shares of Common Stock Beneficially Owned			
	Shares of Common Stock Beneficially Owned Before this Offering		Shares of Common Stock Beneficially Owned After this Offering	
Name of beneficial owner	**Number of Shares**	**Percentage**	**Number of Shares**	**Percentage**
Directors and Executive Officers				
Jude Uzonwanne	350,000	*		
James A. McNulty, CPA	791,000	1.21%		
Adam Kaplin, MD Phd.	1,250,000	1.90%		
Paul M. Rivard	1,000,000	1.52%		
Josh Silverman	100,000	*		
Chris Chapman, MD	1,350,000	2.05%		
Dave Vorhoff	300,000	*		
Brad Kroenig	366,667	*		
Talhia Tuck, JD	200,000	*		
Hugh McColl III	300,000	*		
All current directors and officers as a group[(1)]	**6,007,667**	**9.17%**		
5% Stockholders				
George Cappy, Esq.[(2)]	14,993,000	22.93%		
Alton Cates, CPA[(3)]	3,300,000	5.05%		
David Moser, JD[(4)]	3,376,667	5.16%		
Celeste Williams	3,300,000	5.05%		
Francis M. Williams	3,300,000	5.05%		
Francis E. O'Donnell, Jr. MD[(5)]	3,500,000	5.35%		

Jonnie R. Williams Jr.	3,300,000	5.05%
William J. Nellis[6]	3,400,000	5.20%
Samuel S. Duffey, Esq.[7]	3,350,000	5.12%
Rachel Williams	3,300,000	5.05%
Jonnie R. Williams Sr.	3,000,000	4.59%
Caroline Williams[8]	3,300,000	5.05%

*Represents beneficial ownership of less than 1%

(1) Includes shares subject to options granted under our 2022 Omnibus Incentive Plan that are exercisable within 60 days of the Beneficial Ownership Date held as follows: Mr. Uzonwanne, 250,000 shares; Dr. Kaplin, 250,000 shares; Mr. Silverman, 100,000 shares; Dr. Chapman, 350,000 shares; Mr. Vorhoff, 100,000 shares; Mr. Kroenig, 116,667 shares; Ms. Tuck, 100,000 shares; Mr. McColl, 100,000 shares; and all current officers and directors as a group, 1,366,667 shares. Excludes shares subject to options granted under our 2022 Omnibus Incentive Plan that are not exercisable within 60 days of the Beneficial Ownership Date held as follows: Mr. Uzonwanne, 750,000 shares, Dr. Kaplin, 750,000 shares; Dr. Chapman, 750,000 shares; Mr. Kroenig, 33,333 shares; and all current officers and directors as a group, 2,283,333 shares.

(2) Consists of (i) 100,000 shares held directly by Mr. Cappy, and (ii) 15,093,000 shares held by the Bay Shore Trust. 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 entirely of shares held by the Caroline Constance Williams 2020 Irrevocable Trust. As trustee of the Caroline Constance Williams 2020 Irrevocable Trust, Mr. Cates 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) 60,000 shares held directly by Mr. Moser, (ii) 16,667 shares subject to options granted under our 2022 Omnibus Incentive Plan that are exercisable within 60 days of the Beneficial Ownership Date, 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. Moser 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) 200,000 shares held directly by Dr. O'Donnell and (ii) 3,300,000 shares held by the Francis Murray Williams 2020 Irrevocable Trust. As trustee of the Francis Murray Williams 2020 Irrevocable Trust, Dr. O'Donnell 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.

(6) 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.

(7) 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.

(8) Consists of (i) 1,650,000 shares held directly by Mr. Williams and (ii) 1,650,000 shares held by The Starwood Trust. As trustee of The Starwood Trust, Ms. Williams 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 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".

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. See "Risk Factors—Risks Related to Ownership of Our Common Stock and This Offering — Substantial amounts of our outstanding shares may be sold into the market when lock-up or market standoff periods end. If there are substantial sales of shares of our common stock, the price of our common stock could decline."

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 , 2022, 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 , 2022, 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.

Lock-up Agreements

In connection with this offering, we, our directors, our executive officers and stockholders holding % or more of our shares of common stock outstanding as of , 2022 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.

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.

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(l)(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 will be required to furnish 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.

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.

UNDERWRITING

We and the underwriters named below have entered into an underwriting agreement with respect to the shares being offered. _____ is acting as representative of the underwriters. Subject to the terms and conditions of the underwriting agreement, we have agreed to sell to the underwriters, and each underwriter has severally agreed to purchase, at the public offering price less the underwriting discounts and commissions set forth on the cover page of this prospectus, the number of shares of common stock listed next to its name in the following table:

Underwriters	Number of Shares

Total

The underwriters are committed to purchase all the shares of common stock offered by us if they purchase any shares. The underwriting agreement also provides that if an underwriter defaults, the purchase commitments of non-defaulting underwriters may also be increased or the offering may be terminated. The underwriters have advised us that they do not intend to confirm sales to any accounts over which they exercise discretionary authority. Any shares of common stock sold by the underwriters to securities dealers will be sold at the initial public offering price less a selling concession not in excess of $ per share.

The underwriting fee is equal to the public offering price per share of common stock less the amount paid by the underwriters to us per share of common stock. The underwriting fee is $ per share. The following table summarizes the underwriting discount and commission to be paid to the underwriters by us.

	Per Share	Total Without Option Exercise	Total With Full Option Exercise
Initial public offering price	$	$	$
Underwriting discounts and commissions[(1)]	$	$	$
Proceeds to us, before expenses	$	$	$

(1) Represents underwriting discount and commissions equal to % of the aggregate purchase price paid by the underwriters to us per share.

We estimate that the total expenses paid by us for this offering, excluding underwriting discounts and commissions, will be approximately $ million. Subject to compliance with FINRA Rule 5110(g), we have agreed to reimburse the representative for their out-of-pocket expenses, including legal fees, up to $.

The representative of the underwriters has an option to buy up to additional shares of common stock from us to cover sales of shares by the underwriters which exceed the number of shares specified in the table above. The representative has days from the date of this prospectus to exercise this option to purchase additional shares. If any additional shares of common stock are purchased, the representative will offer the additional shares on the same terms as those on which the shares are being offered.

A prospectus in electronic format may be made available on the web sites maintained by one or more underwriters participating in the offering.

Our officers, directors and stockholders have agreed with the representative to be subject to a lock-up period of days following the closing date of this offering. This means that, during the applicable lock-up period, such persons may not offer for sale, contract to sell, sell, distribute, grant any option, right or warrant to purchase, pledge, hypothecate or otherwise dispose of, directly or indirectly, any shares of common stock or any securities convertible into, or exercisable or exchangeable for, shares of common stock, subject to certain customary exceptions. We have also agreed, in the underwriting agreement, to similar lock-up restrictions on the issuance and sale of our securities for days following the closing date of this offering, subject to certain customary exceptions, and a restriction on the issuance of variable priced securities until one year following the closing date of this offering, without the consent of the representative. The representative may, in its sole discretion and without notice, waive the terms of any of these lock-up agreements.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act of 1933.

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

In connection with this offering, the underwriters may engage in stabilizing transactions, which involves making bids for, purchasing and selling shares of common stock in the open market for the purpose of preventing or retarding a decline in the market price of the common stock while this offering is in progress. These stabilizing transactions may include making short sales of common stock, which involves the sale by the underwriters of a greater number of shares of common stock than they are required to purchase in this offering and purchasing shares of common stock on the open market to cover positions created by short sales. Short sales may be “covered” shorts, which are short positions in an amount not greater than the representative’s option to purchase additional shares referred to above, or may be “naked” shorts, which are short positions in excess of that amount. The underwriters may close out any covered short position either by exercising their option to purchase additional shares, in whole or in part, or by purchasing shares in the open market. In making this determination, the underwriters will consider, among other things, the price of shares available for purchase in the open market compared to the price at which the underwriters may purchase shares through the option to purchase additional shares. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market that could adversely affect investors who purchase in this offering. To the extent that the underwriters create a naked short position, they will purchase shares in the open market to cover the position.

The underwriters have advised us that, pursuant to Regulation M of the Securities Act of 1933, they may also engage in other activities that stabilize, maintain, or otherwise affect the price of the common stock, including the imposition of penalty bids. This means that if the representative of the underwriters purchase of common stock in the open market in stabilizing transactions or to cover short sales, the representative can require the underwriters that sold those shares as part of this offering to repay the underwriting discount received by them.

These activities may have the effect of raising or maintaining the market price of the common stock or preventing or retarding a decline in the market price of the common stock, and, as a result, the price of the common stock may be higher than the price that otherwise might exist in the open market. If the underwriters commence these activities, they may discontinue them at any time. The underwriters may carry out these transactions on the Nasdaq Capital Market, in the over-the-counter market or otherwise.

Prior to this offering, there has been no public market for our common stock. The initial public offering price will be determined by negotiations between us and the representative of the underwriters. In determining the initial public offering price, we and the representative of the underwriters expect to consider a number of factors including:

- the information set forth in this prospectus and otherwise available to the representative;
- our prospects and the history and prospects for the industry in which we compete;
- an assessment of our management;
- our prospects for future earnings;
- the general condition of the securities markets at the time of this offering;
- the recent market prices of, and demand for, publicly traded common stock of generally comparable companies; and
- other factors deemed relevant by the underwriters and us.

Neither we nor the underwriters can assure investors that an active trading market will develop for our shares of common stock, or that the shares will trade in the

public market at or above the initial public offering price.

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.

In the ordinary course of their various business activities, the underwriters and their respective affiliates, officers, directors, and employees may purchase, sell, or hold a broad array of investments and actively traded securities, derivatives, loans, commodities, currencies, credit default swaps, and other financial instruments for their own account and for the accounts of their customers, and such investment and trading activities may involve or relate to assets, securities, and/or instruments of our company (directly, as collateral securing other obligations or otherwise) or persons and entities with relationships with our company. The underwriters and their respective affiliates may also communicate independent investment recommendations, market color, or trading ideas or publish or express independent research views in respect of such assets, securities, or instruments and may at any time hold, or recommend to clients that they should acquire, long and/or short positions in such assets, securities, and instruments.

Certain of the underwriters and their affiliates have provided in the past to us and our affiliates and may provide from time to time in the future certain commercial banking, financial advisory, investment banking and other services for us and such affiliates in the ordinary course of their business, for which they have received and may continue to receive customary fees and commissions. In addition, from time to time, certain of the underwriters and their affiliates may effect transactions for their own account or the account of customers, and hold on behalf of themselves or their customers, long or short positions in our debt or equity securities or loans and may do so in the future.

Selling Restrictions

Other than in the United States, no action has been taken by us or the underwriters 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.

LEGAL MATTERS

The validity of the shares of common stock offered hereby will be passed upon for us by Foley & Lardner LLP, Tampa, Florida. Certain legal matters in connection with this offering will be passed upon for the underwriters by .

EXPERTS

The financial statements of MIRA1a Therapeutics, Inc. as of December 31, 2021 and 2020 and for each of the periods then ended included in this Registration Statement, of which this Prospectus forms a part, have been so included in reliance on the report of Cherry Bekaert LLP, an independent registered public accounting firm, appearing elsewhere herein (the report on the financial statements contains an explanatory paragraph regarding our company's ability to continue as a going concern), 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, some of which is contained in exhibits to the registration statement as permitted by the rules and regulations of the SEC. For further information with respect to us and our common stock, we refer you to the registration statement, including the exhibits filed as a part of the registration statement. Statements contained in this prospectus concerning the contents of any contract or any other document are not necessarily complete. If a contract or document has been filed as an exhibit to the registration statement, please see the copy of the contract or document that has been filed. Each statement in this prospectus relating to a contract or document filed as an exhibit is qualified in all respects by the filed exhibit. The SEC maintains an internet website that contains reports and other information about issuers, like us, that file electronically with the SEC. The address of that website is *www.sec.gov*. You may also request copies of those documents, at no cost to you, by contacting us at the following address:

MIRA1a Therapeutics, Inc.
900 West Platt St Suite 200
Tampa, Florida 33606-2173
(813) 864-2562

On the closing of this offering, we will be subject to the information reporting requirements of the Exchange Act and other reporting requirements of the Nasdaq Capital Market, and we will file reports and other information with the SEC as required and make any proxy statements available to the holders of our capital stock as required by the rules of the Nasdaq Capital Market. These reports, proxy statements and other information will be available for inspection and copying at the public reference room and website of the SEC referred to above.

INDEX TO FINANCIAL STATEMENTS

MIRA1a Therapeutics, Inc. Financial Statements
For the Years Ended December 31, 2021 and 2020

MIRA1a Therapeutics, Inc. Condensed Financial Statements
As of March 31, 2022 and December 31, 2021
For the Three Months Ended March 31, 2022 and 2021

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders
MIRA1a Therapeutics, Inc.
Tampa, Florida

Opinion on the Financial Statements

We have audited the accompanying balance sheets of MIRA1a Therapeutics, Inc. (the "Company") as ofDecember 31, 2021 and 2020, and the related statements of operations, stockholders' equity (deficit) and cash flows for the year ended December 31, 2021 and for the period from September 3, 2020 (Inception) through December 31, 2020, 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, 2021 and 2020, and the results of its operations and its cash flows for the periods 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 11, 2022

MIRA1a Therapeutics, Inc.
BALANCE SHEETS

DECEMBER 31, 2021, AND DECEMBER 31, 2020

	As of December 31,	
	2021	**2020**
ASSETS		
Current assets:		
Cash	$ 2,809,552	$ 3,491
Deferred offering costs	100,000	-
Total current assets	2,909,552	3,491
Advances to affiliates	445,612	18,880
Total assets	**$ 3,355,164**	**$ 22,371**
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		

Trade accounts payable and accrued liabilities	228,406	-
Related party accounts payable	547,600	-
Related party line of credit	293,062	90,000
Related party accrued interest	24,738	364
Total current liabilities	1,093,806	90,364
Total liabilities	1,093,806	90,364
Stockholders' Equity		
Preferred Stock, $0.0001 par value, 5,000,000 shares authorized and none issued or outstanding.	-	-
Common Stock, $0.0001 par value; 95,000,000 shares authorized, 63,369,369 and 58,869,000 issued and outstanding at December 31, 2021 and December 31, 2020, respectively.	6,337	5,887
Investments	-	-
Additional paid-in capital	4,499,550	-
Stock subscription receivable	-	(5,887)
Accumulated deficit	(2,244,529)	(67,993)
Total stockholders' equity (deficit)	2,261,358	(67,993)
Total liabilities and stockholders' equity (deficit)	**$ 3,355,164**	**$ 22,371**

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

MIRA1a Therapeutics, Inc.
STATEMENTS OF OPERATIONS

YEAR ENDED DECEMBER 31, 2021 AND PERIOD ENDED DECEMBER 31, 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	2,152,162	67,629
Interest expense	(24,374)	(364)
Net loss	**$ (2,176,536)**	**$ (67,993)**

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

MIRA1a Therapeutics, Inc.
STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)

YEAR ENDED DECEMBER 31, 2021, AND PERIOD ENDED DECEMBER 31, 2020

	Common Stock		Additional Paid-In	Stock Subscription	Accumulated	Total Stockholders' Equity
	Shares	**Amount**	**Capital**	**Receivable**	**Deficit**	**(Deficit)**
Balances, September 3, 2020	-	$ -	$ -	$ -	$ -	$ -
Issuance of Founders' shares	58,869,000	5,887	-	(5,887)	-	-
Net loss	-	-	-	-	(67,993)	(67,993)
Balances, December 31, 2020	**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**

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

MIRA1a Therapeutics, Inc.
STATEMENTS OF CASH FLOWS

YEAR ENDED DECEMBER 31, 2021, AND PERIOD ENDED DECEMBER 31, 2020

	Year Ended December 31,	
	2021	2020
Cash flows from Operating activities		
Net loss	$ (2,176,536)	$ (67,993)
Adjustments to reconcile net loss to net cash from operations		
Non-cash interest expense	24,374	-
Accounts payable and accrued expenses	776,006	-
Net cash flows from operating activities	(1,376,156)	(67,993)
Financing activities:		
Advances to affiliates	(426,732)	(18,880)
Payment of deferred offering costs	(100,000)	-
Net borrowings under related party line of credit	203,062	90,000
Collection of stock subscription receivable	5,887	-
Proceeds from sale of common stock, less offering costs	4,500,000	-
Net cash flows from financing activities	4,182,217	71,120
Net change in cash	2,806,061	3,127
Cash, beginning of period	3,127	-
Cash, end of period	**$ 2,809,188**	**$ 3,127**
Cash paid for interest	-	-

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

Note 1—Description of business and summary of significant accounting policies

Description of Business – MIRA1a Therapeutics, Inc. ("MIRA1a" or the "Company") 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 in the first quarter of 2023. 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.

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 late Q2 or early Q3 2022. During 2021, the Company incurred $100,000 of legal costs associated with the offering, which have been recorded as deferred offering costs in the accompanying 2021 balance sheet. These deferred offering costs will be derecognized as a reduction in offering proceeds when the offering closes. However, there can be no assurances that the public offering will be successful.

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 with regard to 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.

Concentrations of Credit Risk – Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash. The Company places its cash on deposit with financial institutions in the United States. The Federal Deposit Insurance Corporation provides deposit insurance of $250,000 for substantially all depository accounts. The Company from time to time may have amounts on deposit in excess of the insured limits.

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.

Note 2—Liquidity and management's plans

Historically, the Company has been primarily engaged in developing MIRA1a. In the course of these activities, the Company has sustained substantial losses. The Company's ability to fund ongoing operations and future clinical trials required for Food and Drug Administration 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 3

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 second quarter of 2023, with available borrowings on the related party line of credit and cash proceeds from common stock sales in 2021 and 2022. 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 its product candidate.

Note 3—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 the major shareholder. The facility has an initial term of 24 months, with a maturity date of May 10, 2023, 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 its private placement or anticipated initial public offering.

Note 4—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.

Note 5—Patent assignment and royalty agreement

In December 2021, the Company entered into an agreement with the holders of certain intellectual property relating to the Company's current product candidate, a major stockholder. Under the terms of the agreement, the counterparty assigned its rights and interest in certain patents to the Company in exchange for future royalty payments based on a fixed percentage of future revenues, as defined. The agreement is effective until the later of (1) the date of expiration of the assigned patents or (2) the date of expiration of the last strategic partnership or licensing agreement including the assigned patents.

Note 6—Income taxes

As of December 31, 2021, the Company has federal and state net operating loss carryforwards totaling approximately $2,245,000, which have no expiry date. 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.

Note 7—Related party transactions

Advances to Affiliates – During 2021 and 2020, the Company made working capital advances to companies under common control. These advances are due on demand and are non-interest bearing.

Line of Credit – See Note 3.

Patent Assignment and Royalties – See Note 5.

Travel Expenses – In April 2021, the Company entered into an airplane lease with an entity under common control that incurs monthly $50,000 leasing charges. The airplane lease has an initial two-year leasing term and renews automatically on an annual basis. During the years ended December 31, 2021 and 2020, the Company incurred $697,600 and $0, respectively, for travel-related expenses to the related party for monthly rental charges and airplane- related expenses. As of December 31, 2021 and 2020, amounts due to this related party totaled $547,600 and $0, respectively.

Note 8 – Recent Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-02, Leases (Topic 842). The guidance in ASU 2016-02 supersedes the lease recognition requirements in ASC Topic 840, Leases. ASU 2016-02 requires an entity to recognize assets and liabilities arising from a lease for both financing and operating leases, along with additional qualitative and quantitative disclosures. ASU 2016-02 is effective for the fiscal years beginning after December 15, 2021, with early adoption permitted. The Company is currently evaluating the full effect that the adoption of this standard will have on its financial statements, but believes it will result in the addition of a material right-of-use asset and lease liability to the Company's balance sheet and may impact the timing and amounts of lease expenses recognized.

	March 31, 2022 (Unaudited)	December 31, 2021
ASSETS		
Current assets:		
Cash	$ 2,122,761	$ 2,809,552
Deferred offering costs	100,000	100,000
Total current assets	2,222,761	2,909,552

Operating lease, right of use assets	194,195	-
Advances to affiliates	623,848	445,612
Total assets	**$ 3,040,804**	**$ 3,355,164**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Trade accounts payable and accrued liabilities	$ 145,137	$ 228,406
Related party accounts payable	65,000	547,600
Related party line of credit	243,062	293,062
Related party accrued interest	28,599	24,738
Current portion of operating lease liabilities	52,465	-
Total current liabilities	534,263	1,093,806
Non-current operating lease liabilities	136,229	-
Total liabilities	670,492	1,093,806
Stockholders' Equity		
Preferred Stock, $0.0001 par value, 5,000,000 shares authorized and none issued or outstanding.	-	-
Common Stock, $0.0001 par value; 95,000,000 shares authorized, 65,380,000 and 63,369,369 issued and outstanding at March 31, 2022 and December 31, 2021, respectively.	6,538	6,337
Additional paid-in capital	6,218,349	4,499,550
Stock subscription receivable	(135,000)	-
Accumulated deficit	(3,719,575)	(2,244,529)
Total stockholders' equity	2,370,312	2,261,358
Total liabilities and stockholders' equity	**$ 3,040,804**	**$ 3,355,164**

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

MIRA1a Therapeutics, Inc.
CONDENSED STATEMENTS OF OPERATIONS

THREE MONTHS ENDED MARCH 31, 2022 AND MARCH 31, 2021

	Three months ended March 31,	
	2022	**2021**
	(Unaudited)	**(Unaudited)**
Revenues	$ -	$ -
Operating costs:		
General and administrative expenses	617,234	18,347
Related party travel costs	374,900	-
Research and development expenses	479,050	33,707
Total operating costs	1,471,184	52,054
Interest expense	(3,862)	(4,921)
Net loss	**$ (1,475,046)**	**$ (56,975)**

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

MIRA1a Therapeutics, Inc.
CONDENSED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT) (UNAUDITED)

THREE MONTHS ENDED MARCH 31, 2022, AND MARCH 31, 2021

	Common Stock		Additional Paid-In	Stock Subscription	Accumulated	Total Stockholders'
	Shares	**Amount**	**Capital**	**Receivable**	**Deficit**	**Equity**
Balances, January 1, 2022	63,369,000	$ 6,337	$ 4,499,550	$ -	$ (2,244,529)	$ 2,261,358
Sale of common stock, net	2,011,000	201	1,718,799	(135,000)	-	1,584,000
Net loss	-	-	-	-	(1,475,046)	(1,475,046)
Balances, March 31, 2022	**65,380,000**	**$ 6,538**	**$ 6,218,349**	**$ (135,000)**	**$ (3,719,575)**	**$ 2,370,312**

	Common Stock		Additional Paid-In	Stock Subscription	Accumulated	Total Stockholders'
	Shares	**Amount**	**Capital**	**Receivable**	**Deficit**	**Deficit**
Balances, January 1, 2021	58,869,000	$ 5,887	$ -	$ (5,887)	$ (67,993)	$ (67,993)
Net loss	-	-	-	-	(56,975)	(56,975)
Balances, March 31, 2021	**58,869,000**	**$ 5,887**	**$ -**	**$ (5,887)**	**$ (124,967)**	**$ (124,968)**

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

MIRA1a Therapeutics, Inc.
CONDENSED STATEMENTS OF CASH FLOWS

THREE MONTHS ENDED MARCH 31, 2022, AND MARCH 31, 2021

	Three Months Ended March 31,	
	2022	2021
	(Unaudited)	(Unaudited)
Cash flows from Operating activities		
Net loss	$ (1,475,046)	$ (56,975)
Adjustments to reconcile net loss to net cash from operations		
Non-cash interest expense	3,861	4,921
Change in operating assets and liabilities:		
Right of use lease, net	(5,500)	-
Accounts payable and accrued expenses	(565,870)	35,631
Net cash flows from operating activities	(2,042,555)	(16,423)
Financing activities:		
Advances to affiliates	(178,236)	(23,108)
Net (repayments) borrowings under related party line of credit	(50,000)	40,000
Proceeds from sale of common stock, less offering costs	1,584,000	-
Net cash flows from financing activities	1,355,764	16,892
Net change in cash	(686,791)	469
Cash, beginning of period	2,809,552	3,491
Cash, end of period	**$ 2,122,761**	**$ 3,960**

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

MIRA1a Therapeutics, Inc.
NOTES TO THE FINANCIAL STATEMENTS

MARCH 31, 2022, AND DECEMBER 31, 2021

Note 1—Description of business and summary of significant accounting policies

Description of Business – MIRA1a Therapeutics, Inc. ("MIRA1a" or the "Company") was formed in 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 in first quarter 2023. 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.

Basis of Presentation- The accounting and reporting policies of the Company conform to accounting principles generally accepted in the United States of America ("GAAP"). In the opinion of management, all adjustments considered necessary for the fair presentation of the financial statements for the periods presented have been included. The results of operations for the three months ended March 31, 2022 are not necessarily indicative of the results to be expected for future periods or the full year.

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 the latter half of 2022. During 2021, the Company incurred $100,000 of legal costs associated with the offering, which have been recorded as deferred offering costs in the accompanying 2021 balance sheet. 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.

Note 2—Liquidity and capital resources

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 Food and Drug Administration 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 3 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 second quarter of 2023, with available borrowings on the related party line of credit. 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 candidate.

Note 3—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, with a maturity date of May 10, 2023, 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 4—Capital stock

Classes of 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 three months ended March 31, 2022, the Company sold 2.01 million shares of common stock at $1.00 per share.

Note 5—Related party transactions

Advances to Affiliates – During the three months ended March 31, 2022, the Company made working capital advances to companies under common control. These advances are due on demand and are non-interest bearing.

Line of Credit – See Note 3.

Travel Expenses – In April 2021, the Company entered an airplane lease with an entity under common control that incurs monthly $50,000 leasing charges. The airplane lease has an initial two-year leasing term and renews automatically on an annual basis. During the three months ended March 31, 2022 and 2021, the Company incurred $374,900 and $0, respectively, for travel-related expenses to the related party for monthly rental charges and airplane-related expenses. As of March 31, 2022, amounts due to this related party totaled $65,000.

Lease Reimbursements- See Note 6.

Note 6 – Lease

The Company's corporate headquarters is in Baltimore, Maryland, which remaining lease is $0.01 million for 8 months. The Company also has leased an office in Tampa, Florida, for its finance and general operations. This Tampa office lease began in March 2022 for 37 months. This space is approximately 2,300 square feet and has remaining base rent of $0.2 million payable through March 2025. Rent is payable in monthly installments and is subject to yearly price increases. The Company splits the monthly rent and variable costs with two related parties. As such, the Company will be reimbursed each month for 2/3^{rds} of the rent expense, which will be recorded as a reduction in lease expenses.

The Company also leases a jet from a related party, which extends through April 2023. However, it is the Company's intent to terminate this lease upon closing of the planned IPO and as such, believe that the remaining lease term is less than 12 months as of January 1, 2022. As such, this lease has been excluded from Topic 842.

Variable Lease Costs

Variable lease costs primarily include utilities, property taxes, and other operating costs that are passed on from the lessor.

Accounting Standards

On January 1, 2022, the Company adopted Accounting Standards Codification ("ASC") Topic 842 ASC Topic 842, which is intended to improve financial reporting about leasing transactions. Under the standard, organizations that lease assets, referred to as "Lessees" shall recognize on the balance sheet the assets and liabilities for the rights and obligations created by those leases. In addition, the standard requires disclosures including financial statements to assess the amount, timing and uncertainty of cash flows arising from leases.

The Company made an accounting policy election to account for leases with an initial term of 12 months or less similar to existing guidance for operating leases today. The Company recognized those lease payments in the Condensed Statements of Operations on a straight-line basis over the lease term. Under the new standard, the Company's lease liability is based on the present value of such payments and the related right-of-use asset will generally be based on the lease liability.

The following is a summary of inputs used by the Company in determining the impact of the adoption of Topic ASC 842:

	Three months ended March 31,	
	2022	**2021**

Lease Term and Discount		
Weighted Average remaining lease term	3 years	-
Weighted Average discount rate	5.0%	0.0%

Maturity of Lease Liabilities

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

Maturity of Lease Liabilities

	March 31, 2022
2022	49,569
2023	67,454
2024	69,309
2025	17,444
Total Lease payments	203,776
Less: Interest	(15,082)
Present Value of Lease Liabilities	188,694

Note 7 – Subsequent events

The Company has evaluated subsequent events through June 13, 2022, in connection with the preparation of these financial statements, which is the date the financial statements were available to be issued.

Common Stock

Shares

MIRA1a therapeutics

MIRA1a Therapeutics, Inc.

PROSPECTUS

Through and including , 20 (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.

, 2022

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

MIRA1a Therapeutics, 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.

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 March, 2022, we undertook a private placement solely to accredited investors pursuant to which we issued and sold an aggregate of 6,511,000 shares of our common stock at a price of $1.00 per share, for an aggregate purchase price of approximately $6.5 million to 76 investors.

2. In June 2022, we granted to 12 directors, employees, or other service providers stock options to purchase an aggregate of 3,750,000 shares of our common stock at an exercise price of $1.00 per share pursuant to our 2022 Omnibus Incentive Plan.

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 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 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*. See the Exhibit Index immediately preceding the signature page hereto, which is incorporated by reference as if fully set forth herein.

(B) *Financial Statement Schedules*.

All schedules are omitted because the required information is (i) not applicable, (ii) not present in amounts sufficient to require submission of the schedule and/or (iii) included in the financial statements and accompanying notes thereto included in the prospectus filed as part of this Registration Statement.

Item 17. Undertakings

The undersigned registrant hereby undertakes to provide to the underwriters at the closing specified in the underwriting agreement certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

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 provisions referenced in Item 14 of this registration statement, 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 Securities 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 Securities Act and will be governed by the final adjudication of such issue.

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.

INDEX TO EXHIBITS

Exhibit No.	Exhibit Description
1*	Form of Underwriting Agreement.
3.1*	Amended and Restated Articles of Incorporation of MIRA1a Therapeutics, Inc., to be in effect upon the completion of this offering.

3.2*	Amended and Restated Bylaws of MIRA1a Therapeutics, Inc., to be in effect upon the completion of this offering.
4.1*	Form of Common Stock Certificate.
5*	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*+	Employment Agreement, dated November 1, 2021, by and between MIRA1a Therapeutics, Inc. and Paul M. Rivard, Esq., as amended.
10.4*+	Employment Agreement, dated November 1, 2021, by and between MIRA1a Therapeutics, Inc. and James A. McNulty, CPA., as amended.
10.5*	Form of Indemnification Agreement
10.6*+	Employment Agreement, dated June 15, 2022, by and between MIRA1a Therapeutics, Inc. and Jude Uzonwanne.
10.7*	Confirmatory Patent Assignment and Royalty Agreement, dated November 1, 2021, between SRQ Patent Holdings II, LLC and MIRA1a Therapeutics, Inc.
10.8*	Amended and Restated Limited License Agreement, dated June 27, 2022, between MIRA1a Therapeutics, Inc. and MyMD Pharmaceuticals, Inc.
10.9*	Employment Agreement, dated May 10, 2022, between MIRA1a Therapeutics, Inc. and Adam Kaplin.
10.10*	Consulting Agreement, dated April 1, 2022, between Chapman Pharmaceutical Consulting, Inc. and MIRA1a Therapeutics, Inc.
23.1*	Consent of Cherry Bekaert LLP.
23.2*	Consent of Foley & Lardner LLP (included in Exhibit 5).
24*	Power of Attorney (included on signature page).
107*	Filing Fee Table.

* To be filed by amendment.

\+ Denotes management contract or compensatory plan or arrangement.

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 June, 2022.

MIRA1a Therapeutics, Inc.

By: _____
Name: Jude Uzonwanne
Title: Chief Executive Officer and Co-Chairman

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. Each person whose signature appears below constitutes and appoints each of Jude Uzonwanne and James A. McNulty, 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.

Signature	Title	Date
Jude Uzonwanne	Chief Executive Officer and Co-Chairman of the Board of Directors (Principal Executive Officer)	June , 2022
James A. McNulty	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	June , 2022
Paul M. Rivard	Executive Vice President and General Counsel	June , 2022
Josh Silverman	Co-Chairman of the Board of Directors	June , 2022
Chris Chapman	Director	June , 2022
Dave Vorhoff	Director	June , 2022
Brad Kroenig	Director	June , 2022
Talhia Tuck	Director	June , 2022
Hugh McColl III	Director	June , 2022