Filed Pursuant to Rule 424(b)(4)
Registration No. 333-269188

PROSPECTUS

2,969,823 SHARES OF COMMON STOCK

This prospectus relates to the resale by the selling stockholders identified herein (the "Selling Stockholders") of an aggregate of 2,969,823 shares of common stock, par value $0.0001 per share (the "Common Stock"), of Chromocell Therapeutics Corporation ("Chromocell," the "Company," "we," "us" or "our") issued by us prior to the consummation of this offering. We have registered on the registration statement of which this prospectus forms a part 2,969,823 shares of common stock (the "Selling Stockholder Shares"), which are being registered for resale by the Selling Stockholders, and 1,100,000 shares of Common Stock (the "IPO Shares") in connection with the initial public offering of the Company (the "IPO").

The offering of the Selling Stockholder Shares by the Selling Stockholders is conditioned on the closing of our IPO. The Selling Stockholder Shares may be sold at prevailing market prices, prices related to prevailing market prices or at privately negotiated prices. We will not receive any proceeds from the sale of any of the Stockholder Shares sold by the Selling Stockholders. The offering of the Selling Stockholder Shares by the Selling Stockholders will terminate at the earlier of such time as all of the Selling Stockholder Shares have been sold pursuant to this registration statement and the date on which it is no longer necessary to maintain the registration of the Selling Stockholder Shares as a result of such shares being permitted to be offered and resold without restriction pursuant to the provisions of Rule 144 of the Securities Act of 1933, as amended (the "Securities Act").

We are an emerging growth company as that term is used in the Jumpstart Our Business Startups Act of 2012 and, as such, have elected to comply with certain reduced public company reporting requirements for this prospectus and future filings. See "Prospectus Summary — Implications of Being an Emerging Growth Company and a Smaller Reporting Company."

Investing in our securities involves a high degree of risk. You should review carefully the risks and uncertainties described under the heading "Risk Factors" beginning on page 10 of this prospectus and under similar headings in any amendments or supplements to this prospectus. Neither the Securities and Exchange Commission nor any state securities commission 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.

The date of this prospectus is February 15, 2024

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ABOUT THIS PROSPECTUS

Neither we, the Selling Stockholders nor the underwriters have authorized anyone to provide you with information or make any representations other than those contained in this prospectus or in any free writing prospectuses prepared by or on behalf of us or to which we have referred you. We, the Selling Stockholders and the underwriters take no responsibility for, and provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the securities offered hereby, and only under circumstances and in jurisdictions where it is lawful to do so. You should assume that the information appearing in this prospectus is accurate as of the date on the front cover of this prospectus only. Our business, financial condition, results of operations and prospects may have changed since that date.

For investors outside the United States: we, the Selling Stockholders and the underwriters have not done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about and observe any restrictions relating to, the offering of the shares of common stock and the distribution of this prospectus outside the United States.

Solely for convenience, our trademarks and tradenames referred to in this prospectus and the registration statement of which it forms a part may appear without the ® or ™ 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 and tradenames.

Information contained in, and that can be accessed through our website, www.chromocell.com, does not constitute part of this prospectus or the registration statement of which it forms a part.

INDUSTRY AND MARKET DATA

We obtained the industry, statistical and market data in this prospectus from our own internal estimates and research, as well as from industry and general publications and research, surveys and studies conducted by third parties. In presenting this information, we have made assumptions based on such data and other similar sources, and on our knowledge of, and our experience to date in, the potential markets for our compounds. Although we believe the data from these third-party sources is reliable, the industry in which we operate is subject to a high degree of uncertainty and risk due to a variety of factors, including those described in the section entitled “Risk Factors.” These and other factors could cause results to differ materially from those expressed in the estimates made by third parties and by us.

BASIS OF PRESENTATION

We were incorporated in Delaware on March 19, 2021. On August 10, 2022, we entered into that certain Contribution Agreement (the “Contribution Agreement”) with Chromocell Corporation, a Delaware corporation (“Chromocell Holdings”). Pursuant to the Contribution Agreement, effective July 12, 2022 (the “Contribution Date”), Chromocell Holdings contributed all assets, liabilities and results of operations related to Chromocell Holdings’ therapeutic business, including all patents, pre-clinical and Phase I study results and data, and trade secrets related to the CC8464 compound, in exchange for the issuance by us of 10,000,000 shares of Common Stock and (ii) 600,000 shares of Series A Convertible Preferred Stock (the “Series A Preferred Stock”). Prior to the Contribution Date, we had only nominal assets and liabilities. Accordingly, the financial statements presented in this prospectus for periods prior to the Contribution Date have been prepared on a “carve-out” basis from the financial statements of Chromocell Holdings to represent our financial position and performance as if it had existed on a stand-alone basis. The financial statements presented in this prospectus for periods from and after the Contribution Date reflect our financial position and performance as a stand-alone entity.

All of the assets, liabilities and results of operations of the Company as of and for the periods prior to the Contribution Date were identified based on the assets contributed to the Company from Chromocell Holdings. Management believes the assumptions underlying the Company's carve-out financial statements are reasonable. Nevertheless, the financial statements may not include all of the actual expenses that would have been incurred had the Company operated as a standalone company during the periods presented, and may not reflect the Company's results of operations, financial position and cash flows had the Company operated as a standalone company during the periods presented. Actual costs that would have been incurred if the Company had operated as a standalone company would depend on multiple factors, including organizational structure and strategic decisions made in various areas, including information technology and infrastructure.

On August 2, 2023, we entered into a Side Letter to the Contribution Agreement with Chromocell Holdings (the "Holdings Side Letter"). Pursuant to the Holdings Side Letter, upon closing of the IPO: (a) Chromocell Holdings will re-assume all $1.6 million in direct liabilities previously assumed by the Company in accordance with the Contribution Agreement, (b) Chromocell Holdings will waive the Company's obligations to make a cash payment in the amount of $0.6 million to Chromocell Holdings, and (c) in consideration thereof, the Company will issue to Chromocell Holdings 2,600 shares of Series C Convertible Redeemable Preferred Stock of the Company, par value of $0.0001 per share (the "Series C Preferred Stock").

In connection with the completion of the IPO: (A) we have effected a 1-for-9 reverse stock split (the "Reverse Stock Split"), (B) all 600,000 issued and outstanding shares of our Series A Preferred Stock will automatically convert into 499,429 shares of Common Stock, (C) $389,757 and accrued interest of approximately $28,336 as of February 21, 2024 outstanding under our senior secured convertible notes issued in the April Bridge Financing (as defined below) after giving effect to the Representative Affiliate Transactions (as defined below), will automatically convert into approximately 87,109 shares of Common Stock, (D) $197,421 and accrued interest of $8,169 as of February 21, 2024 outstanding under our senior secured convertible notes issued in the September Bridge Financing (as defined below) after giving effect to the Representative Affiliate Transactions, will automatically convert into approximately 43,385 shares of Common Stock, which includes an additional 549 shares of Common Stock issuable as consideration for the September Bridge Financing (the "Bonus Shares"), (E) we will issue 37,500 shares of Common Stock to an investor as consideration for its previous agreement to provide funding that is no longer necessary in connection with the IPO, (F) we will effect the Representative Affiliate Transactions, (G) we will effect the transactions contemplated by the Holdings Side Letter, and issue an aggregate of 2,600 shares of Series C Preferred Stock to Chromocell Holdings pursuant thereto, and (H) we will issue (i) 93,823 shares to a lender holding a promissory note in the aggregate principal amount of $450,000 and accrued interest of approximately $113,243 (the "Investor Note") and (ii) 29,167 shares to one of our directors holding a promissory note in the aggregate principal amount of $175,000 (the "Director Note") in full satisfaction of our obligations thereunder (in the case of (A) through (D) and (H) above, based on the initial public offering price of $6.00 per IPO Share). We refer to these actions as the "IPO Transactions." In this prospectus, we include certain metrics on an "as adjusted" basis to give effect to the IPO Transactions.

PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus. It may not contain all the information that may be important to you. You should read the entire prospectus carefully, including the section entitled "Risk Factors" and our financial statements and the related notes included elsewhere in this prospectus before making an investment decision to purchase our securities.

In this prospectus, unless we indicate otherwise or the context requires, references to the "Company," "Chromocell," "we," "our," "ours," and "us" refer to Chromocell Therapeutics Corporation. The following summary is qualified in its entirety by the more detailed information and financial statements and notes thereto included elsewhere in this prospectus.

Our Business

Overview

We are a clinical-stage biotech company focused on developing and commercializing new therapeutics to alleviate pain. Our clinical focus is to selectively target the sodium ion-channel known as "NaV1.7", as well as other receptors in the NaV family. NaV1.7 has been genetically validated as a pain receptor in human physiology. Genetic studies have shown that families with a certain inherited NaV1.7 modulation consistently show a pathology of not feeling pain. A NaV1.7 blocker is a chemical entity that modulates the structure of the sodium-channel in a way to prevent the transmission of pain perception to the central nervous system ("CNS"). Our goal is to develop a novel and proprietary class of NaV blockers that target the body's peripheral nervous system, initially for Erythromelalgia ("EM"), a rare condition that primarily affects the feet and, less commonly, the hands (extremities). It is characterized by intense, burning pain of affected extremities, severe redness (erythema), and increased skin temperature that may be episodic or almost continuous in nature.

According to Mordor Intelligence, the global pain management market was valued at approximately $67 billion in 2021, and it is expected to have revenues of $89 billion in 2027, with a compound annual growth rate ("CAGR") of 4.65% over the forecast period. Also, according to Mordor Intelligence, the United States has the largest market for pain management pharmaceuticals and Asia-Pacific is the region showing the strongest growth. North America holds the largest share in the pain management market, with the United States being the most significant contributor to its revenue. According to data published by the Centers for Disease Control and Prevention ("CDC"), in 2019, 20.4% of adults had chronic pain, and 7.4% of adults had chronic pain that had limited work and daily activities frequently. Additionally, according to the CDC, chronic pain increased with age, and the highest level was reported in patients aged 65 years and above. The prescription pain management market in the United States is still largely dominated by opioid analgesics. Opioid analgesics decrease the perception of pain by stimulating a range of opioid receptors that modulate pain signals. The most widely used opioid analgesics, including morphine, fentanyl and hydromorphone, act primarily through the activation of mu opioid receptors in the CNS. However, because of the wide distribution of mu opioid receptors throughout the brain, morphine and other mu opioid analgesics also trigger a characteristic pattern of adverse side effects, in particular severe abuse and addiction.

The global pain market reflects total revenues of drugs mitigating different types of pain, such as backpain, osteoarthritis, post-operative pain and various orphan diseases with pain symptoms. Our current research is focused on EM; correspondingly, our commercial efforts are targeting the potential for EM therapeutics within the overall pain market. According to studies quoted by The Erythromelalgia Association, estimates of the incidence rate for EM vary from 1.3 to 15 per 100,000 persons, reflecting a potential EM patient population up to 5,000 to 50,000 in the U.S. Our lead compound, CC8464, could possibly have applications in pain mitigation outside of EM, but neither biological nor clinical studies have provided sufficient data to enable meaningful predictions on the probability of an expanded range of indications.

CC8464 is designed to address both the underlying condition and mitigate the burning pain symptoms that EM patients experience by blocking the NaV1.7 sodium channel. Genetic studies presented in the Journal of Clinical Investigation have established a correlation between particular mutation in the NaV1.7 gene and the occurrence of EM. Based on the correlation between the mutations and frequency of EM occurrence, we believe CC8464 has the potential to address the underlying condition and mitigate the burning pain symptoms that patients experience. The chemical characteristics of CC8464 restrict its entry into the CNS and limit its effect to the NaV1.7 receptors in the peripheral nervous system, which consists of the nerves outside the brain and spinal cord. Activation of other receptors in the CNS can result in side effects, including addiction and other psychiatric disorders. Since CC8464 is designed to modulate pain signals without activation of receptors in the CNS, it is not expected to produce psychiatric side effects. Based on its characteristics, preclinical studies and the Phase 1 study we have completed to date, we believe that our lead compound CC8464, if approved, could become an attractive option for both patients and physicians as a treatment for moderate-to-severe pain in EM.

We observed certain incidents of rashes during the trial for which we developed a mitigation strategy that involves slower dose escalation, hospitalization and frequent physical examinations. We have developed a dose escalation study design and expect to launch patient procurement in early 2024 with expected first patient dosing in the third quarter of 2024. The dose escalation trial will enroll approximately 32 healthy volunteers who will receive CC8464 over a period of several weeks, with the dose escalation study expected to take approximately nine months. We anticipate that the slower dose escalation will decrease the likelihood of drug-related skin reactions. The primary endpoint of the dose escalation trail will be safety and tolerability of the slower dose titration; however, we will also be measuring blood concentrations of CC8464, which will allow us to better understand the pharmacokinetics of CC8464.

We are currently working on the development of the Phase 2a proof-of-concept plan and expect to launch the Phase 2a proof-of-concept study in 2024 to assess the potential efficacy of CC8464 in genetically validated EM patients. Though the Phase 2a proof-of-concept study design has not yet been completed, we expect to launch the study during the second half of 2025 and expect that the study will take approximately twelve months after it is initiated. We are anticipating dosing approximately 20 patients diagnosed with genetically validated EM. We will be using a cross-over design which has the advantage of increasing the study power while keeping the number of patients relatively low. Each patient will be exposed to both placebo and CC8464 during the two cross-over phases of the trial but neither the investigators nor the patients will know when they are receiving active drug or placebo. During each dosing period we will induce an EM flare. The primary endpoint will be the amount of pain experienced during the flare with secondary endpoints including other measurements like pain relief, time to onset of the flare and neuropathy scores. The final design may change based on feedback from the U.S. Food and Drug Administration ("FDA") or information learned during the dose escalation trial.

We are evaluating whether to conduct the dose escalation and proof-of-concept studies outside of the U.S. to take advantage of certain beneficial tax credits or lower costs. One example is Australia, which has a 43.5% tax credit for clinical expenses incurred in Australia. Data from clinical trials conducted in Australia is accepted by the FDA.

If approved, we believe that CC8464 could provide pain and symptom relief for EM patients. CC8464 is currently the only compound that we have advanced into clinical development.

In addition, there is scientific evidence that the NaV1.7 receptor is present on the cornea and may be a viable biological target for treating eye pain. Eye pain may occur with various conditions, including severe dry eye disease, trauma and surgery. Existing therapies for eye pain (such as steroids, topical non-steroidal anti-inflammatory agents, lubricants, local anaesthetics) are limited in their effectiveness and/or limited in the duration that they may be prescribed because of safety issues. We intend to explore the viability of developing CC8464 as a topical agent for the relief of eye pain. A potential advantage of this approach is that topical administration of CC8464 is unlikely to lead to any hypersensitivity or skin reactions, like what was noted with systemic administration of CC8464, because the systemic absorption from a topical administration would be extremely limited. We have commenced development of a topical ophthalmic formulation of CC8464 that would initially be utilized for toxicology and in vivo studies and then followed by a proof-of-concept trial in patients suffering from various conditions, including severe dry eye disease, trauma and surgery. We expect the trials for this ophthalmic formulation of CC8464 to start in the third quarter of 2024.

We may further expand our pipeline with other internal or external compounds in the future, but all other internally discovered compounds are pre-clinical and no commercial discussions about in-licensing have been initiated to date, other than as disclosed herein with respect to the licensing of the Diclofenac Spray Formulation,

Rizatriptan Spray Formulation and Ondansetron Spray Formulation (collectively, as defined below, the “Spray Formulations”).

Recent Developments

Side Letter Terminating Series B Convertible Preferred Stock Purchase Agreement

On October 11, 2023, we entered into a securities purchase agreement with an institutional investor (the "Standby Investor"), pursuant to which (i) the Standby Investor agreed to purchase, upon close of the IPO and at our election, an aggregate of up to 750 shares of Series B Convertible Preferred Stock, par value of $0.0001 per share (the "Series B Preferred Stock") for a purchase price of $1,000 per share, and (ii) in consideration therefor, we would issue upon close of the IPO, and regardless of whether we would have issued any shares of Series B Preferred Stock, an aggregate of 37,500 shares (such shares, the "Standby Shares") of Common Stock to the Standby Investor (such agreement, the "Series B Securities Purchase Agreement"). In addition, pursuant to the Series B Securities Purchase Agreement, we were required to file a registration statement within 180 calendar days after consummation of the IPO, providing for the resale of the Standby Shares and shares of Common Stock issuable upon conversion of the Series B Preferred Stock, if issued.

Effective November 13, 2023, we entered into a side letter with the Standby Investor (the "Standby Investor Side Letter"), pursuant to which we (i) waived in full the Standby Investor's obligation to fund the aggregate amount to be paid for the Series B Preferred Stock to be purchased under the Series B Securities Purchase Agreement and (ii) agreed to continue to have the obligation to issue the full amount of the Standby Shares upon the closing of the IPO. We and the Standby Investor also agreed to terminate each of our obligations solely with respect to the Series B Preferred Stock under the Series B Securities Purchase Agreement and that certain Registration Rights Agreement between us and the Standby Investor, which was required to be delivered pursuant to the Series B Securities Purchase Agreement. For more information regarding the Series B Securities Purchase Agreement and the Standby Investor Side Letter, please refer to "Management's Discussion and Analysis of Financial Condition and Results of Operations".

Investor Note Side Letters

Effective October 10, 2023, we entered into a side letter (the "October Investor Note Side Letter" and, collectively, with the June Investor Note Side Letter, the August Investor Note Side Letter, the November Investor Note Side Letter and January Investor Note Side Letter (each, as defined herein), the "Investor Note Side Letters") with the holder of the Investor Note (the "Holder of the Investor Note"), pursuant to which we (i) amended and restated the Investor Note to extend the maturity date to November 14, 2023 and (ii) in consideration therefor, issued to such Holder of the Investor Note 30,000 shares of Common Stock (3,334 shares, after giving effect to the Reverse Stock Split). The Investor Note provides for the accrual of interest equal to 2% of the face amount of $450,000 per month ($9,000 per month). In addition, pursuant to the October Investor Note Side Letter, we agreed to register the 30,000 shares of Common Stock (3,334 shares after giving effect to the Reverse Stock Split), for resale, subject to the terms of the lock-up agreement that the holder of the Investor Note entered into with the underwriters.

Effective November 13, 2023, we entered into a side letter with the Holder of the Investor Note (the "November Investor Note Side Letter", pursuant to which we (i) amended and restated the Investor Note to extend the maturity date to January 31, 2024, and (ii) in consideration therefor, agreed to issue to such Holder of the Investor Note 30,000 shares of Common Stock (3,334 shares, after giving effect to the Reverse Stock Split) on each of November 29, 2023, December 29, 2023 and January 29, 2024 (collectively, the "November Leak-Out Shares"), provided the Investor Note remained outstanding as of such date. In addition, pursuant to the November Investor Note Side Letter, we agreed to register the November Leak-Out Shares for resale.

Effective January 30, 2024, we entered into a side letter with the Holder of the Investor Note (the "January Investor Note Side Letter"), pursuant to which we (i) amended and restated the Investor Note to extend the maturity date to February 29, 2024, and (ii) in consideration therefor, agreed to issue to such Holder of the Investor Note 700,000 shares of Common Stock (77,778 shares, after giving effect to the Reverse Stock Split) on the earlier to occur of the IPO or February 29, 2024 (the "January Leak-Out Shares" and, together with the November Leak-Out Shares, the "Leak-Out Shares"). In addition, pursuant to the January Investor Note Side Letter, we agreed to register the January Leak-Out Shares for resale.

Pursuant to the Investor Note Side Letters, we have issued to the Holder of the Investor Note an aggregate of 80,000 shares of Common Stock (8,889 shares, after giving effect to the Reverse Stock Split) prior to September 30, 2023 and an aggregate of 820,000 shares of Common Stock (91,111 shares, after giving effect to the Reverse Stock Split) subsequent to September 30, 2023, all of which are subject to the terms of the lock-up agreement that the Holder of the Investor Note entered into with the underwriters. For more information regarding the Investor Note Side Letters, please refer to "Management's Discussion and Analysis of Financial Condition and Results of Operations".

October Promissory Notes

On October 12, 2023, we and four existing investors entered into promissory notes (the "October Promissory Notes") with an aggregate face amount of $210,000 and an aggregate purchase price of $175,000. The October Promissory Notes mature on November 12, 2023 or, if earlier to occur, upon the closing of this IPO. The October Promissory Notes bear no interest except in the case of certain events of default. On November 7, 2023, we amended and restated the October Promissory Notes to extend the maturity dates of the October Promissory Notes to November 17, 2023. On November 13, 2023, we amended and restated the October Promissory Notes to further extend the maturity dates of the October Promissory Notes to February 29, 2024. For more information regarding the October Promissory Notes, please refer to "Management's Discussion and Analysis of Financial Condition and Results of Operations".

April Promissory Notes

On April 17, 2023, we entered into a bridge loan for working capital purposes, with various accredited investors, all of whom are pre-existing stockholders, in the aggregate principal amount of $389,757 (the "April Bridge Financing"), after giving effect to the Representative Affiliate Transactions. We received an aggregate of $166,903 in advances (the "Advances") prior to the close of the Bridge Financing from certain of the participating investors. The April Bridge Financing consists of senior secured convertible notes that had a maturity date of October 17, 2023. Such notes accrue interest on the unpaid principal amount at a rate of eight percent (8%) per annum and will automatically convert into 87,109 shares of Common Stock at the initial public offering of shares of Common Stock at a twenty percent (20%) discount to the price per IPO Share (based on the initial public offering price of $6.00 per IPO Share). On October 12, 2023, we entered into a first amendment to the senior secured convertible notes in the April Bridge Financing, which extended the maturity of the notes to November 1, 2023. On October 24, 2023, we entered into a second amendment to the senior secured convertible notes in the April Bridge Financing, which extended the maturity of the notes to November 14, 2023. On November 13, 2023, we entered into a third amendment to the senior secured convertible notes in the April Bridge Financing, which further extended the maturity of the notes to February 29, 2024. For more information regarding the April Promissory Notes, please refer to "Management's Discussion and Analysis of Financial Condition and Results of Operations".

Rights Offering

On November 22, 2023, we commenced a rights offering (the "Rights Offering") pursuant to which we distributed non-transferable subscription rights ("Subscription Rights") to each holder of our Common Stock held as of 5:00 p.m. Eastern Standard Time on November 22, 2023, the record date for the Rights Offering (the "Rights Offering Record Date"). The Subscription Rights could be exercised at any time during the subscription period, which commenced on November 22, 2023 and expired at 5:00 p.m., Eastern Standard Time, on December 1, 2023. Each Subscription Right entitled the eligible holder to purchase up to three shares of our Common Stock at a price per whole share of Common Stock of $0.0112 (the "Subscription Price"). Holders who fully exercised their rights could also subscribe for additional shares of Common Stock not subscribed for by other holders on a pro rata basis. In addition, we could distribute to one or more additional persons, at no charge to such person, additional non-transferable subscription rights to purchase shares of our Common Stock in the Rights Offering at the same Subscription Price, without notice to the holders of our Common Stock. Upon the closing of the Rights Offering, we issued an aggregate of 21,982,216 shares of our Common Stock (2,442,468 shares, after giving effect to the Reverse Stock Split) and received aggregate net proceeds of $246,201, after giving effect to the Representative Affiliate Transactions, which we intend to use

primarily for general corporate purposes and expenses associated with our initial public offering. For more information regarding the Rights Offering, please refer to "Management's Discussion and Analysis of Financial Condition and Results of Operations".

Benuvia License Agreement

On December 23, 2023, we entered into an exclusive licensing agreement (the "Benuvia License Agreement") with Benuvia Operations, LLC ("Benuvia") for a sublingual formulation of a Diclofenac spray for the treatment of acute pain (the "Diclofenac Spray Formulation"), a Rizatriptan sublingual spray formulation (the "Rizatriptan Spray Formulation") and an Ondansetron sublingual spray formulation (the "Ondansetron Spray Formulation"), diversifying our pipeline of non-opioid pain treatment therapies, while adding therapeutic options for related conditions. The Diclofenac Spray Formulation is patented and has started clinical development in human volunteers. Preliminary pharmacokinetics suggest that this formulation may have a faster onset of action than oral Diclofenac tablets. Diclofenac is a non-steroidal anti-inflammatory drug (an "NSAID") that is also marketed under additional brand names including Voltaren and Cataflam in its pill form. Rizatriptan, whose brand name is Maxalt, is used for the acute treatment of Migraines as a pill. By a number of clinical measures, it is thought to be superior to Sumatriptan. A sublingual formulation of Rizatriptan may potentially have a faster onset of action than an oral form and may be easier to tolerate than swallowing a pill when patients are experiencing nausea as a result of the migraine headache. Ondansetron is an anti-emetic that is available in oral and intravenous form. An Ondansetron sublingual spray formulation may potentially have a faster onset of action than an oral form and may be easier to tolerate than swallowing a pill when patients are experiencing nausea. Under the terms of the Benuvia License Agreement, Benuvia will be responsible for the manufacturing and supply of the Spray Formulations, but we will have exclusive, worldwide rights to develop, commercialize and distribute the Spray Formulations.

In connection with the Benuvia License Agreement, we agreed to pay Benuvia a six and one-half percent (6.5%) royalty on net sales of the Spray Formulations for a period of up to 15 years from the date of the first commercial sale of the Spray Formulations. In addition, on December 23, 2023, we entered into a stock issuance agreement with Benuvia (the "Benuvia Stock Issuance Agreement"), pursuant to which we issued to Benuvia 3,458,033 shares (384,226 shares, after giving effect to the Reverse Stock Split) of our Common Stock, which may be offered and sold pursuant to the Resale Prospectus.

While we currently do not have strategy and development plans for the Spray Formulations licensed from Benuvia, beginning in the third quarter of 2024, we plan to develop clinical programs for each of the Spray Formulations, determine the labelling strategy that would be obtained from completion of these programs and discuss with the FDA the requirements for bringing each of the Spray Formulations to market. We anticipate bringing the Spray Formulations to market through the FDA 505(b)(2) regulatory pathway for new drug applications; however, the exact details will require further consultation with the FDA. For more information regarding the Benuvia License Agreement and the Benuvia Stock Issuance Agreement, please refer to "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business—Benuvia Spray Formulations".

Amendment to Director Note

On December 28, 2023, we entered into an amendment to the Director Note, which extended the maturity date to February 29, 2024. For more information regarding the Director Note, please refer to "Management's Discussion and Analysis of Financial Condition and Results of Operations".

Equity Line of Credit

We are negotiating an arrangement with the Holder of the Investor Note to enter into an Equity Line of Credit (the "ELOC") subsequent to the IPO, pursuant to which we will have the right, but not the obligation, to sell to the Holder of the Investor Note up to $20,000,000 in newly issued shares of our Common Stock, subject to certain limitations. Pursuant to the terms of the proposed arrangement, we will pay the Holder of the Investor Note a commitment fee of $1,000,000, which may be paid at our election, in cash or shares of Common Stock, upon entry into the ELOC. In addition, we will agree to certain registration rights pursuant to which we will register the securities issuable under the ELOC subsequent to the expiration of the lock-up agreement we enter into with the Representative in connection with the IPO. We also intend to agree, during the proposed two-year term of the ELOC, to not enter into any variable, reset, or otherwise adjustable equity or equity-linked transactions. In the event we do not close the ELOC within forty-five (45) days of the consummation of this IPO and have the registration statement referred to above effective within ninety (90) days of the expiration of any IPO standstill period, we expect to be obligated to pay to the holder a break-up fee in the amount of $1,000,000 and will not be able to raise capital for sixty (60) days thereafter; provided that, we and the Holder of the Investor Note may agree to enter into other form of investments, such as a private investment in public equity transaction.

We anticipate that we will enter into a purchase agreement to issue the shares of Common Stock issuable pursuant to the ELOC subsequent to the closing of the IPO; however, as of the date hereof, an agreement with respect to our proposed ELOC has not been, and may never be, finalized and executed and there is no assurance that we will enter into an ELOC or, if we do enter into such an ELOC, that the terms thereof will be consistent with or as favorable as those described above. For more information regarding the ELOC, please refer to "Management's Discussion and Analysis of Financial Condition and Results of Operations".

Bridge Financing Note Amendments and Recission Agreement

On February 8, 2024, we and certain affiliates of the Representative entered into amendments to the senior secured convertible notes issued to such affiliates of the Representative in the April Bridge Financing and September Bridge Financing to remove the automatic conversion features from such notes (the "Bridge Financing Note Amendments"). Under the Bridge Financing Note Amendments, both notes issued in the April Bridge Financing and the September Bridge Financing have a maturity date of March 1, 2024, and the full principal amount of both notes and any accrued interest thereon shall be payable solely in cash upon the consummation of this IPO. Both notes have an annual interest rate of eight percent (8%), which accrues daily, and is calculated on the basis of a 360-day year (consisting of twelve 30 calendar day periods).

On February 10, 2024, we entered into a Stock Rescission Agreement with certain affiliates of the Representative (the "Stock Rescission Agreement" and, together with the Bridge Financing Note Amendments, the "Representative Affiliate Transactions"), pursuant to which we rescinded 111,129 shares of our Common Stock (after giving effect to the Reverse Stock Split) held by such affiliates of the Representative and agreed to refund an aggregate of $91,512.53 paid by such affiliates of the Representative in consideration therefor within 30 days of the effective date of the Stock Rescission Agreement.

For more information regarding the Representative Affiliate Transactions, including the Bridge Financing Note Amendments and the Rescission Agreement, please refer to "Underwriting".

Attorney's Letter

On February 14, 2024, our board of directors received a demand letter from an attorney representing Chromocell Holdings and our former Chief Executive Officer and former Chief Strategy Officer, Mr. Christian Kopfli, who was released for "cause" as disclosed elsewhere in this prospectus. Mr. Kopfli alleges an improper termination for "cause" and seeks monetary damages in connection therewith in the amount of $479,168.50. Of the $479,168.50 asserted by Mr. Kopfli, as of September 30, 2023, the Company has accrued $319,281 in compensation expenses associated with Mr. Kopfli's prior employment with the Company. To the extent Mr. Kopfli is successful in his assertions, we will pay any amounts owed thereunder from future working capital reserves; however, we believe the assertions made by Mr. Kopfli are without merit and intend to vigorously defend the matter.

Please refer to "Risk Factors—Risks Related to Our Business—We may be subject to litigation for a variety of claims, which could adversely affect our results of operations, harm our reputation or otherwise negatively impact our business".

Corporate Information

Chromocell Holdings, our predecessor, was founded in 2002 to commercialize "Chromovert Technology," a proprietary discovery technology with a potential broad range of applications in the biomedical field, including the potential capability to create complex targets (cell-lines) needed for effective high-throughput screening that is commonly used both in therapeutics and flavors discovery. Initially, Chromocell Holdings focused on applications in the food and flavors space.

In 2012, Chromocell Holdings started applying the technology in the therapeutics area. Chromocell Holdings focused its efforts on projects where it believed that the discovery of novel medications was largely held back by difficulties creating complex targets (cell lines) needed for effective high-throughput screening. The NaV1.7 ion-channel is a complex target with a well-established role in pain modulation and management believed it presented an opportunity to apply the technology in an area of unmet medical need. Upon creating the necessary NaV1.7 assays and conducting a large high-throughput campaign, Chromocell Holdings' research team discovered CC8464. After pre-clinical studies and assessments, an IND was filed and CC8464 was evaluated in a Phase 1 study with more than 100 subjects. In 2015, Chromocell Holdings signed an agreement with Astellas Pharma Inc. ("Astellas") for the joint development and commercialization of CC8464. Astellas terminated such agreement in 2018 and returned all rights, including all intellectual property rights on CC8464, to Chromocell Holding.

As both the flavors and the therapeutics businesses grew and increasingly required different expertise, capital and business concepts, Chromocell Holdings made the strategic decision to separate the two businesses.

Chromocell Therapeutics Corporation (the "Company," "we," "us" and "our") was incorporated in Delaware on March 19, 2021. Our principal executive offices are located at 4400 Route 9 South, Suite 1000, Freehold, NJ 07728, and our telephone number is (732) 514-2636. Our website is www.chromocell.com. Information contained on, or that can be accessed through, our website is not incorporated by reference into this prospectus, and you should not consider information on our website to be part of this prospectus.

Implications of Being an Emerging Growth Company

We qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). An emerging growth company may take advantage of relief from certain reporting requirements and other burdens that are otherwise applicable generally to public companies. These provisions include:

- reduced obligations with respect to financial data, including presenting only two years of audited financial statements and related management's discussion and analysis of financial condition and results of operations in this prospectus;
- an exception from compliance with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act");
- reduced disclosure about our executive compensation arrangements in our periodic reports, proxy statements and registration statements; and
- exemptions from the requirements of holding non-binding advisory votes on executive compensation or golden parachute arrangements.

We may take advantage of these provisions for up to five years or such earlier time that we no longer qualify as an emerging growth company. We would cease to be an emerging growth company upon the earliest of:

- the last day of the fiscal year on which we have $1.235 billion or more in annual revenue,

- the date on which we become a "large accelerated filer" (i.e., as of our fiscal year end, the total market value of our common equity securities held by non-affiliates is $700 million or more as of June 30),

- the date on which we issue more than $1.0 billion of non-convertible debt over a three-year period, or

- the last day of our fiscal year following the fifth anniversary of the date of the completion of the offering of IPO Shares pursuant to the IPO Prospectus.

We have elected to take advantage of certain of the reduced disclosure obligations regarding financial statements (such as not being required to provide audited financial statements for the fiscal year ended December 31, 2020) in this prospectus and executive compensation in this prospectus and expect to elect to take advantage of other reduced burdens in future filings.

In addition, under the JOBS Act, emerging growth companies can take advantage of an extended transition period and delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to use this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for private companies. If we were to subsequently elect instead to comply with public company effective dates, such election would be irrevocable pursuant to the JOBS Act.

Also, we are a "smaller reporting company" (and may continue to qualify as such even after we no longer qualify as an emerging growth company). For as long as we qualify as a "smaller reporting company," we may provide reduced disclosure in the public filings that we make with the SEC than larger public companies, such as the inclusion of only two years of audited financial statements and only two years of management's discussion and analysis of financial condition and results of operations disclosure.

As a result of qualifying as an emerging growth company and a smaller reporting company, to the extent we take advantage of the allowable reduced reporting burdens, the information that we provide to our stockholders may be different than what you might receive from other public reporting companies in which you hold equity interests.

Summary of Risks Associated with Our Business

Our business is subject to a number of risks that you should be aware of before making an investment decision to purchase our securities. You should carefully consider all of the information set forth in this prospectus and, in particular, should evaluate the specific factors set forth in the section titled "Risk Factors" in deciding whether to invest in our securities. Among these important risks are the following:

- there is substantial doubt about our ability to continue as a going concern.

- we have a limited operating history, have incurred losses since inception and expect to incur losses for the foreseeable future and may never achieve or maintain profitability;

- we have identified material weaknesses in our internal control over financial reporting arising from inadequate segregation of duties, ineffective information technology controls and lack of certain financial reporting and transaction processing controls;

- we will need to raise additional funding in order to receive approval for CC8464 or any other compounds that we may develop;

- we are early in our efforts to develop CC8464, which is the only compound that we have advanced into clinical development, and if we are unable to advance development through clinical trials, obtain regulatory approval in the United States or abroad and ultimately commercialize CC8464, or if we experience significant delays in doing so, our business will be materially harmed;

- there is no guarantee that the results from prior clinical and preclinical studies will be indicative of our ability to complete studies or the results to be obtained in the current or future studies and clinical trials;

- CC8464 may cause undesirable side effects or have other properties that could delay or prevent its regulatory approval, limit the commercial potential or result in significant negative consequences following any potential marketing approval;

- we plan to apply for orphan drug designation for CC8464; however, it may not effectively protect us from competition, and we may be unable to obtain similar designations for future lead compounds. Even if such designation is granted for CC8464 or if Breakthrough Therapy designation, and/or Fast Track designation is granted for CC8464, this may not lead to a faster development, regulatory review or approval process and may not increase the likelihood that any future lead compound will receive approval in the United States;

- we may expend our limited resources to pursue a compound or indication and fail to capitalize on different compounds or indications that may be more profitable or for which there is a greater likelihood of success, and we may not be successful in discovering, developing and commercializing additional compounds;

- we need to establish our market development capabilities to commercialize our products and failure to do so may result in an inability to generate any revenue. Our revenue depends on what we can charge for our product, and government pricing controls and regulations, along with insurance coverage and reimbursement approval, could decrease our ability to generate revenue;

- we face significant competition and our competitors may achieve regulatory approval before us or develop therapies that are more advanced or effective than ours, which may adversely affect our financial condition;

- we may face risks to our manufacturing process, including potential disruptions to supply chain and delays in obtaining regulatory approvals of the processes and facilities needed to manufacture future lead compounds, including CC8464. As we may need to utilize third parties to conduct our manufacturing, we could experience delays in our development and commercialization efforts;

- if we are unable to manage expected growth in the scale and complexity of our operations, our performance may suffer;

- we face risks regarding our ability to retain key employees and scientific advisors, and to attract, retain and motivate qualified personnel;

- we are subject to a range of laws and regulations, including federal and state healthcare fraud and abuse laws, false claims laws, health information and privacy and security laws, and environmental, health, and safety laws. Failure to comply with these laws and associated regulations could result in substantial penalties and liabilities;

- an outbreak of an infectious disease, including COVID-19, or other unfavorable global economic conditions may materially and adversely affect our business and our financial results and could cause a disruption to the development of future compounds;

- we carry risks related to our intellectual property. If we are unable to obtain and maintain adequate U.S. and foreign patent protection for our compounds, if we face litigation or administrative proceedings by a third-party over our patents, if there is a change in U.S. or foreign patent law or interpretation thereof diminishing the value of our patents, or if we are unable to protect the confidentiality of our trade secrets, our business may be materially harmed;

- we carry risks related to third party intellectual property. If a third-party institutes patent litigation against us in the U.S. or a foreign jurisdiction asserting that CC8464 and/or additional lead compounds infringe its patent rights the outcome of which would be uncertain and could have a material adverse effect on the success of our business;

- failure to maintain the listing of our Common Stock on the NYSE American LLC ("NYSE American") could materially adversely affect the value of our Common Stock;

- we cannot assure you that we will be able to continue to comply with NYSE American's listing standards. Further, potential investors may not have an opportunity to check the actual post-split market price of our Common Stock prior to confirming their purchases in the IPO;
- The Series C Preferred Stock to be issued upon close of the IPO will have a liquidation preference over our Common Stock, which could result in holders of our Common Stock not receiving any proceeds in the event of our liquidation;
- the price of our securities may be volatile and fluctuate substantially, which could result in substantial losses for purchasers;
- we will incur increased costs as a result of operating as a smaller reporting public company, and our management will be required to devote substantial time to new compliance efforts;
- there is no current public market for our Common Stock;
- there is no assurance that we will enter into our proposed ELOC or that the terms thereof will be consistent with or as favorable as those described in this registration statement of which this prospectus forms a part;
- the issuance of our Common Stock under our proposed ELOC may cause substantial dilution to our existing stockholders and the price of our Common Stock to decline;
- we may not have access to the full amount available under our proposed ELOC; and
- the other factors set forth under "Risk Factors."

These and other risks are more fully described in the section entitled "Risk Factors" in this prospectus. If any of these risks actually occurs, our business, financial condition, results of operations, cash flows, and prospects could be materially and adversely affected. As a result, you could lose all or part of your investment in our securities.

THE OFFERING	
Shares of Common Stock offered by the Selling Stockholders	2,969,823 Selling Stockholder Shares.
Use of proceeds	We will not receive any proceeds from the sale of the Selling Stockholder Shares by the Selling Stockholders pursuant to the Resale Prospectus. See “Use of Proceeds.”

Risk factors	See "Risk Factors" and other information included in this prospectus for a discussion of factors you should consider carefully before deciding to invest in our securities.
Transfer agent and registrar	Our transfer agent and registrar for our Common Stock is Nevada Agency and Transfer Company, located at 50 W. Liberty Street, Suite 880, Reno, NV 89501.
Proposed NYSE American symbol	We have applied to list our Common Stock on NYSE American under the symbol "CHRO".

Unless we specifically state otherwise or the context otherwise requires, the share information in this prospectus is based on 3,876,285 shares of Common Stock outstanding as of February 21, 2024 (after giving effect to the Reverse Stock Split) and:

- gives effect to the IPO Transactions, which include, among other items: (i) a 1-for-9 Reverse Stock Split, (ii) the issuance of 499,429 shares of Common Stock upon conversion of all issued and outstanding shares of Series A Preferred Stock, (iii) the issuance of 130,494 shares of Common Stock upon conversion of the senior secured convertible notes issued in connection with the Bridge Financings (as defined below), which includes an additional 549 Bonus Shares and includes interests calculated to and through February 21, 2024, (iv) the issuance of 37,500 shares of Common Stock to the Standby Investor, (v) the Representative Affiliate Transactions, (vi) the close of the transactions contemplated by the Holdings Side Letter, and the issuance of an aggregate of 2,600 shares of Series C Preferred Stock to Chromocell Holdings pursuant thereto, and (vii) the issuances of (x) 93,823 shares to the holder of the Investor Note and (y) 29,167 shares to the holder of the Director Note in full satisfaction of our obligations thereunder (in the case of each of (i) through (iii) and (vii) above, based on the initial public offering price of $6.00 per IPO Share, and in the case of each of (ii) through (v) and (vii) above, after giving effect to the Reverse Stock Split);
- gives effect to the issuance of 1,100,000 IPO Shares in the IPO;
- assumes issuance of the Leak-Out Shares issuable on February 29, 2024 pursuant to the January Investor Note Side Letter;
- assumes no exercise of the underwriters' option to purchase additional IPO Shares from us in the IPO;
- assumes no exercise of the warrants issuable to the representative of the underwriters at the closing the of IPO;
- assumes no conversion of the Series C Preferred Stock to be issued at the close of the IPO; and
- does not reflect 444,444 shares of Common Stock that are reserved for future grants or sale under our omnibus equity incentive plan, as amended, which amount includes 208,667 shares underlying currently outstanding stock options with a weighted average exercise price of $22.68 (all after giving effect to the Reverse Stock Split).

SUMMARY HISTORICAL FINANCIAL DATA

The following tables summarize our financial data as of and for the periods indicated. The balance sheet data as of December 31, 2022, and the statements of operations data for the years ended December 31, 2022 and 2021, are derived from the audited financial statements included elsewhere in this prospectus. The balance sheet data as of September 30, 2023, and the statements of operations data for the nine months ended September 30, 2023 and 2022, are derived from the unaudited interim financial statements included elsewhere in this prospectus. These historical results have been prepared on a carve-out basis and are not necessarily indicative of results that may be expected in the future. Please see "Basis of Presentation" in the forepart of this prospectus for more information.

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

Statements of Operations Data:	**For the Nine Months Ended September 30, 2023** (Unaudited)	**For the Nine Months Ended September 30, 2022** (Unaudited)	**For the Year Ended December 31, 2022** (Audited)	**For the Year Ended December 31, 2021** (Audited)
REVENUE				
Grant revenue	$ -	$ -	$ -	$ -
Total revenue	-	-	-	-
OPERATING EXPENSES				
General and administrative expenses	1,677,078	371,283	1,098,848	496,667
Research and development	285,204	97,147	391,730	209,047
Professional fees	1,021,187	634,913	827,581	133,282
Total operating expenses	2,983,469	1,103,343	2,318,159	838,996
NET LOSS FROM OPERATIONS	(2,983,469)	(1,103,343)	(2,318,159)	(838,996)
OTHER INCOME (EXPENSE)				
Interest expenses	(358,171)	(97,818)	(140,430)	(253)
Gain on forgiveness of PPP loan			-	243,862
Total other expense	(358,171)	(97,818)	(140,430)	243,609
Net loss before provision for income taxes	(3,341,640)	(1,201,161)	(2,458,589)	(595,387)
Provision for income taxes	-	-	-	-
NET LOSS	$ (3,341,640)	$ (1,201,161)	$ (2,458,589)	$ (595,387)
Pro forma net (loss) income per common share, basic and diluted[(1)]	$ (0.36)	$ (0.64)	$ (0.25)	$ (0.06)
Weighted-average shares used to compute pro forma net (loss) income per common share, basic and diluted[(1)]	9,286,928	1,868,132	10,000,000	10,000,000

Balance Sheet Data:	**September 30, 2023** (Unaudited)	**December 31, 2022** (Audited)
Total assets	$ 22,786	$ 55,074
Total liabilities	5,927,374	3,761,611
Stockholders' / parent's net deficit	(5,904,588)	(3,706,537)
Total liabilities and stockholders' / parent's net deficit	22,786	55,074

(1) Gives effect to (i) the transactions contemplated by the Contribution Agreement and (ii) the IPO Transactions, in each case, as if each had occurred on January 1, 2022.

RISK FACTORS

Investing in our securities involves a high degree of risk. You should carefully consider the following risks and all other information contained in this prospectus, including our financial statements and the related notes, before investing in our securities. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, also may become important factors that affect us. If any of the following risks occur, our business, financial condition, results of operations and prospects could be materially and adversely affected. In these circumstances, the market price of our Common Stock could decline, and you may lose all or part of your investment.

Risks Related to Our Business

The report of the independent registered public accounting firm on our 2022 and 2021 financial statements contains a going concern qualification.

The report of the independent registered public accounting firm covering our financial statements for the years ended December 31, 2022 and 2021 stated that certain factors, including that we have suffered recurring losses from operations and have an accumulated deficit at December 31, 2022, raised substantial doubt as to our ability to continue as a going concern. Because we are not yet producing sufficient revenue to sustain our operating costs, we are dependent upon raising capital to continue our business. If we are unable to raise capital, we may be unable to continue as a going concern.

We are a clinical stage biopharmaceutical company with a limited operating history.

The operations of our company, contributed to us by Chromocell Holdings, to date have been limited to financing and staffing our Company, developing and licensing compounds, conducting preclinical and clinical studies of CC8464 for EM and other pain indications. We have not yet demonstrated the ability to successfully complete a large-scale, pivotal clinical trial, obtain marketing approval, manufacture a commercial scale product, arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, predictions about our future success or viability may not be as accurate as they could be if we had a history of successfully developing and commercializing pharmaceutical products.

Accordingly, you should consider our prospects in light of the costs, uncertainties, delays and difficulties frequently encountered by companies in the early stages of development, especially early-stage clinical pharmaceutical companies such as ours. Potential investors should carefully consider the risks and uncertainties that a company with a limited operating history will face. In particular, potential investors should consider that we cannot assure you that we will be able to, among other things:

- successfully implement or execute our current business plan, and we cannot assure you that our business plan will lead to an approval or successful commercialization;
- successfully manufacture our clinical lead compound and establish commercial supply;
- successfully complete the clinical trials necessary to obtain regulatory approval for the marketing of our lead compound;
- secure market exclusivity and/or adequate intellectual property rights for our lead compound in each jurisdiction in which we do or plan to commercialize our lead compound or where our competitors are organized or may engage in competitive activity;
- attract and retain an experienced management and advisory team;
- secure acceptance of our lead compound in the medical community and with third-party payors and consumers;
- raise sufficient funds in the capital markets or otherwise to effectuate our business plan; and
- utilize the funds that we do have and/or raise in this offering or in the future to efficiently execute our business strategy.

If we cannot successfully execute any one of the foregoing, our business may fail and your investment will be adversely affected.

We have incurred net losses since inception. We expect to incur losses for the foreseeable future and may never achieve or maintain profitability.

There are numerous risks and uncertainties associated with pharmaceutical product and biological development, and we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability.

We have had net losses since inception, and we had an accumulated deficit of approximately $9.5 million and $6.1 million as of September 30, 2023 and December 31, 2022, respectively, which includes a net loss of approximately $3.3 million and $1.2 million for the nine months ended September 30, 2023 and 2022, and approximately $2.5 million and $0.6 million for the years ended December 31, 2022 and 2021, respectively. Overall, these conditions have raised substantial doubt regarding our ability to continue as a going concern beyond one year of the filing of our financial statements. Our ability to continue as a going concern is dependent upon the ability to complete clinical studies and implement our business plan, raise capital, generate sufficient revenues and to control operating expenses.

We have primarily financed our operations through a combination of a series of cash advances, equity raises, bridge and promissory note issuances, licensing arrangements and government grants. Our ability to achieve significant profitability depends on our ability to successfully complete the development of, and obtain the regulatory approvals necessary to commercialize, CC8464 and/or additional lead compounds. We expect that it will take several years, if ever, before we have a commercialized lead compound. The net losses we incur may fluctuate significantly from quarter to quarter.

If we are required by the FDA, the European Medicines Agency ("EMA"), or other international regulatory authorities to which we may be subject, to perform studies in addition to those currently expected, or if there are any delays in completing our clinical trials or the development of CC8464 and/or other lead compounds, our expenses could increase and revenue could be further delayed. We anticipate that our expenses will increase substantially if, and as, we:

- continue our research and the clinical development of CC8464;
- launch in vivo and toxicology studies of CC8464 for the treatment of eye pain;
- initiate additional clinical trials and preclinical studies for any additional lead compounds that we may pursue in the future;
- prepare a U.S. New Drug Application ("NDA") for filing with the FDA, a marketing authorization application, and approvals in certain other countries;
- oversee the manufacturing of material for clinical trials or potential commercial sales;
- develop a lead compound portfolio;
- establish a business development operation to in- our out-license certain assets;
- establish a sales, marketing and distribution infrastructure to commercialize any lead compound for which we may obtain marketing approval;
- develop, maintain, expand, protect and enforce our intellectual property rights portfolio; and/or
- acquire or in-license other compounds and technologies.

To become and remain profitable, we must develop and eventually commercialize one or more lead compounds with significant market potential. This will require us to be successful in a range of challenging activities, including completing the clinical trials, developing and validating commercial scale manufacturing processes, obtaining marketing approval for this lead compound, manufacturing, marketing. Licensing and selling any future lead compounds for which we may obtain marketing approval and satisfying any post-marketing requirements. If we were required to discontinue development of CC8464, if CC8464 does not receive regulatory approval, if we do not obtain our targeted indication(s) for CC8464, or if CC8464 fails to achieve sufficient market acceptance for any indication, we could be delayed by many years in our ability to achieve profitability. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in the value of our company also could cause you to lose all or part of your investment.

We have identified material weaknesses in our internal control over financial reporting.

Prior to our initial public offering, we were a private company and had limited accounting and financial reporting personnel and other resources with which to address our internal controls and related procedures. In connection with the audit and review, as applicable, of our financial statements for the years ended December 31, 2022 and 2021 and the nine months ended September 30, 2023 and 2022, we identified material weaknesses in our internal control over financial reporting. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. The material weaknesses in our case arose from inadequate segregation of duties, ineffective information technology controls and lack of certain financial reporting and transaction processing controls. If we are unable to remedy our material weaknesses, or if we generally fail to establish and maintain effective internal controls appropriate for a public company, we may be unable to produce timely and accurate financial statements, and we may conclude that our internal control over financial reporting is not effective, which could adversely impact our investors' confidence and our stock price.

We will need to raise additional funding to receive approval for CC8464 or any other lead compound. Such funding may not be available on acceptable terms, or at all. Failure to obtain this necessary capital when needed may force us to delay, limit, sell or terminate certain of our product development efforts or other operations.

To complete the process of obtaining regulatory approval for CC8464 and to build the sales, marketing, licensing and distribution infrastructure that we believe will be necessary to commercialize CC8464, if approved, we will require substantial additional funding. In addition, if we obtain marketing approval for CC8464, we expect to incur significant expenses related to product sales, medical affairs, marketing, manufacturing and distribution.

Our future capital requirements will depend on many factors, including:

- the progress, timing, results and costs of our phase 2a clinical trial for CC8464;
- the progress, timing and costs of manufacturing clinical trial for our planned pivotal clinical trials;
- the potential development and the filing on an IND application for other lead compounds;
- the initiation, scope, progress, timing, costs and results of drug discovery, laboratory testing, manufacturing, preclinical studies and clinical trials for any other lead compounds that we may pursue in the future, if any;
- the outcome, timing and costs of seeking regulatory approvals;
- the costs associated with the manufacturing process development and evaluation of third-party manufacturers;
- the costs of future activities, including product sales, medical affairs, marketing, manufacturing and distribution, in the event we receive marketing approval for CC8464 or any other lead compounds we may develop;
- the extent to which the costs of future lead compounds, if approved, will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or will be reimbursed by government authorities, private health coverage insurers and other third-party payors;
- the costs of commercialization activities for CC8464 and other future lead compounds if we receive marketing approval for CC8464 or any other lead compounds we may develop, including the costs and timing of establishing product sales, medical affairs, marketing, distribution and manufacturing capabilities;
- subject to receipt of marketing approval, if any, revenue received from commercial sale of CC8464 or any of our other lead compounds;
- the terms and timing of any future collaborations, licensing, consulting or other arrangements that we may establish;
- the amount and timing of any payments we may be required or decide to make, or that we may receive, in connection with the licensing, filing, prosecution, maintenance, and enforcement of any patents or other intellectual property rights and defense against third party intellectual property infringement claims, including milestone and royalty payments and patent prosecution fees that we are obligated to pay pursuant to our license agreements, if any;

- the development of alternative treatments for EM or other pain indications;
- our ability to establish and maintain collaborations and licenses on favorable terms, if at all; and
- the extent to which we acquire or in-license other compounds and technologies.

Identifying potential lead compounds and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. Our lead compounds, if approved, may not achieve commercial success. Our future lead compound's revenues, if any, will be derived from or based on sales of lead compounds that may not be commercially available for many years, if at all. Accordingly, it is unlikely that we will generate product or licensing revenue during the next twelve months and will need to continue to rely on additional financing to achieve our business objectives. Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize future lead compounds. Moreover, the terms of any financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our shares to decline. The sale of additional equity or convertible securities would dilute all our stockholders. The incurrence of indebtedness would result in increased fixed payment obligations and a portion of our operating cash flows, if any, being dedicated to the payment of principal and interest on such indebtedness, and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Furthermore, existing securityholders may not agree with our financing plans or the terms of such financings. Adequate additional financing may not be available to us on acceptable terms, or at all. The terms of additional financing may be impacted by, among other things, general market conditions, and the market's perception of future lead compounds. If adequate funds are not available, we may be required to curtail our operations or other business activities or obtain funds through arrangements with strategic partners or others that may require us to relinquish rights to certain technologies or potential markets.

We may be subject to litigation for a variety of claims, which could adversely affect our results of operations, harm our reputation or otherwise negatively impact our business.

We may be subject to litigation for a variety of claims arising from our normal business activities. These may include claims, suits, and proceedings involving labor and employment, wage and hour, commercial and other matters. The outcome of any litigation, regardless of its merits, is inherently uncertain. Any claims and lawsuits, and the disposition of such claims and lawsuits, could be time-consuming and expensive to resolve, divert management attention and resources, and lead to attempts on the part of other parties to pursue similar claims. Any adverse determination related to litigation could adversely affect our results of operations, harm our reputation or otherwise negatively impact our business. In addition, depending on the nature and timing of any such dispute, a resolution of a legal matter could materially affect our future operating results, our cash flows or both.

Risks Related to Development, Clinical Testing, and Regulatory Approval

We are early in our efforts to develop CC8464, which is the only compound that we have advanced into clinical development. If we are unable to advance CC8464 through clinical trials, obtain regulatory approval and ultimately commercialize CC8464, or if we experience significant delays in doing so, our business will be materially harmed.

We are early in our development of CC8464. The development and commercialization of CC8464 (or any other compound that we may advance towards clinical development in the future) is subject to many uncertainties, including the following:

- successful enrollment and completion of the two studies we are planning to conduct in the next phase of our clinical trials (Phase 2);
- positive results from our current and planned future clinical trials;
- receipt of regulatory approvals from applicable regulatory authorities;
- successful development of our internal manufacturing processes on an ongoing basis and maintenance of our potential future arrangements with third-party manufacturers for clinical supply;
- commercial launch of CC8464, if and when approved, whether alone or in collaboration with others; and
- acceptance of CC8464, if and when approved, by patients, the medical community and third-party payors.

If we fail in one or more of these factors, we could experience significant delays or an inability to successfully commercialize CC8464, which would materially harm our business. If we do not receive regulatory approvals for CC8464, our business, financial condition, results of operations and prospects could be materially and adversely affected. Advancing a different compound than CC8464 towards clinical development would take substantial time and resources and be subject to the same risks as described here for CC8464.

Our lead compound, CC8464, is in early-stage development, and there is no guarantee that the results from prior clinical and preclinical studies will be indicative of our ability to complete or the results to be obtained in the current or future studies and clinical trials. CC8464 is our only compound in clinical development and advancing a different compound would require substantial time and resources as well as being subject to the same risks and uncertainties as described here for CC8464.

There is no guarantee that results of our potential future clinical trials will be positive or that we will be able to complete this or any potential future clinical trials on the anticipated timelines or at all. Furthermore, research and discoveries by us or others may identify serious adverse events, undesirable side effects or other unexpected properties of our current and future lead compounds, including CC8464, that could delay, prevent or cause the withdrawal of regulatory approval, limit the commercial potential, or result in significant negative consequences following marketing approval.

The regulatory authorities may not complete their review processes in a timely manner, or we may not be able to obtain regulatory approval. Additional delays may result if an FDA Advisory Committee or other regulatory authority recommends non-approval or restrictions on approval. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory authority policy during the period of product development, clinical trials and the review process.

Regulatory authorities also may approve a future lead compound for more limited indications than requested or they may impose significant limitations in the form of narrow indications, warnings or post-approval safety monitoring program. These regulatory authorities may require precautions or contra-indications with respect to conditions of use or they may grant approval subject to the performance of costly post-marketing clinical trials. In addition, regulatory authorities may not approve the labeling claims that are necessary or desirable for the successful commercialization of CC8464. Any of the foregoing scenarios could materially harm the commercial prospects for CC8464 and materially and adversely affect our business, financial condition, results of operations and prospects.

We may encounter substantial delays in our clinical trials, or we may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities.

Before obtaining marketing approval from regulatory authorities for the sale of our drug candidates, CC8464 included, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the drug candidate for its intended indications. Clinical trials are expensive, time consuming and uncertain as to outcome. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. A failure of one or more clinical trials can occur at any stage of testing. As CC8464 is our only compound in clinical development, any setback may have a significant negative effect on our business. Events that may prevent successful or timely completion of clinical development include:

- delays in reaching a consensus with regulatory authorities on trial design;
- delays in opening sites and recruiting suitable patients to participate in our clinical trials;
- imposition of a clinical hold by regulatory authorities as a result of a serious adverse event or concerns with a class of drug candidates, or after an inspection of our clinical trial operations or trial sites;
- delays in having patients complete participation in a trial or return for post-treatment follow-up;
- occurrence of serious adverse events associated with the drug candidate that are viewed to outweigh its potential benefits; or
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols.

In addition, if we had to make manufacturing or formulation changes to CC8464, we would need to conduct additional studies to bridge our modified lead compound to earlier versions. Clinical trial delays could also shorten any periods during which we may have the exclusive right to commercialize CC8464 or allow our competitors to bring products to market before we do, which could limit our potential revenue or impair our ability to successfully commercialize CC8464and may harm our business, financial condition, results of operations and prospects. Any delays, setbacks or failures in our clinical trials could materially and adversely affect our business, financial condition, results of operations and prospects.

Additionally, if the results of our clinical trials are inconclusive or if there are safety concerns or serious adverse events associated with our drug candidates, we may:

- be delayed in obtaining marketing approval, if at all, or be required to conduct additional confirmatory safety and/or efficacy studies causing additional expenses;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be subject to additional post-marketing testing requirements;
- be required to perform additional clinical trials to support approval or be subject to additional post-marketing testing requirements;
- have regulatory authorities withdraw, or suspend, their approval of the drug or impose restrictions on its distribution;
- be subject to the addition of labeling statements, such as warnings or contraindications;
- be sued; or
- experience damage to our reputation.

As CC8464 is our only compound in clinical development, any setback may have a significant negative effect on our business.

Our drug development costs will increase if we experience delays in testing or obtaining marketing approvals. We do not know whether any of our preclinical studies or clinical trials will begin as planned, need to be restructured or be completed on schedule, if at all.

We, the FDA or an Institutional Review Board may suspend our clinical trials at any time if it appears that we or our collaborators are failing to conduct a trial in accordance with regulatory requirements, including the FDA's current Good Clinical Practice ("GCP"), regulations, that we are exposing participants to unacceptable health risks, or if the FDA finds deficiencies in our IND applications or the conduct of these trials. Therefore, we cannot predict with any certainty the schedule for commencement and completion of future clinical trials. If we experience delays in the commencement or completion of our clinical trials, or if we terminate a clinical trial prior to completion, the commercial prospects of our drug candidates could be negatively impacted, and our ability to generate revenues from our drug candidates may be delayed. As CC8464 is our only compound in clinical development, any setback may have a significant negative effect on our business.

Even if we complete the necessary clinical trials, we cannot predict when, or if, we will obtain regulatory approval to commercialize CC8464 and the approval may be for a narrower indication than we seek.

We cannot commercialize a lead compound until the appropriate regulatory authorities have reviewed and approved the lead compound. Even if CC8464 meets its safety and efficacy endpoints in clinical trials, the regulatory authorities may not complete their review processes in a timely manner, or we may not be able to obtain regulatory approval. Additional delays may result if an FDA Advisory Committee or other regulatory authority recommends non-approval or restrictions on approval. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory authority policy during the period of product development, clinical trials and the review process.

Regulatory authorities also may approve a lead compound for more limited indications than requested or they may impose significant limitations in the form of narrow indications, warnings or a post-approval safety monitoring program. These regulatory authorities may require precautions or contra-indications with respect to conditions of use or they may grant approval subject to the performance of costly post-marketing clinical trials. In addition, regulatory authorities may not approve the labeling claims that are necessary or desirable for the successful commercialization of CC8464. Any of the foregoing scenarios could materially harm the commercial prospects for CC8464 and materially and adversely affect our business, financial condition, results of operations and prospects as CC8464 is our only compound in clinical development.

CC8464 may cause undesirable side effects or have other properties that could delay or prevent its regulatory approval, limit the commercial potential or result in significant negative consequences following any potential marketing approval.

Our Phase 1 clinical trials have shown that CC8464 can lead to rashes. In addition to this side effect and possibly others caused by the lead compound, the administration process or related procedures also can cause adverse side effects. If any such adverse events occur, our clinical trials could be suspended or terminated. If in the future we are unable to demonstrate that such adverse events were caused by the administration process or related procedures, the FDA, the European Commission, the EMA or other regulatory authorities could order us to cease further development of, or deny approval of, CC8464 for any or all targeted indications. Even if we can demonstrate that any serious adverse events are not product- related, such occurrences could affect patient recruitment or the ability of enrolled patients to complete the trial. Moreover, if we elect, or are required, to delay, suspend or terminate any clinical trial of CC8464, the commercial prospects of such lead compound may be harmed and our ability to generate revenues from this lead compound may be delayed or eliminated. Any of these occurrences may harm our ability to develop other product candidates, and may harm our business, financial condition and prospects significantly. As CC8464 is our only compound in clinical development, any setback may have a significant negative effect on our business.

Additionally, if CC8464 receives marketing approval, the FDA could require us to adopt a post-approval safety monitoring program to ensure that the benefits outweigh its risks, which may include, among other things, a medication guide outlining the risks of the product for distribution to patients and a communication plan to health care practitioners. Furthermore, if we or others later identify undesirable side effects caused by CC8464, several potentially significant negative consequences could result, including:

- regulatory authorities may suspend or withdraw approvals of such lead compound;
- regulatory authorities may require additional warnings on the label;
- we may be required to change the way a lead compound is administered or conduct additional clinical trials;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of CC8464 and could significantly harm our business, financial condition, results of operations and prospects.

Additionally, other regulatory regimes in other geographies, such as the European Union (“EU”), India and Japan, where we are initially targeting our products, may impose similar conditions or post-monitoring requirements as a result of such findings.

CC8464 is based on a specific mode of administration (dose escalation regime), which makes it difficult to predict the time and cost of development and of subsequently obtaining regulatory approval.

The clinical trial requirements of the FDA, EMA and other regulatory authorities and the criteria these regulators use to determine the safety and efficacy of a compound vary substantially according to the type, complexity, novelty and intended use and market of such compounds. The regulatory approval process for novel compounds such as ours can be more expensive and take longer than for other, better known or more extensively studied compounds.

Regulatory requirements governing pain medication products have been changing as side effects and the addictive nature of opioids became more apparent. The regulatory framework for pain medications has been tightened and these changes may affect our programs and its commercial potential despite our expectations that CC8464 will not show addictive features. While we are subject to the FDA and EMA regulatory regimes, these are not the only regulatory regimes to which we may be subject in the event we are able to execute on our objectives.

These regulatory review committees and advisory groups and the new guidelines they promulgate may lengthen the regulatory review process, require us to perform additional studies, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of CC8464 or future lead compounds or lead to significant post-approval limitations or restrictions. As we advance CC8464, we will be required to consult with these regulatory and advisory groups and comply with applicable guidelines. If we fail to do so, we may be required to delay or discontinue development of CC8464. These additional processes may result in a review and approval process that is longer than we otherwise would have expected. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential product to market could decrease our ability to generate sufficient product revenue, and our business, financial condition, results of operations and prospects would be materially and adversely affected.

Even if we obtain regulatory approval for CC8464, our only compound in clinical development will remain subject to regulatory oversight.

Even if we obtain any regulatory approval for CC8464, our lead compound, it will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping and submission of safety and other post-market information. Any regulatory approvals that we receive for CC8464 may also be subject to a post-approval safety monitoring program, limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the quality, safety and efficacy of the product. For example, the holder of an approved NDA is obligated to monitor and report adverse events and any failure of a product to meet the specifications in the NDA. The holder of an approved NDA also must submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Advertising and promotional materials must comply with FDA rules and are subject to FDA review, in addition to other potentially applicable federal and state laws.

In addition, product manufacturers and their facilities are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP requirements and adherence to commitments made in the NDA or foreign marketing application. If we, or a regulatory authority, discover 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 that product, a regulatory authority may impose restrictions relative to that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing.

If we fail to comply with applicable regulatory requirements following approval of CC8464 or any future lead compound, a regulatory authority may:

- issue a warning letter asserting that we are in violation of the law;
- seek an injunction or impose administrative, civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve a pending NDA or comparable foreign marketing application (or any supplements thereto) submitted by us or our strategic partners;

- restrict the marketing or manufacturing of the product;
- seize or detain the product or otherwise require the withdrawal of the product from the market;
- refuse to permit the import or export of compounds; or
- refuse to allow us to enter into supply contracts, including government contracts.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize CC8464 and adversely affect our business, financial condition, results of operations and prospects.

The FDA's policies, and those of equivalent foreign regulatory agencies, may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of CC8464. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would materially and adversely affect our business, financial condition, results of operations and prospects.

Even if we obtain and maintain approval for our lead compound CC8464 from the FDA, we may never obtain approval for them outside of the United States, which would limit our market opportunities and adversely affect our business.

Approval of a compound in the United States by the FDA does not ensure approval of such compound by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. Sales of CC8464 or other future lead compounds outside of the United States will be subject to foreign regulatory requirements governing clinical trials and marketing approval. Even if the FDA grants marketing approval for a compound, comparable regulatory authorities of foreign countries also must approve the manufacturing and marketing of the compound in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and more onerous than, those in the United States, including additional preclinical studies or clinical trials. In many countries outside the United States, a compound must be approved for reimbursement before it can be approved for sale in that country. In some cases, the price that we intend to charge for our compounds, if approved, is also subject to approval. We intend to submit a marketing authorization application to the EMA for approval of CC8464 in the European Union, but obtaining such approval from the European Commission following the opinion of the EMA is a lengthy and expensive process. Even if a compound is approved, the FDA or the European Commission, as the case may be, may limit the indications for which the product may be marketed, require extensive warnings on the product labeling or require expensive and time-consuming additional clinical trials or reporting as conditions of approval. Regulatory authorities in countries outside of the United States and the European Union also have requirements for approval of compounds with which we must comply prior to marketing in those countries. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our compounds in certain countries.

Further, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries. Also, regulatory approval for any of our compounds may be withdrawn. If we fail to comply with the regulatory requirements, our target market will be reduced and our ability to realize the full market potential of CC8464 or our future compounds will be harmed and our business, financial condition, results of operations and prospects will be adversely affected.

While we plan to apply for orphan drug designation for CC8464 in the future, it may not effectively protect us from competition, and we may be unable to obtain similar designations for our future lead compounds. For instance, if our competitors are able to obtain orphan drug exclusivity for products that constitute the same drug and treat the same indications as our lead compounds before us, we may not be able to have competing products approved by the applicable regulatory authority for a significant period of time. To date, we have not submitted an application for orphan drug designation.

In connection with the application for our lead compound, CC8464, for the treatment of EM, we also plan to seek orphan drug designation from the FDA. As of the date of this prospectus, we have not submitted an application for orphan drug designation for CC8464. Under the Orphan Drug Act of 1983, the FDA may designate a lead compound as an orphan drug if it is intended to treat a rare disease or condition, which is generally defined as having a patient population of fewer than 200,000 individuals in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States.

Generally, if a compound with an orphan drug designation receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA from approving another marketing application for a product that constitutes the same drug treating the same indication for that marketing exclusivity period, except in limited circumstances. If another sponsor receives such approval before we do (regardless of our orphan drug designation), we will be precluded from receiving marketing approval for our product for the applicable exclusivity period. The applicable period is seven years in the United States.

Even though we may obtain orphan drug exclusivity for CC8464, that exclusivity may not effectively protect the compound from competition because different drugs can be approved for the same condition. In the United States, even after an orphan drug is approved, the FDA may subsequently approve another drug for the same condition if the FDA concludes that the latter drug is not the same drug or is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. In the EU, marketing authorization may be granted to a similar medicinal product for the same orphan indication if:

- the second applicant can establish in its application that its medicinal product, although like the orphan medicinal product already authorized, is safer, more effective or otherwise clinically superior;
- the holder of the marketing authorization for the original orphan medicinal product consents to a second orphan medicinal product application; or
- the holder of the marketing authorization for the original orphan medicinal product cannot supply enough quantities of orphan medicinal product.

If we are not able to secure an orphan drug designation, or if the exclusivity associated with such designation does not effectively protect us from competition, our business, financial condition, results of operations and prospects will be adversely affected.

FDA designations to expedite drug development and review, including "orphan drug" designation, Breakthrough Therapy designation, and/or Fast Track designation, even if granted for any of our lead compounds, may not lead to a faster development, regulatory review or approval process and do not increase the likelihood that any of our lead compounds will receive marketing approval in the United States.

As with any future application for "orphan drug" designation for CC8464 from the FDA, there is no assurance that any of our other compounds that we may develop in the future will receive a similar designation from the FDA or that we will receive Breakthrough Therapy or Fast Track designations lead compound. Further, even if we do receive favorable designations from the FDA, the receipt of any of these designations may not result in a faster development process, review or approval compared to products considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA.

We may expend our limited resources to pursue a compound or indication and fail to capitalize on lead compounds or indications that may be more profitable or for which there is a greater likelihood of success.

We have limited financial and managerial resources. As a result, we may forego or delay pursuit of opportunities with other lead compounds or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to timely capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and lead compounds for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular lead compound, we may relinquish valuable rights to that lead compound through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such lead compound.

If we are not successful in discovering, developing and commercializing additional lead compounds, our ability to expand our business and achieve our strategic objectives would be impaired.

Although a substantial amount of our effort initially focuses on developing CC8464 towards approval in the US and other countries, an additional component of our strategy is to discover, develop and potentially commercialize a portfolio of lead compounds to treat orphan diseases and potentially, non-orphan diseases. Identifying new lead compounds requires substantial technical, financial and human resources, whether any lead compounds are ultimately identified. We may not be able to identify new molecules with the potential for clinical development and ultimate approval. Even if we identify lead compounds that initially show promise, we may fail to successfully develop and commercialize such lead compounds for many reasons, including the following:

- the research methodology used may not be successful in identifying potential lead compounds;
- competitors may develop alternatives that render our lead compounds obsolete;
- lead compounds we develop may nevertheless be covered by third parties' patents or other exclusive rights;
- a lead compound may, on further study, be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;
- a lead compound may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- a lead compound may not be accepted as safe and effective by patients, the medical community or third-party payors.

If we are unsuccessful in identifying and developing additional lead compounds, our potential for growth may be impaired.

We face significant competition in an environment of rapid technological change and the possibility that our competitors may achieve regulatory approval before us or develop therapies that are more advanced or effective than ours, which may adversely affect our financial condition and our ability to successfully market or commercialize our lead compound, CC8464.

Many of our potential competitors, alone or with their strategic partners, have substantially greater financial, technical and other resources, such as larger research and development, clinical, marketing and manufacturing organizations. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of competitors. Our commercial opportunity could be reduced or eliminated if competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any compound that we may develop. Competitors also may obtain FDA or other regulatory approval for their products more rapidly or earlier than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. Additionally, technologies developed by our competitors may render CC8464 uneconomical or obsolete, and we may not be successful in marketing CC8464 against competitors.

In addition, as a result of the expiration or successful challenge of our patent rights, we could face more litigation with respect to the validity and/or scope of patents relating to our competitors' products. The availability of our competitors' products could limit the demand, and the price we are able to charge, for any compound that we may develop and commercialize.

On December 23, 2023, we entered into the Benuvia License Agreement. We are dependent on the Benuvia License Agreement, and the termination of the Benuvia License Agreement could have an adverse effect on our business.

On December 23, 2023, we entered into the Benuvia License Agreement for the Diclofenac Spray Formulation, the Rizatriptan Spray Formulation and the Ondansetron Spray Formulation, diversifying our pipeline of non-opioid pain treatment therapies, while adding therapeutic options for related conditions. The Diclofenac Spray Formulation is patented and has started clinical development in human volunteers. Preliminary pharmacokinetics suggest that this formulation may have a faster onset of action than oral Diclofenac tablets. Diclofenac is an NSAID that is also marketed under additional brand names including Voltaren and Cataflam in its pill form. Rizatriptan, whose brand name is Maxalt, is used for the acute treatment of Migraines as a pill. Ondansetron is an anti-emetic that is available in oral and intravenous form. Under the terms of the Benuvia License Agreement, Benuvia will be responsible for the manufacturing and supply of the Spray Formulations, but we will have exclusive, worldwide rights to develop, commercialize and distribute the Spray Formulations. If we breach the Benuvia License Agreement, Benuvia may be able to terminate it, and as a result of this termination, our business could be negatively impacted.

If Benuvia does not properly maintain or enforce the intellectual property underlying the Benuvia License Agreement, our competitive position and business prospects could be harmed. Benuvia may also seek to terminate our license.

We are a party to the Benuvia License Agreement. To this end, we are dependent on our license with Benuvia. Our success will depend in part on the ability of Benuvia to obtain, maintain and enforce its licensed intellectual property. Benuvia may not successfully prosecute any applications for or maintain intellectual property to which we have licenses, may determine not to pursue litigation against other companies that are infringing such intellectual property, or may pursue such litigation less aggressively than we would. Without protection for the intellectual property we license, other companies might be able to offer similar products for sale, which could adversely affect our competitive business position and harm our business prospects. If we lose any of our right to use third-party intellectual property, it could adversely affect our ability to commercialize our technologies, products or services, as well as harm our competitive business position and our business prospects.

Rizatriptan is an off-patent branded generic that can be manufactured and sold by other pharmaceutical manufacturers, which may increase the competition we face and reduce our ability to diversify our pipeline of non-opioid pain treatment therapies, while adding therapeutic options for related conditions under the Benuvia License Agreement.

Benuvia is an off-patent branded generic pharmaceutical and is currently not protected by intellectual property rights. As a result, other pharmaceutical companies may sell products similar to the Rizatriptan Spray Formulation at a lower cost, and this might result in a commensurate loss in expected sales or require us to lower our prices to compete. If other pharmaceutical companies sell products that are similar to the Rizatriptan Spray Formulation, we may face additional competition and our business and profitability may be adversely affected, and our ability diversifying our pipeline of non-opioid pain treatment therapies, while adding therapeutic options for related conditions under the Benuvia License Agreement may be reduced.

Risks Related to Manufacturing

Delays in obtaining regulatory approvals of the process and facilities needed to manufacture CC8464 or any of our lead compounds or disruptions in our manufacturing process may delay or disrupt our product development and commercialization efforts.

Before we can begin to commercially manufacture CC8464 or any of our lead compounds, whether in a third-party facility or in our own facility, if established, we must pass a pre-approval inspection of our manufacturing facility by the FDA. A manufacturing authorization must also be obtained from the appropriate regulatory authorities. The timeframe required for us to obtain such approvals is uncertain. To obtain approval, we will need to ensure that all our processes, methods and equipment are compliant with cGMP, and perform extensive audits of vendors, contract laboratories and suppliers. If any of our vendors, contract laboratories or suppliers is found to be out of compliance with cGMP, we may experience delays or disruptions in manufacturing while we work with these third parties to remedy the violation or while we work to identify suitable replacement vendors. The cGMP requirements govern quality control of the manufacturing process and documentation policies and procedures. In complying with cGMP, we will be obligated to expend time, money and effort in production, record keeping and quality control to assure that the product meets applicable specifications and other requirements. If we fail to comply with these requirements, we would be subject to possible regulatory action and may not be permitted to sell any compound that we may develop.

In addition, the manufacturing process used to produce our lead compounds is complex, novel and has not been validated for commercial use. To produce enough quantities of our lead compounds for future clinical trials and initial US commercial demand, we will need to increase the scale of our manufacturing process. We employ multiple steps to control our manufacturing process to assure that the process works and that CC8464 is made strictly and consistently in compliance with the process. Problems with, or deviations from, the manufacturing process, even if minor, could result in product defects or manufacturing failures that result in lot failures, product recalls, product liability claims or insufficient inventory. We may encounter problems achieving adequate quantities and quality of clinical-grade materials that meet FDA, EMA or other applicable standards or specifications with consistent and acceptable production yields and costs.

Any contamination in our manufacturing process, shortages of raw materials or failure of any of our key suppliers to deliver necessary components could result in delays in our clinical development or marketing schedules.

Given the nature of sterile product manufacturing, there is a risk of contamination. Any contamination could materially adversely affect our ability to produce CC8464 on schedule and could, therefore, harm our results of operations and cause reputational damage.

Some of the raw materials required in our manufacturing process may be derived from biologic sources. Such raw materials are difficult to procure and may be subject to contamination or recall. A material shortage, contamination, recall or restriction on the use of biologically derived substances in the manufacture of CC8464 could adversely impact or disrupt the commercial manufacturing or the production of clinical material, which could materially and adversely affect our development timelines and our business, financial condition, results of operations and prospects.

Risks Related to Commercialization of Our Lead Compounds

If we are unable to expand our market development capabilities or enter into agreements with third parties to market and sell our lead compounds, we may be unable to generate any revenue.

We currently do not have a market development organization. To successfully commercialize CC8464, if approved, we will need to expand our capabilities to promote market access and build awareness. To successfully commercialize any other products that may result from our development programs, we will need to further expand our market development organization, either on our own or with a third party. The development of our own market development team will be expensive and time-consuming and could delay any product launch. Moreover, we cannot be certain that we will be able to successfully develop this capability. We may enter into collaboration agreements regarding any of our lead compounds with third parties to utilize their established marketing and distribution capabilities, but we may be unable to enter into such agreements on favorable terms, if at all. If any future collaborators do not commit sufficient resources to commercialize our products, or we are unable to develop the necessary capabilities on our own, we will be unable to generate sufficient product revenue to sustain our business. We compete with many companies that currently have extensive, experienced and well-funded medical affairs, marketing and sales operations to recruit, hire, train and retain marketing and sales personnel. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our lead compounds. Without an internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

Our efforts to educate the medical community and third-party payors on the benefits of our lead compounds may require significant resources and may never be successful. Such efforts may require more resources than are typically required due to the complexity and uniqueness of our potential products. If any of our lead compounds is approved but fails to achieve market acceptance among physicians, patients or third-party payors, we will not be able to generate significant revenues from such product, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

If the market opportunities for CC8464 or our future lead compounds are smaller than we believe they are, our revenues may be adversely impacted, and our business may suffer.

We are currently focusing our research and product development efforts on CC8464 for the management of EM and, potentially, other fields of neuropathic pain. Our understanding of both the number of people who have EM, as well as the subset of people with this disease who have the potential to benefit from treatment with CC8464, are based on estimates in published literature. These estimates may prove to be incorrect and new studies may reduce the estimated incidence or prevalence of this disease. The number of patients in the United States, the EU and elsewhere may turn out to be lower than expected or these patients may not be otherwise amenable to treatment with CC8464 or may become increasingly difficult to identify and access, all of which would adversely affect our business, financial condition, results of operations and prospects.

Further, there are several factors that could contribute to making the actual number of patients who receive CC8464 less than the potentially addressable market. These include the increased use of currently available medication for mild cases as physicians gain a better understanding diagnosis and treatment of EM, the discovery of novel medications for EM and the lack of widespread availability of, and limited reimbursement for, new therapies in many underdeveloped markets.

Government price controls or other changes in pricing regulation could restrict the amount that we are able to charge for CC8464, if approved, or any of our other lead compounds that may be approved in the future, which would adversely affect our revenue and results of operations.

We expect that coverage and reimbursement of pharmaceutical costs may be increasingly restricted both in the U.S. and internationally. The escalating cost of health care has led to increased pressure on the health care industry to reduce costs. Drug pricing by pharmaceutical companies recently has come under increased scrutiny and continues to be subject to intense political and public debate in the U.S. and abroad. Government and private third-party payors have proposed health care reforms and cost reductions. A number of federal and state proposals to control the cost of health care, including the cost of drug treatments, have been made in the US. Specifically, there have been several recent U.S. Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs. In some international markets, the government controls the pricing, which can affect the profitability of drugs. Current government regulations and possible future legislation regarding health care may affect coverage and reimbursement for medical treatment by third-party payors, which may render our lead compounds, if approved, not commercially viable or may adversely affect our anticipated future revenues and gross margins.

We cannot predict the extent to which our business may be affected by these or other potential future legislative or regulatory developments. However, future price controls or other changes in pricing regulation or negative publicity related to the pricing of pharmaceutical drugs generally could restrict the amount that we are able to charge for our future products, which would adversely affect our anticipated revenue and results of operations.

The insurance coverage and reimbursement status of newly approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for our products, if approved, could limit our ability to market those products and decrease our ability to generate product revenue.

We expect that coverage and reimbursement by government and private payors will be essential for most patients to be able to afford these treatments. Accordingly, sales of our lead compounds will depend substantially, both domestically and abroad, on the extent to which the costs of our lead compounds will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or will be reimbursed by government authorities, private health coverage insurers and other third-party payors. Coverage and reimbursement by a third- party payor may depend upon several factors, including the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Obtaining coverage and reimbursement for a product from third-party payors is a time-consuming and costly process that could require us to provide to the payor supporting scientific, clinical and cost-effectiveness data. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. If coverage and reimbursement are not available, or are available only at limited levels, we may not be able to successfully commercialize our lead compounds. Even if coverage is provided, the approved reimbursement amount may not be adequate to realize a sufficient return on our investment.

There is significant uncertainty related to third-party coverage and reimbursement of newly approved products. In the United States, third-party payors, including government payors such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs and biologics will be covered and reimbursed. The Medicare and Medicaid programs increasingly are used as models for how private payors and government payors develop their coverage and reimbursement policies.

Outside the United States, international operations generally are subject to extensive government price controls and other market regulations and increasing emphasis on cost-containment initiatives in the European Union, Canada and other countries may put pricing pressure on us. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. It also can take a significant amount of time after approval of a product to secure pricing and reimbursement for such product in many counties outside the United States. In general, the prices of medicines under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for medical products but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our lead compounds. Accordingly, in markets outside the United States, the reimbursement for our products will be reduced compared with the United States and may be insufficient to generate commercially reasonable product revenues.

Moreover, increasing efforts by government and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for new products approved and, as a result, they may not cover or provide adequate payment for our lead compounds. Payors increasingly are considering new metrics as the basis for reimbursement rates, such as average sales price, average manufacturer price, and Actual Acquisition Cost. The existing data for reimbursement based on some of these metrics is relatively limited, although certain states have begun to survey acquisition cost data for the purpose of setting Medicaid reimbursement rates, and CMS has begun making pharmacy National Average Drug Acquisition Cost and National Average Retail Price data publicly available on at least a monthly basis. Therefore, it may be difficult to project the impact of these evolving reimbursement metrics on the willingness of payors to cover candidate products that we or our partners are able to commercialize. We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become intense. As a result, increasingly high barriers are being erected to the entry of new products such as ours.

Risks Related to Our Business Operations

We may not be successful in our efforts to identify or discover additional compounds and may fail to capitalize on programs or compounds that may be a greater commercial opportunity or for which there is a greater likelihood of success.

Beyond the development and commercialization of CC8464, the future success of our business depends upon our ability to identify, develop and commercialize compounds based on the platform technology. CC8464 was discovered in our labs using our technologies. Research programs to identify new compounds will require to invest substantial technical, financial and human resources. We may fail to identify other potential compounds for clinical development for several reasons. For example, our research may be unsuccessful in identifying potential compounds or our potential compounds may be shown to have harmful side effects, may be commercially impracticable to manufacture or may have other characteristics that may make the products unmarketable or unlikely to receive marketing approval.

Additionally, because we have limited resources, we may forego or delay pursuit of opportunities with certain programs or compounds or for indications that later prove to have greater commercial potential. Our spending on current and future research and development programs may not yield any commercially viable products. If we do not accurately evaluate the commercial potential for a particular compound, we may relinquish valuable rights to that compound through strategic collaboration, licensing or other arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such compound. Alternatively, we may allocate internal resources to a compound in a therapeutic area in which it would have been more advantageous to enter into a partnering arrangement.

If any of these events occur, we may be forced to abandon our development efforts with respect to a particular compound or fail to develop a potentially successful compound, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

If we are unable to manage expected growth in the scale and complexity of our operations, our performance may suffer.

If we are successful in executing our business strategy, we will need to expand our managerial, operational, financial and other systems and resources to manage our operations, continue our research and development activities and, in the longer term, build a commercial infrastructure to support commercialization of any of our lead compounds that are approved for sale. Future growth would impose significant added responsibilities on members of management. It is likely that our management, finance, development personnel, systems and facilities currently in place may not be adequate to support this future growth. Our need to effectively manage our operations, growth and lead compounds requires that we continue to develop more robust business processes and improve our systems and procedures in each of these areas and to attract and retain enough numbers of talented employees. We may be unable to successfully implement these tasks on a larger scale and, accordingly, may not achieve our research, development and growth goals.

Our future success depends on our ability to retain key employees and scientific advisors and to attract, retain and motivate qualified personnel.

Our success is dependent upon certain key management and technical personnel, the loss of whose services may adversely impact the achievement of our objectives. Our Interim Chief Executive Officer, Chief Financial Officer, Chief Medical Officer, Treasurer and Corporate Secretary have played key roles in the founding, management, technology development and/or promotion of the Company. We currently do not hold key man insurance on our executives. Even if we do seek to obtain such insurance, we cannot assure you that such insurance will be available on acceptable terms or at all. The loss of the services of either our Interim Chief Executive Officer, Chief Financial Officer, Chief Medical Officer, Treasurer or Corporate Secretary could have a material adverse effect on our business, financial condition, and results of operations.

We employ additional staff that are critical to implementing our clinical development and business strategy, and further development of our products will require that we recruit additional employees or consultants, particularly qualified scientific and technical personnel. Any inability to retrain and attract key employees or advisors may impede the progress of our research, development and commercialization objectives which could have a material adverse effect on our business, financial condition, results of operations and prospects. In addition, failure to succeed in preclinical or clinical trials or applications for marketing approval may make it more challenging to recruit and retain qualified personnel.

Our employees, principal investigators and advisors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators and advisors. Misconduct by these parties could include intentional failures to comply with FDA regulations or the regulations applicable in the EU and other jurisdictions, provide accurate information to the FDA, the EMA and other regulatory authorities, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. Sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct also could involve the improper use of information obtained during clinical trials or interactions with the FDA or other regulatory authorities, which could result in criminal and civil penalties or sanctions and cause serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from government investigations or other actions or lawsuits stemming from a failure to comply with these 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, financial condition, results of operations and prospects, including the imposition of significant fines, criminal penalties, or other sanctions.

In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA. The FDA may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the trial. The FDA may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA and may ultimately lead to the denial of marketing approval of our current and future drug candidates.

We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

If we obtain FDA approval for CC8464 and begin commercializing it in the United States, our operations will be directly, or indirectly through our prescribers, customers and purchasers, subject to various federal and state fraud and abuse laws and regulations, including, without limitation, the federal Anti-Kickback Statute, federal civil and criminal false claims laws and the Physician Payments Sunshine Act and regulations. These laws will impact, among other things, our proposed sales, marketing and educational programs. In addition, we may be subject to patient privacy laws by both the federal government and the states in which we conduct our business as well as other jurisdictions. The laws that will affect our operations include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, in return for the purchase, recommendation, leasing or furnishing of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand, and prescribers, purchasers and formulary managers on the other. The PPACA amended the intent requirement of the federal Anti-Kickback Statute to clarify that a person or entity does not have to have actual knowledge of this statute or specific intent to violate it;

- federal civil and criminal false claims laws and civil monetary penalty laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid or other government payors that are false or fraudulent. The PPACA provides that a claim for items or services resulting from an Anti-Kickback Statute violation is a false claim under the federal False Claims Act (the "FCA"). Cases against pharmaceutical manufacturers support the view that certain marketing practices, including off-label promotion, may implicate the FCA;

- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which created new federal criminal statutes that prohibit a person from knowingly and willfully executing a scheme or from making false or fraudulent statements to defraud any healthcare benefit program, regardless of the payor (e.g., public or private);

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"), and its implementing regulations, and as amended again by the final HIPAA omnibus rule, Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules under HITECH and the Genetic Information Nondiscrimination Act;

- other modifications to HIPAA, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization by entities subject to the rule, such as health plans, health care clearinghouses and health care providers;

- federal transparency laws, including the federal Physician Payment Sunshine Act, that require certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to the CMS information related to: (i) payments or other "transfers of value" made to physicians and teaching hospitals and (ii) ownership and investment interests held by physicians and their immediate family members;

- state and foreign law equivalents of each of the above federal laws, state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts in certain circumstances, such as specific disease states; and

- state and foreign laws that govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. If our operations are found to be in violation of any of the laws described above or any other government regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in government health care programs, such as Medicare and Medicaid, imprisonment and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion of products from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations.

The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. The shifting compliance environment and the need to build and maintain a robust and expandable systems to comply with multiple jurisdictions with different compliance and/or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the generation, handling, use, storage, treatment, manufacture, transportation and disposal of, and exposure to, hazardous materials and wastes, as well as laws and regulations relating to occupational health and safety. Our operations involve the use of hazardous and flammable materials, including chemicals and biologic materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended.

Although we maintain workers' compensation insurance for certain costs and expenses, we may incur due to injuries to our employees resulting from the use of hazardous materials or other work-related injuries, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for toxic tort claims that may be asserted against us in connection with our storage or disposal of biologic, hazardous or radioactive materials.

We also may incur substantial costs to comply with current or future environmental, health and safety laws and regulations, which have tended to become more stringent over time. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions or liabilities, which could materially adversely affect our business, financial condition, results of operations and prospects.

Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets, including conditions that are outside of our control, such as the impact of health and safety concerns, including SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2) ("COVID-19") and the Omicron COVID-19 variant, as well as the recent inflation in the United States, foreign and domestic government sanctions imposed on Russia as a result of its recent invasion of Ukraine, and other disruptions to global supply chains. Each of these events has caused or may continue to result in extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn, whether due to inflationary pressures or otherwise, could result in a variety of risks to our business, including weakened demand for our lead compounds and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could strain our suppliers, possibly resulting in supply disruption, or cause delays in payments for our services by third-party payors or our collaborators. Any of the foregoing could harm our business and we cannot anticipate all the ways in which the current economic climate and financial market conditions could adversely impact our business.

Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults or non-performance by financial institutions or transactional counterparties, could adversely affect our current and projected business operations and financial condition and results of operations.

Events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. Most recently, on March 10, 2023, Silicon Valley Bank ("SVB") was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation ("FDIC") as receiver. Similarly, on March 12, 2023, Signature Bank and Silvergate Capital Corp. were each swept into receivership. Although a statement by the Department of the Treasury, the Federal Reserve and the FDIC indicated that all depositors of SVB would have access to all of their money after only one business day of closure, including funds held in uninsured deposit accounts, borrowers under credit agreements, letters of credit and certain other financial instruments with SVB, Signature Bank or any other financial institution that is placed into receivership by the FDIC may be unable to access undrawn amounts thereunder.

Although we regularly assess our banking relationships and the location of the assets held in the company's account as we believe necessary or appropriate, our access to funding sources and other credit arrangements could be significantly impaired by factors that affect the financial services industry or economy in general. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry.

A pandemic, epidemic, or outbreak of an infectious disease, such as COVID-19, may materially and adversely affect our business and our financial results and could cause a disruption to the development of our compounds.

Public health crises such as pandemics or similar outbreaks could adversely impact our business. In December 2019, COVID-19 surfaced in Wuhan, China and has since spread worldwide, including to New Jersey where our primary office and laboratory space is located. In response to the COVID-19 pandemic, we reduced staff and slowed down development activities as capital and testing options available to us were more limited. The extent to which COVID-19 will impact our future operations or those of our third-party partners, including our clinical trial operations, will also depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration of the pandemic, adverse impacts of the Omicron COVID-19 variant or other COVID-19 variants, new information that will emerge concerning the severity of COVID-19 and the actions to contain COVID-19 or treat its impact, among others.

The continued spread of COVID-19 globally could adversely impact our preclinical or clinical trial operations, including our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19. COVID-19 may also affect employees of third-party CROs located in affected geographies that we rely upon to carry out our clinical trials.

In addition, the patient populations that our lead and other compounds target may be particularly susceptible to COVID-19, which may make it more difficult for us to identify patients able to enroll in our future clinical trials and may impact the ability of enrolled patients to complete any such trials. Any negative impact COVID-19 has to patient enrollment or treatment, or the execution of our lead compounds could cause costly delays to clinical trial activities, which could adversely affect our ability to obtain regulatory approval for and to commercialize our lead compounds, increase our operating expenses, and have a material adverse effect on our financial results.

On May 11, 2023, the United States government declared an end to the COVID-19 pandemic, but the negative effects from COVID-19 described above may still be present for the foreseeable future.

Our internal computer systems, or those of our collaborators or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs.

Our internal computer systems and those of our current and any future collaborators and other contractors or consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other proprietary information or other similar disruptions. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, our competitive position could be harmed, and the further development and commercialization of our compounds could be delayed.

Cyber-security incidents, including data security breaches or computer viruses, could harm our business by disrupting our delivery of services, damaging our reputation or exposing us to liability.

We receive, process, store and transmit, often electronically, confidential data of others. Unauthorized access to our computer systems or stored data could result in the theft or improper disclosure of confidential information, the deletion or modification of records, or could cause interruptions in our operations. These cyber-security risks increase when we transmit information from one location to another, including transmissions over the Internet or other electronic networks. Despite implemented security measures, our facilities, systems, and procedures, and those of our third-party service providers, may be vulnerable to security breaches, acts of vandalism, software viruses, misplaced or lost data, programming and/or human errors, or other similar events which may disrupt our delivery of services or expose the confidential information of our customers and others. Any security breach involving the misappropriation, loss or other unauthorized disclosure or use of confidential information of others, whether by us or a third party, could: (i) subject us to civil and criminal penalties; (ii) have a negative impact on our reputation; or (iii) expose us to liability to our customers, third parties or government authorities.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.

Our business exposes us to significant potential product liability risks that are inherent in the development, manufacturing, marketing and sale of human device and drug products. Product liability claims could delay or prevent completion of its development programs, clinical or otherwise. If we succeed in marketing and selling products, such claims could result in a recall of any products or a limitation or other change in the indications for which they may be used. If we cannot successfully defend ourselves against claims that our compounds or drugs caused injuries, we will incur substantial liabilities. Depending on their merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or drugs that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards paid to trial participants or patients;
- loss of revenue;
- reduced resources of our management to pursue our business strategy; and
- the inability to commercialize any products that we may develop.

In addition, we currently do not have product liability insurance, but plan to obtain such insurance at appropriate levels prior to initiating studies in humans or clinical trials and prior to marketing and selling any drug or device products. Any insurance we obtain may not provide sufficient coverage against potential liabilities. These liabilities could prevent or interfere with our product development and commercialization efforts. Furthermore, if we were unable or otherwise failed to obtain and maintain sufficient insurance at a reasonable cost to protect it against any such liabilities, that inability could have a material adverse effect on its business.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain adequate U.S. and foreign patent protection for our lead compounds, including CC8464, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize products and technologies similar or identical to ours, and our ability to successfully commercialize CC8464 and any of our other current or future lead compounds may be adversely affected.

Our success depends, in large part, on our ability to obtain and maintain patent protection in the United States and other countries with respect to CC8464, additional lead compounds in our product pipeline, and our institutional knowledge. The patent prosecution process is expensive, time- consuming and complex. In particular, we may not be able to file, prosecute, maintain, and/or enforce all necessary or desirable patent applications and issued patents at a reasonable cost or in a timely manner.

We have secured U.S. Patent No. 9,458,118 (the "CC8464 Patent"), covering the chemical composition and use of our clinical-stage NaV1.7 blocker. Apart from the CC8464 Patent, we have filed multiple patent applications in foreign jurisdictions, including Canada, France, India and Japan. It is possible that some of our pending patent applications in foreign jurisdictions will not result in issued patents in a timely fashion or at all, and even if we are granted the patents we are currently pursuing in foreign jurisdictions, the patents may not be issued in a form that will provide us with the full scope of protection that we desire, they may not prevent competitors or other third parties from competing with us, and/or they may not otherwise provide us with a competitive advantage. Our competitors, or other third parties, may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner. For example, there is no assurance that the CC8464 Patent, or any other patent that we may be granted, will prevent third parties from developing competing technologies. Moreover, our patent estate, including the CC8464 Patent, does not preclude third parties from obtaining intellectual property rights that could interfere with our freedom to use our platform for other indications. Even assuming patents issue from our pending and future patent applications, changes in either the patent laws or interpretation of the patent laws in the United States and foreign jurisdictions may diminish the value of our patents or narrow their scope of protection.

We may not be able to protect our intellectual property or enforce our intellectual property rights adequately throughout the world.

Filing and prosecuting patent applications on CC8464 and future lead compounds, current and future innovations related to our technology, and our institutional knowledge in all countries throughout the world would be prohibitively expensive, and intellectual property protections available in some countries outside the United States, and the enforceability thereof, may differ in scope from those in the United States. Thus, in some cases, we will not seek to obtain patent protection for certain technologies in some jurisdictions outside the United States. In addition, the laws of some foreign countries do not protect intellectual property to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from utilizing our inventions in all countries outside the United States, even in jurisdictions where we do pursue patent protection. Competitors may use our technologies in jurisdictions where we have not pursued and obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our lead compounds, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting intellectual property 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, trade secrets and other intellectual property protections, particularly those relating to biotechnology products and those of foreign entities. Such challenges in enforcing rights in these countries could make it difficult for us to stop the infringement of our patents, if pursued and obtained, or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our current and future patent rights in foreign jurisdictions could result in substantial costs and may divert our efforts and attention from other aspects of our business; could put our asserted patents at risk of being invalidated or interpreted narrowly; could put any future patent applications, including continuation and divisional applications, at risk of not issuing; and could provoke third parties to assert their own patent claims against us or to attack the validity of our other patents. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce any intellectual property rights around the world stemming from intellectual property that we develop may be inadequate to obtain a significant commercial advantage in these foreign jurisdictions.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

Our commercial success depends upon our ability (and the ability of any potential future collaborators) to develop, manufacture, market and sell CC8464 and future lead compounds, and to freely use our proprietary technologies (*e.g.*, without infringing the intellectual property rights of others). Many companies and institutions have filed, and continue to file, patent applications related to various aspects of pain management and opioid sparing technology. Because patent applications can take many years to issue, may be confidential for 18 months or more after filing, and can be revised before and after issuance, there may be issued patents and patent applications now pending which may later result in issued patents that a third party asserts are infringed by the manufacture, use, sale, or importation of our products. The biotechnology and pharmaceutical industries are characterized by extensive and complex litigation regarding patents and other intellectual property rights. Our competitors or other third parties may assert infringement claims against us, alleging that our therapeutics, manufacturing methods, formulations or administration methods are covered by their patents. Moreover, we may face patent infringement claims from non-practicing entities that have no relevant product revenue, and against whom our patent portfolio may therefore have no deterrent effect.

Third parties may initiate legal or administrative proceedings attacking the validity of our patents protecting CC8464 and future lead compounds the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

We may in the future become party to, or be threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to CC8464 or any other lead compound, or related technologies, including, for example, interference proceedings, post grant review challenges, and *inter partes* review before the United States Patent and Trademark Office ("USPTO"). For example, a third party may bring an *inter partes* review challenging our patents and any future patent that may be granted to us. Such proceedings often are used as a tactic by defendants in a patent litigation suit to threaten a patentee's patents, both asserted in the litigation and unasserted. Thus, a competitor, either in response to litigation initiated by us or in the ordinary course, may threaten the validity, enforceability, and breadth of our patents which could have a negative impact on our business and render our patents or other intellectual property rights ineffective or insufficient to prevent competition.

Instituting and defending against patent and other types of intellectual property litigation and administrative proceedings could cause us to spend substantial resources, distract our personnel from their normal responsibilities, and have uncertain outcomes.

Patent and other types of intellectual property litigation and administrative proceedings can involve complex factual and legal questions, and their outcomes are uncertain. A finding of infringement could prevent us from manufacturing and commercializing our technologies, including CC8464, or force us to cease some or all our business operations. If we are found or believe there is a risk that we may be found, to infringe a third party's valid and enforceable intellectual property rights, we could be required (or may choose) to obtain a license from such a third party to continue developing, manufacturing and marketing our technologies. However, we may not be able to obtain any required license on commercially reasonable terms, if at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and further, it could require us to make substantial licensing and royalty payments. We could be forced, including by court order, to cease developing, manufacturing and commercializing the infringing technologies, including CC8464. We also could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent or other intellectual property right. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business, financial condition, results of operations and prospects.

Litigation or other legal or administrative proceedings relating to intellectual property claims, with or without merit, is unpredictable and generally expensive and time consuming. Competitors may infringe our current or future patents, should such patents issue, or we may be required to defend against claims of infringement or other unauthorized use of third-party intellectual property or third-party attacks against our intellectual property rights. Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property may cause us to incur significant expenses and could distract our scientific and management personnel from their normal responsibilities. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation and administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation despite our attempts to prevent such disclosure. In addition, there could be public announcements of the results of hearings, motions, or other interim proceedings or developments and, if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our Common Stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or distribution activities.

We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing, misappropriating, or successfully challenging our intellectual property rights. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

Changes in United States patent law and its administrative and judicial interpretation could diminish the value of patents in general, thereby impairing our ability to protect our lead compounds.

Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. As patent reform legislation can inject serious uncertainty into the patent prosecution and litigation processes, it is not clear what impact future patent reform legislation will have on the operation of our business. However, such future legislation, and its implementation, could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of any issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Moreover, the patent positions of companies engaged in the development and commercialization of pharmaceuticals are particularly uncertain. We cannot assure you that our efforts to seek patent protection for CC8464 and future lead compounds will not be negatively impacted by the future court decisions or changes in guidance or procedures issued by the USPTO. These decisions, and any guidance issued by the USPTO (or changes thereto), could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property rights in the future.

Intellectual property rights and regulatory exclusivity rights do not necessarily address all potential threats.

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

- others may be able to make products that are similar to our current and future lead compound but that are not covered by the claims of our current patents or of patents that we may own or license in the future;
- we, or any future license partners or collaborators, might not have been the first to file patent applications covering certain aspects of the concerned technologies;
- others may independently develop similar or alternative technologies, or duplicate any of our technologies, potentially without falling within the scope of our current or future issued claims, thus not infringing our intellectual property rights;
- it is possible that our filed or future patent applications will not lead to issued patents;
- issued patents to which we currently hold rights or to which we may hold rights in the future may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- others may have access to any future intellectual property rights licensed to us on a non-exclusive basis;

- our competitors might conduct research and development activities in countries where we have or intend to pursue patent rights, and then use the information learned from such activities to develop competitive products for sale in our major commercial markets where we do not have patent rights;

- we may not develop additional proprietary technologies that are patentable;

- the patents or other intellectual property rights of others may have an adverse effect on our business; and

- we may choose not to file a patent application covering certain of our trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could significantly harm our business, financial condition, results of operations and prospects.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed. Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

In addition to patent protection, we also rely on the protection of trade secrets, know-how and confidential and proprietary information. The disclosure of our trade secrets would impair our competitive position and could harm our business. However, trade secrets are difficult to protect. To maintain the confidentiality of trade secrets and proprietary information, we rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers, and/or other advisors, and inventions agreements with employees, consultants, and advisors, to protect our trade secrets and other proprietary information. These agreements require that all confidential information developed by the individual or made known to the individual by us during the course of the individual's relationship with us be kept confidential and not disclosed to third parties. Our agreements with employees and consultants also provide that inventions conceived by the individual in the course of rendering services to us will be our exclusive property. Despite these efforts, we cannot provide any assurances that these agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information.

In the event of unauthorized use or disclosure of trade secrets or proprietary information, these agreements, even if obtained, may not provide sufficient protection for our trade secrets or other confidential information. Further, to the extent that our employees, consultants or contractors use technology or know-how owned by others in their work for the Company, disputes may arise as to the rights in related inventions. This can be of particular concern with respect to university collaborators with us, who typically have pre-existing obligations to their universities to assign intellectual property rights, which university rights generally are superior to assignment rights that we might receive from such individuals.

Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. Moreover, third parties may still obtain this information or may come upon this or similar information independently, and we would have no right to prevent them from using that technology or information to compete with us. Trade secrets will over time be disseminated within the industry through independent development, the publication of journal articles, and the movement of personnel skilled in the art from company to company or academic to industry scientific positions. Though our agreements with third parties typically restrict the ability of our advisors, employees, collaborators, licensors, suppliers, third-party contractors, and/or consultants to publish data potentially relating to our trade secrets, our agreements may contain certain limited publication rights. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position. Because from time to time we expect to rely on third parties in the development, manufacture, and distribution of our products and provision of our services, we must, at times, share trade secrets with them. Despite employing the contractual and other security precautions described above, the need to share trade secrets increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. If any of these events occurs or if we otherwise lose protection for our trade secrets, the value of this information may be greatly reduced and our competitive position would be harmed. If we do not apply for patent protection prior to such publication or if we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, then our ability to obtain patent protection or to protect our trade secret information may be jeopardized.

Risks Related to this Offering and Ownership of our Common Stock

The market prices and trading volume of our shares of Common Stock may experience rapid and substantial price volatility, which could cause purchasers of our Common Stock to incur substantial losses.

Recently, the market prices and trading volume of shares of Common Stock of other small publicly traded companies with a limited number of shares available to purchasers, have experienced rapid and substantial price volatility unrelated to the financial performance of those companies. Similarly, subsequent to the offering of IPO Shares pursuant to the IPO Prospectus, shares of our Common Stock may experience similar rapid and substantial price volatility unrelated to our financial performance, which could cause purchasers of our Common Stock to incur substantial losses, which may be unpredictable and not bear any relationship to our business and financial performance. Extreme fluctuations in the market price of our Common Stock may occur in response to strong and atypical retail investor interest, including on social media and online forums, the direct access by retail investors to broadly available trading platforms, the amount and status of short interest in our Common Stock and our other securities, access to margin debt, trading in options and other derivatives on our shares of Common Stock and any related hedging and other trading factors.

If there is extreme market volatility and trading patterns in our Common Stock, it may create several risks for investors, including the following:

- the market price of our Common Stock may experience rapid and substantial increases or decreases unrelated to our operating performance or prospects, or macro or industry fundamentals;
- if our future market capitalization reflects trading dynamics unrelated to our financial performance or prospects, purchasers of our Common Stock could incur substantial losses as prices decline once the level of market volatility has abated;
- if the future market price of our Common Stock declines, purchasers of shares of Common Stock may be unable to resell such shares at or above the price at which they acquired them. We cannot assure such purchasers that the market of our Common Stock will not fluctuate or decline significantly in the future, in which case investors could incur substantial losses.

Further, we may incur rapid and substantial increases or decreases in our Common Stock price in the foreseeable future that may not coincide in timing with the disclosure of news or developments by or affecting us. Accordingly, the market price of our Common Stock may fluctuate dramatically, and may decline rapidly, regardless of any developments in our business. Overall, there are various factors, many of which are beyond our control, that could negatively affect the market price of our Common Stock or result in fluctuations in the price or trading volume of our Common Stock, including:

- actual or anticipated variations in our annual or quarterly results of operations, including our earnings estimates and whether we meet market expectations with regard to our earnings;
- our current inability to pay dividends or other distributions;
- publication of research reports by analysts or others about us or the industry in which we operate, including the pharmaceutical or biotechnology industry which may be unfavorable, inaccurate, inconsistent or not disseminated on a regular basis;
- changes in market valuations of similar companies;
- market reaction to any additional equity, debt or other securities that we may issue in the future, and which may or may not dilute the holdings of our existing stockholders;
- additions or departures of key personnel;
- actions by institutional or significant stockholders;
- short interest in our Common Stock or our other securities and the market response to such short interest;
- the dramatic increase in the number of individual holders of our Common Stock and their participation in social media platforms targeted at speculative investing;
- speculation in the press or investment community about our company or industries in which we operate;
- strategic actions by us or our competitors, such as acquisitions or other investments;
- legislative, administrative, regulatory or other actions affecting our business, our industry, including positions taken by the FDA;
- investigations, proceedings, or litigation that involve or affect us;
- the occurrence of any of the other risk factors included in this registration statement of which this prospectus forms a part; and
- general market and economic conditions.

NYSE American may delist our Common Stock from trading, which could limit investors' ability to make transactions in our securities and subject us to additional trading restrictions.

Should we fail to satisfy the continued listing requirements for remaining listed on NYSE American, such as the corporate governance requirements or the minimum closing bid price requirement, NYSE American may take steps to delist our Common Stock. Such a delisting would likely have a negative effect on the price of our Common Stock and would impair your ability to sell or purchase our Common Stock when you wish to do so. In the event of a delisting, we would take actions to restore our compliance with NYSE American's listing requirements, but we can provide no assurance that any such action taken by us would allow our Common Stock to become listed again, stabilize the market price or improve the liquidity of our Common Stock, prevent our Common Stock from dropping below NYSE American's minimum bid price requirement or prevent future non-compliance with such listing requirements.

If we cannot maintain the listing of our Common Stock for trading on NYSE American, we could face significant material adverse consequences, including:

- a limited availability of market quotations for our Common Stock;
- reduced liquidity for our Common Stock;
- a determination that our Common Stock is a "penny stock" which will require brokers trading in our Common Stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our Common Stock;

- a limited amount of news and analyst coverage; and
- a decreased ability to issue additional Common Stock or obtain additional financing in the future.

Provisions in our corporate charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our corporate charter and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions also could limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from the board;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call stockholder meetings;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a stockholder rights plan, or so-called "poison pill," that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- authorize "blank check" preferred stock, which could be issued by our board of directors without stockholder approval and may contain voting, liquidation, dividend, and other rights superior to our common stock.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the General Corporation Law of the State of Delaware (the "DGCL"), which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Our amended and restated certificate of incorporation (which, as so amended and restated, we refer to as our "certificate of incorporation") and our bylaws, as amended (which we refer to as our "bylaws") provide that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our certificate of incorporation and our bylaws provide that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the DGCL, our certificate of incorporation or our bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. Notwithstanding the foregoing, the exclusive forum provision does not apply to suits brought to enforce any liability or duty created by the Securities Act, the Exchange Act, or any other claim for which the federal courts have exclusive or concurrent jurisdiction. Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act of the rules and regulations thereunder, and Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder, and notwithstanding the provisions of our Certificate of Incorporation and our Bylaws, compliance with the federal securities laws and the rules and regulations thereunder may not be waived by our investors. The choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. Alternatively, if a court were to find the choice of forum provision contained in our certificate of incorporation and our bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could materially and adversely affect our business, financial condition, and results of operation.

A significant portion of our total outstanding shares are restricted from immediate resale but may be sold into the market in the near future, which could cause the market price of our Common Stock to drop significantly, even if our business is performing well.

Sales of substantial amounts of our shares of Common Stock in the public market following the IPO, or the perception that these sales could occur, could cause the market price of our securities to decline. These sales, or the possibility that these sales may occur, also might make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate.

After giving effect to the IPO Transactions, the issuance of the Leak-Out Shares not yet issued as of the date of this prospectus and sale of the IPO Shares pursuant to the IPO Prospectus, we will have 5,767,525 outstanding shares of Common Stock. All of the IPO Shares sold pursuant to the IPO Prospectus will be immediately tradable without restriction under the Securities Act of 1933, as amended, or the Securities Act, except for any securities held by "affiliates," as that term is defined in Rule 144 under the Securities Act, or Rule 144.

The remaining shares of Common Stock, other than the Selling Stockholder Shares, will be restricted securities within the meaning of Rule 144 under the Securities Act but will be eligible for resale subject to applicable volume, means of sale, holding period and other limitations of Rule 144 under the Securities Act or pursuant to an exception from registration under Rule 701 under the Securities Act, subject to the lock-up agreements executed in conjunction with the IPO. See "Shares Eligible for Future Sale" for more information.

In addition, we have registered the Selling Stockholder Shares pursuant to the Resale Prospectus and, as a result, all of the Selling Stockholder Shares are freely tradable under the Securities Act, subject to the terms of the lock up agreements.

Upon completion of the IPO, we intend to file one or more registration statements on Form S-8 under the Securities Act to register the shares of Common Stock to be issued under our equity compensation plans and, as a result, all shares of Common Stock acquired under our plans will also be freely tradable under the Securities Act, subject to the terms of the lock-up agreements, unless purchased by our affiliates. In addition, 444,444 shares of our Common Stock will be reserved for future issuances under the equity incentive plan that we have adopted.

In connection with the Bridge Financings, we are required to file a registration statement within 180 calendar days after the consummation of the IPO, providing for the resale of Common Stock, which includes 549 Bonus Shares, received by holders of the senior secured convertible notes upon conversion of such notes.

In connection with our proposed ELOC, we intend to file a registration statement subsequent to the expiration of the lock-up agreement we enter into with the Representative in connection with the IPO, providing for the resale of the shares of Common Stock issuable pursuant to the proposed ELOC, if issued. An agreement with respect to our proposed ELOC has not been, and may never be, finalized and executed and there is no assurance that we will enter into an ELOC or, if we do enter into such an ELOC, that the terms thereof will be consistent with or as favorable as those described in the registration statement of which this prospectus forms a part.

In the future, we may issue additional shares of Common Stock or other equity or debt securities convertible into Common Stock in connection with draw-downs under our proposed ELOC, a financing, acquisition, litigation settlement or employee arrangement or otherwise. Any of these issuances could result in substantial dilution to our existing stockholders and could cause the trading price of our securities to decline.

The Series C Preferred Stock to be issued upon the close of the IPO, will have a liquidation preference over our Common Stock.

The Series C Preferred Stock to be issued upon close of the IPO, will have a liquidation preference that gets paid prior to any payment on our Common Stock. As a result, if we were to liquidate, dissolve or wind-up, each holder of our Series C Preferred Stock would have the right to receive payment out of our assets available for distribution, before any amount is paid to the holders of our Common Stock, in an amount in cash equal to the aggregate liquidation value of all of the shares of preferred stock held by such holder. Holders of the Series C Preferred Stock will not be entitled to dividends. The payment of the liquidation preferences on the Series C Preferred Stock could result in holders of our Common Stock not receiving any proceeds if we were to liquidate, dissolve or wind up, either voluntarily or involuntarily.

The existence of the liquidation preferences may reduce the value of our Common Stock, make it harder for us to sell shares of Common Stock in offerings in the future, or prevent or delay a change of control.

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

The trading market for our Common Stock will rely, in part, on the research and reports that industry or financial analysts publish about us or our business. If securities analysts do not commence coverage of us, the trading price of our stock could decrease. Additionally, if one or more of the analysts covering our business downgrade their evaluations of our stock, the price of our stock could decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price to decline.

The price of our securities may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our securities in this offering.

The offering price for our securities may not reflect the market price of our securities following this offering. In addition, the market price of our securities is likely to be highly volatile due to many factors, including:

- our ability to successfully proceed to and conduct clinical trials;
- results of clinical trials of our lead compound or those of our competitors;
- the success of competitive products or technologies;
- commencement or termination of collaborations;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our current or future lead compounds or clinical development programs;
- the results of our efforts to discover, develop, acquire or in-license additional lead compounds;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- our inability to obtain or delays in obtaining adequate product supply for any approved product or inability to do so at acceptable prices;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or stockholder litigation;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions; and
- the other factors described in this “Risk Factors” section.

In particular, we cannot assure you that you will be able to resell your securities at or above your purchase price. The stock markets have experienced extreme volatility in recent years that has been unrelated to operating performance. These broad market fluctuations may adversely affect the trading price of our securities. In the past, following periods of volatility in the market price of a company’s securities, class action litigation has often been instituted against the affected company. Any litigation of this type brought against us could result in substantial costs and a diversion of our management’s attention and resources, which would harm our business, results of operations, financial condition and cash flows.

No public market for our Common Stock currently exists, and an active trading market may not develop or be sustained.

Prior to the IPO, there has been no public market for our Common Stock. Although our Common Stock is listed on NYSE American, an active trading market may not develop following the closing of the offering of IPO Shares pursuant to the IPO Prospectus or, if developed, may not be sustained. The lack of an active market may impair your ability to sell your shares of Common Stock at the time you wish to sell them or at a price that you consider reasonable. The lack of an active market may also reduce the fair market value of your shares of Common Stock. An inactive market may also impair our ability to raise capital to continue to fund operations by selling shares and may impair our ability to acquire other companies or technologies by using our shares as consideration. The initial public offering price for IPO Shares was determined by negotiations between us and the underwriters and may not be indicative of the future prices of our Common Stock.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or CC8464.

We may seek additional capital through a combination of draw-downs under our proposed ELOC, public and private equity offerings, debt financings, collaborations and licensing arrangements. To the extent that we raise additional capital through the sale of equity or debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. The incurrence of indebtedness would result in increased fixed payment obligations and could involve restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or CC8464 or grant licenses on terms unfavorable to us.

We are an "emerging growth company" and the reduced disclosure requirements applicable to emerging growth companies may make our Common Stock less attractive to investors.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"), and we may take advantage of certain exemptions and relief from various reporting requirements that are applicable to other public companies that are not "emerging growth companies." In particular, while we are an "emerging growth company: (i) we will not be required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act; (ii) we will be exempt from any rules that may be adopted by the Public Company Accounting Oversight Board requiring mandatory audit firm rotations or a supplement to the auditor's report on financial statements; (iii) we will be subject to reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements; and (iv) we will not be required to hold nonbinding advisory votes on executive compensation or stockholder approval of any golden parachute payments not previously approved. Investors may find our Common Stock less attractive if we rely on the exemptions and relief granted by the JOBS Act. If some investors find our Common Stock less attractive as a result, there may be a less active trading market for our Common Stock and our stock price may decline or become more volatile.

We have taken advantage of reduced reporting burdens in this prospectus. In particular, we have not included all of the executive compensation information that would be required if we were not an emerging growth company. We cannot predict whether investors will find our Common Stock less attractive if we rely on certain or all of these exemptions. If some investors find our Common Stock less attractive as a result, there may be a less active trading market for our Common Stock and our stock price may be more volatile.

In addition, the JOBS Act provides that an emerging growth company may take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

We will incur increased costs as a result of operating as a smaller reporting public company, and our management will be required to devote substantial time to new compliance initiatives.

As a smaller reporting public company, and particularly after we are no longer an emerging growth company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act and rules subsequently implemented by the SEC and NYSE American have imposed various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance.

Pursuant to Section 404, we will be required to furnish a report by our management on our internal control over financial reporting, including an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that neither we nor our independent registered public accounting firm will be able to conclude within the prescribed timeframe that our internal control over financial reporting is effective as required by Section 404. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our Common Stock will be your sole source of gain for the foreseeable future.

Risks Related to our Proposed ELOC

There is no assurance that we will enter into our proposed ELOC or that the terms thereof will be consistent with or as favorable as those described in this registration statement of which this prospectus forms a part.

We anticipate that we will enter into a purchase agreement to issue the shares of Common Stock issuable pursuant to the ELOC subsequent to the closing of the IPO; however, as of the date hereof, an agreement with respect to our proposed ELOC has not been, and may never be, finalized and executed and there is no assurance that we will enter into an ELOC or, if we do enter into such an ELOC, that the terms thereof will be consistent with or as favorable as those described in the registration statement of which this prospectus forms a part.

Issuances of our Common Stock to the Holder of the Investor Note under our proposed ELOC may have a significant dilutive effect.

We are negotiating an arrangement with the Holder of the Investor Note to enter into a proposed ELOC subsequent to the IPO, pursuant to which we will have the right, but not the obligation, to sell to the Holder of the Investor Note up to $20,000,000 in newly issued shares of our Common Stock, subject to certain limitations. Depending on the number of shares of Common Stock we issue to the Holder of the Investor Note pursuant to the proposed ELOC, it could have a significant dilutive effect upon our existing stockholders. Although the number of shares of Common Stock that we may issue pursuant to the proposed ELOC will vary based on our stock price (the higher our stock price, the fewer shares of our Common Stock we have to issue), there may be a potential dilutive effect to our stockholders, based on different potential future stock prices, if the full amount of the proposed ELOC is realized. Dilution is based upon shares of Common Stock "put" to the Holder of the Investor Note and the stock price discounted to the Holder of the Investor's purchase price of 95% of the lowest volume-weighted average price during the three (3) consecutive trading days immediately following our notice to the Holder of the Investor Note of our exercise of our "put" right, with the lesser of (i) one hundred percent (100%) of the average daily trading volume over the five days before our notice to the Holder of the Investor Note, (ii) forty percent (40%) of the daily trading volume on the date of our notice to the Holder of the Investor Note or (iii) $2,000,000, delivered in shares of our Common Stock for each particular "put".

Our existing stockholders may experience significant dilution from the sale of our shares of Common Stock pursuant to our proposed ELOC.

The sale of our Common Stock to the Holder of the Investor Note in accordance with the proposed ELOC may have a dilutive impact on our stockholders. As a result, the market price of our Common Stock could decline. In addition, the lower our stock price is at the time we exercise our put options, the more shares of our Common Stock we will have to issue to the Holder of the Investor Note in order to exercise a put under the proposed ELOC. If our stock price decreases, then our existing stockholders would experience greater dilution for any given dollar amount raised through the proposed ELOC.

The perceived risk of dilution may cause our stockholders to sell their shares, which may cause a decline in the price of our Common Stock. Moreover, the perceived risk of dilution and the resulting downward pressure on our stock price could encourage investors to engage in short sales of our Common Stock. By increasing the number of shares offered for sale, material amounts of short selling could further contribute to progressive price declines in our Common Stock.

We may not have access to the full amount available under our proposed ELOC.

Under our proposed ELOC, we will have the right to direct the Holder of the Investor Note to purchase shares of our Common Stock from time to time by presenting the Holder of the Investor Note with a purchase notice directing it to purchase shares according to the terms of the related purchase agreement.

Although, pursuant to our proposed ELOC, we may sell up to $20,000,000 in shares of our Common Stock to the Holder of the Investor Note, depending on the market prices of our Common Stock, we may not be able to nor desire to sell all of the shares of Common Stock contemplated by our proposed ELOC. In addition, we will be required to file one or more additional registration statements to register any shares issued under our proposed ELOC.

The extent to which we rely on the Holder of the Investor Note as a source of funding will depend on a number of factors, including the prevailing market price of our Common Stock and the extent to which we are able to secure working capital from other sources. Even if we sell a significant amount of shares under our proposed ELOC to the Holder of the Investor Note, we may still need additional capital to fully implement our business, operating and development plans. Should the financing we require to sustain our working capital needs be unavailable or prohibitively expensive when we require it, the consequences could be a material adverse effect on our business, operating results, liquidity, financial condition and prospects.

The Holder of the Investor Note will pay less than the then-prevailing market price for shares of our Common Stock, which could cause the price of our Common Stock to decline.

The purchase price of Common Stock sold to the Holder of the Investor Note under our proposed ELOC will be 95% of the lowest volume-weighted average price during the three (3) consecutive trading days immediately following our notice to the Holder of the Investor Note of our exercise of our "put" right. Therefore, shares of Common Stock to be sold to the Holder of the Investor Note pursuant to our proposed ELOC will be purchased at a discounted price as described above. As a result of this pricing structure, the Holder of the Investor Note has a financial incentive to sell our shares of Common Stock immediately upon receiving them to realize the profit between the discounted price

and the market price, subject to certain limitations. If the Holder of the Investor Note sells our shares of Common Stock, the price of our Common Stock may decrease. If our Common Stock price decreases, the Holder of the Investor Note may have further incentive to sell such shares. Accordingly, the discounted sales price in our proposed ELOC may cause the price of our Common Stock to decline.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements that involve substantial risks and uncertainties. The forward-looking statements are contained principally in the sections entitled "Prospectus Summary," "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business." Forward-looking statements include information concerning our strategy, future operations, future financial position, future revenue, projected expenses, prospects and plans and objectives of management. Forward-looking statements include all statements that are not historical facts and can be identified by terms such as "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict, "project," "seek," "should," "target," "will," "would" or similar expressions and the negatives of those terms.

Forward-looking statements contained in this prospectus include, but are not limited to, statements about the following:

- the initiation, timing, progress and results of preclinical and clinical trials for CC8464 and any other lead compounds, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available and our research and development programs;
- the timing, scope or results of regulatory filings and approvals, including timing of final FDA marketing and other regulatory approval of CC8464;
- our ability to achieve certain accelerated or orphan drug designations from the FDA;
- our estimates regarding the potential market opportunity for CC8464;
- our research and development programs for our lead compound;
- our plans and ability to successfully develop and commercialize future lead compounds, including CC8464;
- our ability to identify and develop new lead compounds;
- our ability to identify, recruit and retain key personnel;
- our commercialization, marketing and manufacturing capabilities and strategy;
- the implementation of our business model, strategic plans for our business, lead compounds and technology;
- the scalability and commercial viability of our proprietary manufacturing methods and processes;
- the rate and degree of market acceptance and clinical utility of lead compounds;
- our competitive position;
- our intellectual property position and our ability to protect our intellectual property and enforce our intellectual property rights;
- our financial performance;
- developments and projections relating to our competitors and our industry;
- our ability to establish and maintain collaborations or obtain additional funding;
- our expectations related to the use of proceeds from the offering of the IPO Shares;

- our estimates regarding expenses, future revenue, capital requirements and needs for or ability to obtain additional financing;
- the impact of laws and regulations; and
- our expectations regarding the time during which we will be an emerging growth company under the JOBS Act.

Forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in "Risk Factors" and elsewhere in this prospectus. Moreover, we operate in a very competitive and rapidly changing environment, and new risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this prospectus may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Also, forward-looking statements represent our management's beliefs and assumptions only as of the date of this prospectus. You should read this prospectus and the documents that we have filed as exhibits to the registration statement, of which this prospectus is a part, completely and with the understanding that our actual future results may be materially different from what we expect.

Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

USE OF PROCEEDS

We will not receive any proceeds from the sale of the Stockholder Shares by the Selling Stockholders pursuant to the Resale Prospectus.

DIVIDEND POLICY

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings for use in the operation of our business and do not anticipate paying any dividends on our Common Stock in the foreseeable future. Any future determination to declare dividends will be made at the discretion of our board of directors and will depend on our financial condition, operating results, capital requirements, general business conditions and other factors that our board of directors may deem relevant.

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

You should read the following discussion and analysis of our financial condition and results of operations together with the section entitled "Summary Historical Financial Data" and our financial statements and related notes appearing in this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this prospectus, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a clinical-stage biotech company focused on developing and commercializing new therapeutics to alleviate pain. Our clinical focus is to selectively target the sodium ion-channel known as "NaV1.7", as well as other receptors in the NaV family. NaV1.7 has been genetically validated as a pain receptor in human physiology. Our goal is to develop a novel and proprietary class of NaV blockers that target the body's peripheral nervous system and have demonstrated safety in a Phase 1 study with more than 100 subjects.

We observed certain incidents of rashes during the trial for which we developed a mitigation strategy that involves slower dose escalation, hospitalization and frequent physical examinations. We have developed a dose escalation study design and expect to launch patient procurement in early 2024 with expected first patient dosing in the third quarter of 2024. The dose escalation trial will enroll approximately 32 healthy volunteers who will receive CC8464 over a period of several weeks, with the dose escalation study expected to take approximately nine months. We anticipate that the slower dose escalation will decrease the likelihood of drug-related skin reactions. The primary endpoint of the dose escalation trail will be safety and tolerability of the slower dose titration; however, we will also be measuring blood concentrations of CC8464, which will allow us to better understand the pharmacokinetics of CC8464.

We are currently working on the development of the Phase 2a proof-of-concept plan and expect to launch the Phase 2a proof-of-concept study in 2024 to assess the potential efficacy of CC8464 in genetically validated EM patients. Though the Phase 2a proof-of-concept study design has not yet been completed, we expect to launch the study during the second half of 2025 and expect that the study will take approximately twelve months after it is initiated. We are anticipating dosing approximately 20 patients diagnosed with genetically validated EM. We will be using a cross-over design which has the advantage of increasing the study power while keeping the number of patients relatively low. Each patient will be exposed to both placebo and CC8464 during the two cross-over phases of the trial but neither the investigators nor the patients will know when they are receiving active drug or placebo. During each dosing period we will induce an EM flare. The primary endpoint will be the amount of pain experienced during the flare with secondary endpoints including other measurements like pain relief, time to onset of the flare and neuropathy scores. The final design may change based on feedback from the FDA or information learned during the dose escalation trial.

We were incorporated in Delaware on March 19, 2021. On August 10, 2022, we entered into the Contribution Agreement with Chromocell Holdings. Pursuant to the Contribution Agreement, as of the Contribution Date, we acquired from Chromocell Holdings all assets, liabilities and results of operations related to Chromocell Holdings' therapeutic business, including all patents, pre-clinical and Phase I study results and data, and trade secrets related to the CC8464 compound, in exchange for the issuance by us of 10,000,000 shares of Common Stock and (ii) 600,000 shares of Series A Preferred Stock.

Prior to the Contribution Date, we had only nominal assets and liabilities. Accordingly, the financial statements presented in this prospectus for periods prior to the Contribution Date have been prepared on a "carve-out" basis from the financial statements of Chromocell Holdings to represent our financial position and performance as if it had existed on a stand-alone basis. The financial statements presented in this prospectus for periods from and after the Contribution Date reflect our financial position and performance as a stand- alone entity.

All of the assets, liabilities and results of operations of the Company as of and for the periods prior to the Contribution Date were identified based on the assets acquired by the Company from Chromocell Holdings. Management believes the assumptions underlying the Company's carve-out financial statements are reasonable. Nevertheless, the financial statements may not include all of the actual expenses that would have been incurred had the Company operated as a standalone company during the periods presented, and may not reflect the Company's results of operations, financial position and cash flows had the Company operated as a standalone company during the periods presented. Actual costs that would have been incurred if the Company had operated as a standalone company would depend on multiple factors, including organizational structure and strategic decisions made in various areas, including information technology and infrastructure.

On August 2, 2023, we entered into the Holdings Side Letter to the Contribution Agreement. Pursuant to the Holdings Side Letter, upon closing of the IPO: (a) Chromocell Holdings will re-assume all $1.6 million in direct liabilities previously assumed by the Company in accordance with the Contribution Agreement, (b) Chromocell Holdings will waive the Company's obligations to make a cash payment in the amount of $0.6 million to Chromocell Holdings, and (c) in consideration thereof, we will issue to Chromocell Holdings 2,600 shares of Series C Preferred Stock.

In connection with the completion of the IPO: (A) we have effected a 1-for-9 Reverse Stock Split, (B) all 600,000 issued and outstanding shares of our Series A Preferred Stock will automatically convert into 499,429 IPO Shares, (C) $587,179 and accrued interest of $36,506 as of February 21, 2024 outstanding under our senior secured convertible notes issued in the Bridge Financings will automatically convert into 130,494 shares of Common Stock, which includes an additional 549 Bonus Shares, (D) we will issue 37,500 Standby Shares to the Standby Investor, (E) we will effect the Representative Affiliate Transactions, (F) we will effect the transactions contemplated by the Holdings Side Letter, and issue an aggregate of 2,600 shares of Series C Preferred Stock to Chromocell Holdings pursuant thereto, and (G) we will issue (i) 93,823 shares to the holder of the Investor Note and (ii) 29,167 shares to the holder of the Director Note in full satisfaction of our obligations thereunder (in the case of (A) through (C) and (G) above, based on the initial public offering price of $6.00 per IPO Share). We refer to these actions as the "IPO Transactions."

Trends and Other Factors Affecting Our Business

On December 23, 2023, we entered into the Benuvia License Agreement for the Spray Formulations, diversifying our pipeline of non-opioid pain treatment therapies, while adding therapeutic options for related conditions. The Diclofenac Spray Formulation is patented and has started clinical development in human volunteers. Preliminary pharmacokinetics suggest that this formulation may have a faster onset of action than oral Diclofenac tablets. Diclofenac is an NSAID that is also marketed under additional brand names including Voltaren and Cataflam in its pill form. Rizatriptan, whose brand name is Maxalt, is used for the acute treatment of Migraines as a pill. By a number of clinical measures it is thought to be superior to Sumatriptan. A sublingual formulation of Rizatriptan may potentially have a faster onset of action than an oral form and may be easier to tolerate than swallowing a pill when patients are experiencing nausea as a result of the migraine headache. Ondansetron is an anti-emetic that is available in oral and intravenous form. An Ondansetron sublingual spray formulation may potentially have a faster onset of action than an oral form and may be easier to tolerate than swallowing a pill when patients are experiencing nausea. Under the terms of the Benuvia License Agreement, Benuvia will be responsible for the manufacturing and supply of the Spray Formulations, but we will have exclusive, worldwide rights to develop, commercialize and distribute the Spray Formulations.

In connection with the Benuvia License Agreement, we agreed to pay Benuvia a six and one-half percent (6.5%) royalty on net sales of the Spray Formulations for a period of up to 15 years from the date of the first commercial sale of any of the Spray Formulations. In addition, on December 23, 2023, we entered into the Benuvia Stock Issuance Agreement pursuant to which we issued to Benuvia 3,458,033 shares (384,226 shares, after giving effect to the Reverse Stock Split) of our Common Stock, which may be offered and sold pursuant to the Resale Prospectus.

While we currently do not have strategy and development plans for the Spray Formulations licensed from Benuvia, beginning in the third quarter of 2024, we plan to develop clinical programs for each of the Spray Formulations, determine the labelling strategy that would be obtained from completion of these programs and discuss with the FDA the

requirements for bringing each of the Spray Formulations to market. We anticipate bringing the Spray Formulations to market through the FDA 505(b)(2) regulatory pathway for new drug applications; however, the exact details will require further consultation with the FDA.

As a result, our results of operations and balance sheets may not be indicative of future operating results or of our future financial condition.

Going Concern

For the nine months ended September 30, 2023 and 2022 and years ended December 31, 2022 and 2021, respectively, we had a net loss of $3.3 million, $1.2 million, $2.5 million, and $0.6 million, respectively, and will require significant additional capital in order to operate in the normal course of business and fund clinical studies. As a result, these conditions have raised substantial doubt regarding our ability to continue as a going concern beyond one year of the filing of our financial statements. While we believe in the viability of management's strategy to raise funds and control costs during the development stage, there can be no assurances to that effect. Our ability to continue as a going concern is dependent upon the ability to complete clinical studies and implement our business plan, raise capital, generate sufficient revenues and to control operating expenses.

Results of Operations

Comparison of the Nine Months Ended September 30, 2023 and 2022

The following table summarizes our results of operations for the nine months ended September 30, 2023 and 2022:

	For the Nine Months Ended September 30, 2023 (Unaudited)	For the Nine Months Ended September 30, 2022 (Unaudited)	$ Change	% Change
OPERATING EXPENSES				
General and administrative expenses	$ 1,677,078	$ 371,283	$ 1,305,795	352%
Research and development	285,204	97,147	188,057	194%
Professional fees	1,021,187	634,913	386,274	61%
Total operating expenses	2,983,469	1,103,343	1,880,126	170%
Loss from operations	(2,983,469)	(1,103,343)	(1,880,126)	(170)%
Other expense	(358,171)	(97,818)	(260,353)	(266)%
Net loss before provision for income taxes	(3,341,640)	(1,201,161)	(2,140,479)	(178)%
Provision for income taxes	-	-	-	NA
Net loss	$ (3,341,640)	$ (1,201,161)	$ (2,140,479)	(178)%

Operating Expenses

Our operating expenses consist of general and administrative expenses, research and development expenses and professional fees.

General and Administrative Expenses

We incurred general and administrative expenses for the nine months ended September 30, 2023 and 2022 of $1,677,078 and $371,283, respectively. For the nine months ended September 30, 2023, compared to the same period in 2022, this represented an increase of $1,305,795, or 352%, primarily as a result of increases of $941,989 in stock-based compensation.

Research and Development Expenses

We incurred research and development expenses for the nine months ended September 30, 2023 and 2022 of $285,204, and $97,147, respectively. For the nine months ended September 30, 2023, compared to the same period in 2022, this represented an increase of $188,057, or 194%, with the details set forth in the table below:

	For the Nine Months Ended September 30, 2023 (Unaudited)	For the Nine Months Ended September 30, 2022 (Unaudited)	$ Change	% Change
Consultant	$ 36,200	$ 42,850	$ (6,650)	(16)%
Lab Gas	-	5,731	(5,731)	(100)%
Lab Cell Storage	33,000	31,904	1,096	3%
IP Services	216,004	16,662	199,342	1,196%
Total	$ 285,204	$ 97,147	$ 188,057	194%

The Company incurred higher research and development expenses for the nine months ended September 30, 2023, versus the corresponding period in 2022 primarily as a result of intellectual property services in support of the patent portfolio and development of CC8464.

Professional Fees

We incurred professional expenses for the nine months ended September 30, 2023 and 2022 of $1,021,187 and $634,913, respectively. For the nine months ended September 30, 2023, compared to the same period in 2022, this represented an increase of $386,274, or 61%, as a result of higher auditing and legal expenses associated with IPO readiness activities.

Other (Expense) Income

We incurred other expense for the nine months ended September 30, 2023 of $358,171 as compared to other expense for the nine months ended September 30, 2022 of $97,818. For the nine months ended September 30, 2023, compared to the same period in 2022, this represented an increase of $260,353, or 266%. The other expense for the nine months ended September 30, 2023 was the result of interest expense and the other expense for the nine months ended September 30, 2022 was the result of the amortization of a debt discount for debt incurred in 2022 and costs incurred related to our current period debt extensions.

Comparison of the Years Ended December 31, 2022 and 2021

The following table summarizes our results of operations for the years ended December 31, 2022 and 2021:

	December 31, 2022	December 31, 2021	$ Change	% Change
Revenue	$ -	$ -	$ -	0%
General and administrative expenses	1,098,848	496,667	602,181	121%
Research and development	391,730	209,047	182,683	87%
Professional fees	827,581	133,282	694,299	521%
Total operating expenses	2,318,159	838,996	1,479,163	176%
Loss from operations	(2,318,159)	(838,996)	(1,479,163)	176%
Total other (expense) income	(140,430)	243,609	(384,039)	(158%)
Net income (loss) loss before provision for income taxes	(2,458,589)	(595,387)	(1,863,202)	313%
Provision for income taxes	-	-	-	NA
Net loss	$ (2,458,589)	$ (595,387)	$ (1,863,202)	313%

Operating Expenses

Our operating expenses consist of general and administrative expenses, research and development expenses and professional fees. Our research and development expenses primarily consist of consultants in regulatory, clinical development and CMC matters to prepare for the Phase 2 trials as well as maintenance fees for our patent portfolio plus lab material costs in connection with work for an NIH grant.

General and Administrative Expenses

Our general and administrative expenses for the years ended December 31, 2022 and 2021 were $1,098,848 and $496,667, respectively, representing an increase of $602,181, or 121%. The increase is primarily comprised of an increase of $0.1 million in stock-based compensation expenses and an increase of $0.3 million increase in payroll expenses.

Research and Development Expenses

For the years ended December 31, 2022 and 2021, we incurred research and development expenses of $391,730 and $209,047, respectively, representing an increase of $182,683 or 87%. Details of the research and development expenses are set forth in the table below:

	December 31		$	%
	2022	**2021**	**Change**	***Change***
Consultant	$ 86,802	$ 120,480	$ (33,678)	(28%)
Lab gas	13,871	$ 8,628	5,243	61%
Lab cell storage	62,197	$ 65,260	(3,063)	(5%)
CSC	3,800	$ -	3,800	100%
IP services	225,060	$ 14,679	210,381	1,433%
Total	**$ 391,730**	**$ 209,047**	**$ 182,683**	87%

The increase in research and development expenses is primarily due to an increase of $0.2 million in legal fees and maintenance costs related to the Company's patent portfolio.

Professional Fees

Professional fees for the years ended December 31, 2022 and 2021 were $827,581 and $133,282, respectively, representing an increase of $694,299, or 521%. The increase is primarily due to a greater accounting and legal services expenses in preparation for the initial public offering.

Other Income

For the years ended December 31, 2022 and 2021, we recognized $140,430 in other expense and $243,609 in other income, respectively. The other expense for the year ended December 31, 2022 was due to interest expense in the amount of $140,430 and other income for the year ended December 31, 2021 was due to gain on forgiveness of a PPP loan in the amount of $243,862, offset by interest expense of $253.

Liquidity

Sources of Liquidity and Capital

We are in our early stages of development and growth, without established records of sales or earnings. We will be subject to numerous risks inherent in the business and operations of financially unstable and early stage or emerging growth companies. We have not yet commercialized any products, and we do not expect to generate revenue from sales of any lead candidates for several years.

Cash totaled $0.0 million and $0.1 million as of September 30, 2023 and December 31, 2022, respectively. As of September 30, 2023 and December 31, 2022, we had an accumulated deficit of approximately $9.5 million and $6.1 million, respectively, and had a working capital deficit of $5.9 million and $3.7 million, respectively.

Historically, we have funded our operations from a series of cash advances from Chromocell Holdings, licensing arrangements, bridge and note issuances and grants from the National Institutes of Health.

Starting in May 2021, we received a series of advances from Chromocell Holdings that were subsequently codified in the Contribution Agreement as an equity investment, pursuant to which, the Company issued 10,000,000 shares of Common Stock and 600,000 shares of Series A Preferred Stock to Chromocell Holdings in exchange for the assets contributed by Chromocell Holdings to the Company.

On February 4, 2022, the Company entered into the Investor Note, as amended from time to time, for $450,000. The Investor Note has an original issuance discount of $150,000, a maturity date of February 3, 2023, and accrues no interest. As of September 30, 2023, the debt discount was fully amortized. On February 27, 2023, the maturity date of the Investor Note was extended to May 15, 2023, in return for the payment of monthly interest of 2% on the full value, which shall accrue, and the Holder of the Investor Note agreeing to settle the Investor Note in IPO Shares. On June 23, 2023, we entered into a side letter with the Holder of the Investor Note (the "June Investor Note Side Letter"), pursuant to which the Investor Note was further amended to extend the maturity date to August 15, 2023 and we issued to the Holder 50,000 shares of Common Stock. On August 17, 2023, we entered into a side letter with the Holder of the Investor Note (the "August Investor Note Side Letter"), which extended the maturity date to September 30, 2023 and we issued to the Holder of the Investor Note 30,000 shares of Common Stock. On September 24, 2023, we entered into an amendment to the Investor Note, which extended the maturity date to October 10, 2023. Effective October 10, 2023, we entered into a side letter with the Holder of the Investor Note (the "October Investor Note Side Letter"), which extended the maturity date to November 14, 2023 and we issued to the Holder of the Investor Note 30,000 shares of Common Stock. Effective November 13, 2023, we entered into the November Investor Note Side Letter, which further extended the maturity date to January 31, 2024 and we issued to the Holder of the Investor Note the November Leak-Out Shares. Effective January 30, 2024, we entered into the January Investor Note Side Letter, which further extended the maturity date to February 29, 2024 and we issued to the Holder of the Investor Note the January Leak-Out Shares.

On December 6, 2022, the Company and Mr. Todd Davis, one of our directors, entered into the Director Note for $175,000. The Director Note has an original issuance discount of $75,000, and matures on December 31, 2023, or, if earlier to occur, upon the closing of an underwritten offering of securities resulting in at least $15 million in gross proceeds. Mr. Davis, as lender, has the right but not the obligation to subscribe to the underwritten offering by presenting the Director Note in whole or in part to purchase such securities as legal tender therefor, on a dollar-for-dollar basis based upon the offering price of such securities to the public. The Director Note bears no interest except in the case of certain events of default. As of September 30, 2023, there was an unamortized debt discount of $17,784. On December 28, 2023, we entered into an amendment to the Director Note, which extended the maturity date to February 29, 2024.

On April 17, 2023, we entered into the April Bridge Financing for working capital purposes, with various accredited investors, all of whom are pre-existing stockholders, in the aggregate principal amount of $389,757 (together with the September Bridge Financing, the "Bridge Financings"), after giving effect to the Representative Affiliate Transactions. During the nine months ended September 30, 2023, the Company received Advances in the amount of $166,903 prior to the close of the April Bridge Financing from certain of the participating investors. Such Advances accrued interest at a rate of eight percent (8%) per annum until close of the April Bridge Financing on April 17, 2023, for a total of $1,870 in aggregate interest on all Advances. The April Bridge Financing consists of senior secured convertible notes that had a maturity date of October 17, 2023. On October 12, 2023, we entered into a first amendment to the senior secured convertible notes in the April Bridge Financing, which extended the maturity of the notes to

November 1, 2023. On October 24, 2023, we entered into a second amendment to the senior secured convertible notes in the April Bridge Financing, which extended the maturity of the notes to November 14, 2023. On November 13, 2023, we entered into a third amendment to the senior secured convertible notes in the April Bridge Financing, which further extended the maturity of the notes to February 29, 2024. Such notes accrue interest on the unpaid principal amount at a rate of eight percent (8%) per annum and will automatically convert into 87,109 shares of Common Stock in connection with the IPO at a twenty percent (20%) discount to the price per IPO Share (based on the initial public offering price of $6.00 per IPO Share). The senior secured convertible notes issued in the April Bridge Financing are secured by a security interest in all of our assets (including our patents and intellectual property licenses). In connection with the April Bridge Financing, on April 17, 2023, we also entered into a securities purchase agreement with holders of the notes, pursuant to which we are required to file a registration statement within 180 calendar days after consummation of the IPO, providing for the resale of Common Stock received by holders of the notes upon conversion of such notes.

On August 2, 2023, we entered into the Holdings Side Letter to the Contribution Agreement. Pursuant to the Holdings Side Letter, upon closing of the IPO: (a) Chromocell Holdings will re-assume all $1.6 million in direct liabilities previously assumed by the Company in accordance with the Contribution Agreement, (b) Chromocell Holdings will waive the Company's obligations to make a cash payment in the amount of $0.6 million to Chromocell Holdings, and (c) in consideration thereof, we will issue to Chromocell Holdings 2,600 shares of Series C Preferred Stock.

The Series C Preferred Stock will have a liquidation preference of $1,000 per share. Holders of the Series C Preferred Stock will not be entitled to dividends, will have no voting rights other than as required by law, will be convertible into shares of Common Stock following the IPO at the holder's option, will convert into shares of Common Stock automatically if, following the IPO, the trading price of the Common Stock exceeds certain thresholds, and will be redeemable by the Company for cash. For more information, see "Description of Capital Stock–Series C Preferred Stock."

On September 1, 2023, we entered into a bridge loan for working capital purposes, with various accredited investors, all of whom are pre-existing stockholders, in the aggregate principal amount of $197,421 (the "September Bridge Financing"), after giving effect to the Representative Affiliate Transactions. The September Bridge Financing consists of senior secured convertible notes that have a maturity date of March 1, 2024. Such notes accrue interest on the unpaid principal amount at a rate of eight percent (8%) per annum and will automatically convert into shares of Common Stock in connection with the IPO at a twenty percent (20%) discount to the price per IPO Share plus 549 Bonus Shares (43,385 shares, based on the initial public offering price of $6.00 per IPO Share). The senior secured convertible notes issued in the September Bridge Financing are secured by a security interest in all of our assets (including our patents and intellectual property licenses). In connection with the September Bridge Financing, on March 1, 2023, we also entered into a securities purchase agreement with holders of the notes, pursuant to which we are required to file a registration statement within 180 calendar days after consummation of the IPO, providing for the resale of Common Stock received by holders of the notes upon conversion of such notes. Additionally, we entered into a subordination and intercreditor agreement, effective September 1, 2023, with the holders of the senior secured convertible notes issued in the April Bridge Financing, pursuant to which those notes and certain liens of the Company will be subordinated to the rights of the holders of the notes issued in the September Bridge Financing.

In connection with the September Bridge Financing, the Company and certain holders of the senior secured convertible notes issued in the April Bridge Financing and the September Bridge Financing agreed to waive certain prohibitions in order to permit the issuance of Series C Preferred Stock and the shares of Common Stock issuable in connection with this IPO.

On October 11, 2023, we entered into a securities purchase agreement with the Standby Investor pursuant to which (i) the Standby Investor agreed to purchase, upon close of the IPO and at our election, an aggregate of up to 750 shares of Series B Preferred Stock for a purchase price of $1,000 per share, and (ii) in consideration therefor, we would issue upon close of the IPO, and regardless of whether we would have issued any shares of Series B Preferred Stock, an aggregate of 37,500 Standby Shares to the Standby Investor. In addition, pursuant to the Series B Securities Purchase Agreement, we were required to file a registration statement within 180 calendar days after consummation of the IPO, providing for the resale of the Standby Shares and shares of Common Stock issuable upon conversion of the Series B Preferred Stock, if issued. Effective November 13, 2023, we entered into the Standby Investor Side Letter, pursuant to which we (i) waived in full the Standby Investor's obligation to fund the aggregate amount to be paid for the Series B Preferred Stock to be purchased under the Series B Securities Purchase Agreement and (ii) agreed to continue to have the obligation to issue the full amount of the Standby Shares upon the closing of the IPO. We and the Standby Investor also agreed to terminate each of our obligations solely with respect to the Series B Preferred Stock under the Series B Securities Purchase Agreement and that certain Registration Rights Agreement between us and the Standby Investor, which was required to be delivered pursuant to the Series B Securities Purchase Agreement.

On October 12, 2023, we and four existing investors entered into the October Promissory Notes with an aggregate face amount of $210,000 and an aggregate purchase price of $175,000. The October Promissory Notes mature on November 12, 2023 or, if earlier to occur, upon the closing of this IPO. The October Promissory Notes bear no interest except in the case of certain events of default. On November 7, 2023, we amended and restated the October Promissory Notes to extend the maturity dates of the October Promissory Notes to November 17, 2023. On November 13, 2023, we amended and restated the October Promissory Notes to further extend the maturity dates of the Promissory Notes to February 29, 2024.

On November 22, 2023, we commenced the Rights Offering pursuant to which we distributed Subscription Rights to each holder of our Common Stock held as of the Rights Offering Record Date. The Subscription Rights could be exercised at any time during the subscription period, which commenced on November 22, 2023 and expired at 5:00 p.m., Eastern Standard Time, on December 1, 2023. Each Subscription Right entitled the eligible holder to purchase up to three shares of our Common Stock at a price per whole share of Common Stock of $0.0112. Holders who fully exercised their rights could also subscribe for additional shares of Common Stock not subscribed for by other holders on a pro rata basis. In addition, we could distribute to one or more additional persons, at no charge to such person, additional non-transferable subscription rights to purchase shares of our Common Stock in the Rights Offering at the same Subscription Price, without notice to the holders of our Common Stock. Upon the closing of the Rights Offering, we issued an aggregate of 21,982,216 shares of our Common Stock and received aggregate net proceeds of $246,201, after giving effect to the Representative Affiliate Transactions, which we intend to use primarily for general corporate purposes and expenses associated with our initial public offering.

We are negotiating an arrangement with the Holder of the Investor Note to enter into an ELOC subsequent to the IPO, pursuant to which we will have the right, but not the obligation, to sell to the Holder of the Investor Note up to $20,000,000 in newly issued shares of our Common Stock, subject to certain limitations. Pursuant to the terms of the proposed arrangement, we will pay the holder a commitment fee of $1,000,000, which may be paid at our election, in cash or shares of Common Stock, upon entry into the ELOC. In addition, we will agree to certain registration rights pursuant to which we will register the securities issuable under the ELOC subsequent to the expiration of the lock-up agreement we enter into with the Representative in connection with the IPO. We also intend to agree, during the proposed two-year term of the ELOC, to not enter into any variable, reset, or otherwise adjustable equity or equity-linked transactions. In the event we do not close the ELOC within forty-five (45) days of the consummation of this IPO and have the registration statement referred to above effective within ninety (90) days of the expiration of any IPO standstill period, we expect to be obligated to pay to the holder a break-up fee in the amount of $1,000,000 and will not be able to raise capital for sixty (60) days thereafter; provided that, we and the Holder of the Investor Note may agree to enter into other form of investments, such as a private investment in public equity transaction.

We anticipate that we will enter into a purchase agreement to issue the shares of Common Stock issuable pursuant to the ELOC subsequent to the closing of the IPO; however, as of the date hereof, an agreement with respect to our proposed ELOC has not been, and may never be, finalized and executed and there is no assurance that we will enter into an ELOC or, if we do enter into such an ELOC, that the terms thereof will be consistent with or as favorable as those described in the registration statement of which this prospectus forms a part.

On February 8, 2024, we and certain affiliates of the Representative entered into the Bridge Financing Note Amendments. Under the Bridge Financing Note Amendments, both notes issued in the April Bridge Financing and the September Bridge Financing have a maturity date of March 1, 2024, and the full principal amount of both notes and any accrued interest thereon shall be payable solely in cash upon the consummation of this IPO. Both notes have an annual interest rate of eight percent (8%), which accrues daily, and is calculated on the basis of a 360-day year (consisting of twelve 30 calendar day periods).

On February 10, 2024, we entered into the Stock Rescission Agreement with certain affiliates of the Representative, pursuant to which we rescinded 111,129 shares of our Common Stock (after giving effect to the Reverse Stock Split) held by such affiliates of the Representative and agreed to refund an aggregate of $91,512.53 paid by such affiliates of the Representative in consideration therefor within 30 days of the effective date of the Stock Rescission Agreement.

Future Funding Requirements

Our primary use of cash is to fund clinical development, operating expenses and repay accrued liabilities associated with our initial public offering.

With respect to the Company's future expected operations expenses, the primary expense drivers will be research and development and management overhead, including costs of being a public company. Of these, it is expected that research and development will be the largest expense and comprise approximately $3.0 million in the twelve months following the offering of IPO Shares pursuant to the IPO Prospectus, which will be utilized for the Company's escalation study and Phase II drug trial costs. We have based the research and development costs on current trial parameters and expectations on certain existing tax credits, and there is no certainty that the trial parameters or tax credits available to the Company will remain as they are, which could lead to changes in our research and development expenditures. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable, accrued expenses and prepaid expenses.

We expect to continue to incur significant and increasing expenses and operating losses in connection with our ongoing research and development activities. In addition, upon the closing of the IPO, we expect to incur additional costs associated with operating as a public company. As a result, we expect to incur substantial operating losses and negative operating cash flows for the foreseeable future.

Based on our current operating plan, we believe that the net proceeds from the IPO pursuant to the IPO Prospectus, together with our existing cash, will be sufficient to fund our operations and capital expenses through the end of 2024. However, we have based this estimate on assumptions that may prove to be incorrect, and we could exhaust our capital resources sooner than we expect.

We may also raise additional funding through strategic relationships, public or private equity or debt financings, credit facilities, grants or other arrangements. If such funding is not available or not available on terms acceptable to us, our current development plan and plans for expansion of our general and administrative infrastructure may be curtailed. If we raise additional funds through the issuance of preferred stock, convertible debt securities or other debt financing, these securities or other debt could contain covenants that restrict our operations. Any other third- party funding arrangement could require us to relinquish valuable rights.

The source, timing and availability of any future financing will depend principally upon market conditions. Funding may not be available when needed, at all, or on terms acceptable to us. Lack of necessary funds may require us to, among other things, delay, scale back or eliminate expenses including some or all of our planned development. There is substantial doubt about our ability to continue as a going concern.

Cash Flows

The following table summarizes our cash flows for the nine months ended September 30, 2023 and 2022:

	For the Nine Months Ended September 30, 2023	For the Nine Months Ended September 30, 2022	$ Change	% Change
	(Unaudited)	(Unaudited)		
Net cash used in operating activities	$ (624,224)	$ (900,531)	$ 276,307	(31)%
Net cash used in investing activities	-	-	-	-
Net cash provided by financing activities	591,936	1,073,771	(481,835)	(45)%
Net (decrease) increase in cash	$ (32,288)	$ 173,240	$ (205,528)	(119)%

The following table summarizes our cash flows for the year ended December 31, 2022 and 2021:

	December 31, 2022	December 31, 2021	$ Change	% Change
Net cash used in operating activities	(1,567,149)	(1,593,011)	25,862	(2%)
Net cash used in investing activities	-	-	-	-
Net cash provided by financing activities	1,622,223	1,593,011	29,212	2%
Net increase in cash	55,074	-	55,074	100%

Net Cash Used in Operating Activities

For the nine months ended September 30, 2023, we incurred a net loss of $3,341,640, and net cash flows used in operating activities was $624,224. The cash flow used in operating activities was primarily due to a net loss of $3,341,640, offset by stock-based compensation expense of $941,989, a change in account payable and accrued expense of $1,166,880, share issuance cost associated with the extension of the bridge loan in the amount of $201,600 and an increase in accrued compensation in the amount of $340,161.

For the nine months ended September 30, 2022, we incurred a net loss of $1,201,161, and net cash flows used in operating activities was $900,531. The cash flow used in operating activities was due to a net loss of $1,201,161, offset by a change in amortization of debt discount of $97,818 and an increase in accrued compensation in the amount of $120,481.

For the year ended December 31, 2022, we incurred a net loss of $2,458,589, and net cash flows used in operating activities was $1,567,149. The cash flow used in operating activities resulted from the net loss of $2,458,589, primarily offset by $110,146 in stock-based compensation expenses, $140,430 of debt discount amortization, an increase in accounts payable and accrued expenses of $413,603 and an increase in accrued compensation of $221,875.

For the year ended December 31, 2021, we incurred a net loss of $595,387, and net cash flows used in operating activities was $1,593,011. The cash flow used in operating activities was primarily due to a change in account payable and accrued expense of $827,703 and the forgiveness of the PPP loan in the amount of $241,793.

Net Cash (Used in) Provided by Investing Activities

The Company neither received nor used cash in investing activities during the nine months ended September 30, 2023 and 2022, and for the years ended December 31, 2022 and 2021.

Net Cash Provided by Financing Activities

For the nine months ended September 30, 2023, net cash flows provided by financing activities were $591,936 resulting from proceeds from loans, with $410,928 of that amount derived from related parties.

For the nine months ended September 30, 2022, net cash flows provided by financing activities were $1,073,771, primarily consisting of cash received from a bridge loan in the amount of $300,000 and an advance from Chromocell Holdings, net of contribution, in the amount of $773,771.

For the year ended December 31, 2022, net cash flows provided by financing activities were $1,622,223, consisting of cash received from an advance by Chromocell Holdings in the amount of $800,050, cash transfers from Chromocell Holdings to the Company in the amount of $422,173 and total net proceeds from the issuance of two notes in the amount of $400,000.

For the year ended December 31, 2021, net cash flows provided by financing activities were $1,593,011, consisting of cash received from an advance by Chromocell Holdings in the amount of $1,099,950 and cash transfers from Chromocell Holdings to the Company in the amount of $493,061.

Off-Balance Sheet Arrangements

During the nine months ended September 30, 2023 and 2022 and the years ended December 31, 2022 and 2021, we did not have, and we do not currently have, any off-balance sheet arrangements, as defined under applicable SEC rules.

Critical Accounting Estimates

The following discussions are based upon our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States.

The preparation of these financial statements requires management to make estimates, judgments and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosures of contingencies. We continually evaluate the accounting policies and estimates used to prepare the financial statements. We base our estimates on historical experiences and assumptions believed to be reasonable under current facts and circumstances. Actual amounts and results could differ from these estimates made by management.

See Note 3 – Summary of Significant Accounting Policies to the accompanying financial statements for a detailed description of our significant accounting policies.

Income Taxes

We are subject to income taxes in the U.S. Significant judgment is required in determining income tax expense, deferred taxes and uncertain tax positions. The underlying assumptions are also highly susceptible to change from period to period. In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some or all the deferred tax assets will be realized. The ultimate realization of deferred taxes assets is dependent upon generation of future taxable income during the period in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, projected future taxable income, and taxable income in carryback years and tax-planning strategies when making this assessment. There is currently significant negative evidence which contributes to our recording a valuation allowance against our deferred tax assets due to cumulative losses since inception.

Although we believe our assumptions, judgments, and estimates are reasonable, changes in tax laws or our interpretation of tax laws and the resolution of any tax audits could significantly impact the amounts provided for income taxes in our consolidated financial statements. The effect on deferred tax assets and liabilities from a change in tax rates is recognized in income in the period that includes the enactment date. Adjustments to income tax expense, to the extent we establish a valuation allowance or adjust the allowance in a future period, could have a material impact on our financial condition and results of operations.

The critical accounting estimates below do not represent a material estimate in the preparation of our financial statements.

Recently Issued and Adopted Accounting Pronouncements

In December 2019, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update, or ASU, No. 2019-12, Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes, or ASU 2019-12, which is intended to simplify various aspects related to accounting for income taxes. ASU 2019-12 removes certain exceptions to the general principles in Topic 740 and also clarifies and amends existing guidance to improve consistent application. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020, with early adoption permitted. The adoption of ASU 2019-12 did not have a material effect on the Company's financial statements.

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments – Credit Losses (Topic 326) Measurement of Credit Losses on Financial Instruments (ASU 2016-13), which requires an entity to utilize a new impairment model known as the current expected credit loss (CECL) model to estimate its lifetime "expected credit loss" and record an allowance that, when deducted from the amortized cost basis of the financial assets and certain other instruments. ASU 2016-13 requires a cumulative effect adjustment to the balance sheet as of the beginning of the first reporting period in which the guidance is effective. In November 2019, the FASB issued ASU 2019-10, Financial Instruments—Credit Losses (Topic 326), Derivatives and Hedging (Topic 815) and Leases (Topic 842): Effective Dates, which defers the effective date of ASU 2016-13 to fiscal years beginning after December 15, 2022 for all entities except SEC reporting companies that are not smaller reporting companies. ASU 2016-13 became effective for the Company beginning January 1, 2023. The adoption of this ASU did not have a material effect on the Company's financial statements.

In August 2020, the FASB issued ASU 2020-06, which simplifies the guidance on the issuer's accounting for convertible debt instruments by removing the separation models for convertible debt with a cash conversion feature and convertible instruments with a beneficial conversion feature. As a result, entities will not separately present in equity an embedded conversion feature in such debt and will account for a convertible debt instrument wholly as debt, unless certain other conditions are met. The elimination of these models will reduce reported interest expense and increase reported net income for entities that have issued a convertible instrument that is within the scope of ASU 2020-06. Also, ASU 2020-06 requires the application of the if-converted method for calculating diluted earnings per share and treasury stock method will be no longer available. ASU 2020-06 is applicable for fiscal years beginning after December 15, 2022, with early adoption permitted no earlier than fiscal years beginning after December 15, 2020. The Company does not intend to early adopt, and continues to evaluate the impact of the provisions of ASU 2020-06 on its consolidated financial statements.

The FASB issues ASUs to amend the authoritative literature in ASC. There have been several ASUs to date, including those above, that amend the original text of ASC. Management believes that those issued to date either (i) provide supplemental guidance, (ii) are technical corrections, (iii) are not applicable to us or (iv) are not expected to have a significant impact on our financial statements.

Other accounting standards that have been issued or proposed by FASB and do not require adoption until a future date are not expected to have a material impact on the consolidated financial statements upon adoption. Management does not believe that any other recently issued, but not yet effective, accounting standard if currently adopted would have a material effect on the accompanying financial statements.

BUSINESS

Overview

We are a clinical-stage biotech company focused on developing and commercializing new therapeutics to alleviate pain. Our clinical focus is to selectively target the sodium ion-channel known as "NaV1.7", as well as other receptors in the NaV family. NaV1.7 has been genetically validated as a pain receptor in human physiology. Genetic studies have shown that families with a certain inherited NaV1.7 modulation consistently show a pathology of not feeling pain. A strong correlation between such inherited NaV1.7 modulation and EM patients who suffer from burning pain in their hand and feet was confirmed in a separate study that was reported in the Journal of Clinical Investigation. The study assessed the pattern of pain, natural history, somatosensory profile, psychosocial status and olfactory testing in patients with primary inherited erythromelalgia with mutations of SCN9A, the gene encoding Na(v)1.7. All subjects reported pain and heat in the extremities (usually feet and/or hands), with pain attacks triggered by heat or exercise and relieved mainly by non-pharmacological maneuvers such as cooling. A NaV1.7 blocker is a chemical entity that modulates the structure of the sodium-channel in a way to prevent the transmission of pain perception to the CNS. Our goal is to develop a novel and proprietary class of NaV blockers that target the body's peripheral nervous system, initially EM, a rare condition that primarily affects the feet and, less commonly, the hands (extremities). It is characterized by intense, burning pain of affected extremities, severe redness (erythema), and increased skin temperature that may be episodic or almost continuous in nature.

According to Mordor Intelligence, the global pain management market was valued at approximately $67 billion in 2021, and it is expected to have revenues of $89 billion in 2027, with a CAGR of 4.65% over the forecast period. Also, according to Mordor Intelligence, the United States has the largest market for pain management pharmaceuticals and Asia-Pacific is the region showing the strongest growth. North America holds the largest share in the pain management market, with the United States being the most significant contributor to its revenue. According to data published by the Centers for Disease Control and Prevention ("CDC"), in 2019, 20.4% of adults had chronic pain, and 7.4% of adults had chronic pain that had limited work and daily activities frequently. Additionally, according to the CDC, chronic pain increased with age, and the highest level was reported in patients aged 65 years and above. The prescription pain management market in the United States is still largely dominated by opioid analgesics. Opioid analgesics decrease the perception of pain by stimulating a range of opioid receptors that modulate pain signals. The most widely used opioid analgesics, including morphine, fentanyl and hydromorphone, act primarily through the activation of mu opioid receptors in the CNS. However, because of the wide distribution of mu opioid receptors throughout the brain, morphine and other mu opioid analgesics also trigger a characteristic pattern of adverse side effects, in particular severe abuse and addiction.

The global pain market reflects total revenues of drugs mitigating different types of pain, such as backpain, osteoarthritis, post-operative pain and various orphan diseases with pain symptoms. Our current research is focused on EM; correspondingly, our commercial efforts are targeting the potential for EM therapeutics within the overall pain market. According to studies quoted by The Erythromelalgia Association, estimates of the incidence rate for EM vary from 1.3 to 15 per 100,000 persons, reflecting a potential EM patient population from 5,000 to 50,000 in the U.S. Our lead compound, CC8464, could possibly have applications in pain mitigation outside of EM, but neither biological nor clinical studies have provided sufficient data to enable meaningful predictions on the probability of an expanded range of indications.

CC8464 is designed to address both the underlying condition and mitigate the burning pain symptoms that EM patients experience by blocking the NaV1.7 sodium channel. Genetic studies presented in the Journal of Clinical Investigation have established a correlation between particular mutation in the NaV1.7 gene and the occurrence of EM where patients suffer from burning pain in their hand and feet. The study assessed the pattern of pain, and other criteria in patients with primary inherited erythromelalgia with mutations of SCN9A, the gene encoding Na(v)1.7. All subjects reported pain and heat in the extremities (usually feet and/or hands), with pain attacks triggered by heat or exercise and relieved mainly by non-pharmacological maneuvers such as cooling. Based on the correlation between the mutations and frequency of EM occurrence, we believe CC8464 has the potential to address the underlying condition and mitigate the burning pain symptoms that patients experience. The chemical characteristics of CC8464 restrict its entry into the CNS and limit its effect to the NaV1.7 receptors in the peripheral nervous system, which consists of the nerves outside the brain and spinal cord. Activation of other receptors in the CNS can result in side effects, including addiction and other psychiatric disorders. Since CC8464 is designed to modulate pain signals without activation of receptors in the CNS, it is not expected to produce psychiatric side effects. Based on its characteristics, preclinical studies (described below) and the Phase 1 study we have completed to date, we believe that our lead compound CC8464, if approved, could become an attractive option for both patients and physicians as a treatment for moderate-to-severe pain in EM.

We observed certain incidents of rashes during the trial for which we developed a mitigation strategy that involves slower dose escalation, hospitalization and frequent physical examinations. We have developed a dose escalation study design and expect to launch patient procurement in early 2024 with expected first patient dosing in the third quarter of 2024. The dose escalation trial will enroll approximately 32 healthy volunteers who will receive CC8464 over a period of several weeks, with the dose escalation study expected to take approximately nine months. We anticipate that the slower dose escalation will decrease the likelihood of drug-related skin reactions. The primary endpoint of the dose escalation trail will be safety and tolerability of the slower dose titration; however, we will also be measuring blood concentrations of CC8464, which will allow us to better understand the pharmacokinetics of CC8464.

We are currently working on the development of the Phase 2a proof-of-concept plan and expect to launch the Phase 2a proof-of-concept study in 2024 to assess the potential efficacy of CC8464 in genetically validated EM patients. Though the Phase 2a proof-of-concept study design has not yet been completed, we expect to launch the study during the second half of 2025 and expect that the study will take approximately twelve months after it is initiated. We are anticipating dosing approximately 20 patients diagnosed with genetically validated EM. We will be using a cross-over design which has the advantage of increasing the study power while keeping the number of patients relatively low. Each patient will be exposed to both placebo and CC8464 during the two cross-over phases of the trial but neither the investigators nor the patients will know when they are receiving active drug or placebo. During each dosing period we will induce an EM flare. The primary endpoint will be the amount of pain experienced during the flare with secondary endpoints including other measurements like pain relief, time to onset of the flare and neuropathy scores. The final design may change based on feedback from the FDA or information learned during the dose escalation trial.

We are evaluating whether to conduct the dose escalation and proof-of-concept studies outside of the U.S. to take advantage of beneficial tax credits or lower costs. One example is Australia, which has a 43.5% tax credit for clinical expenses incurred in Australia. Data from clinical trials conducted in Australia is accepted by the FDA.

If approved, we believe that CC8464 could provide pain and symptom relief for EM patients. CC8464 is currently the only compound that we have advanced into clinical development.

In addition, there is scientific evidence that the NaV1.7 receptor is present on the cornea and may be a viable biological target for treating eye pain. Eye pain may occur with various conditions, including severe dry eye disease, trauma and surgery. Existing therapies for eye pain (such as steroids, topical non-steroidal anti-inflammatory agents, lubricants, local anesthetics) are limited in their effectiveness and/or limited in the duration that they may be prescribed because of safety issues. We intend to explore the viability of developing CC8464 as a topical agent for the relief of eye pain. A potential advantage of this approach is that topical administration of CC8464 is unlikely to lead to any hypersensitivity or skin reactions, like what was noted with systemic administration of CC8464, because the systemic absorption from a topical administration would be extremely limited. We have commenced development of a topical ophthalmic formulation of CC8464 that would initially be utilized for toxicology and in vivo studies and then followed by a proof-of-concept trial in patients suffering from various conditions, including severe dry eye disease, trauma and surgery. We expect the trials for this ophthalmic formulation of CC8464 to start in the third quarter of 2024.

We may further expand our pipeline with other internal or external compounds in the future, but all other internally discovered compounds are pre-clinical and no commercial discussions about in-licensing have been initiated to date, other than as disclosed herein with respect to the licensing of the Spray Formulations.

On December 23, 2023, we entered into the Benuvia License Agreement for the Spray Formulations, diversifying our pipeline of non-opioid pain treatment therapies, while adding therapeutic options for related conditions. The Diclofenac Spray Formulation is patented and has started clinical development in human volunteers. Preliminary pharmacokinetics suggest that this formulation may have a faster onset of action than oral Diclofenac tablets. Diclofenac is an NSAID that is also marketed under additional brand names including Voltaren and Cataflam in its pill form. Rizatriptan, whose brand name is Maxalt, is used for the acute treatment of Migraines as a pill. By a number of clinical measures it is thought to be superior to Sumatriptan. A sublingual formulation of Rizatriptan may potentially have a faster onset of action than an oral form and may be

easier to tolerate than swallowing a pill when patients are experiencing nausea as a result of the migraine headache. Ondansetron is an anti-emetic that is available in oral and intravenous form. An Ondansetron sublingual spray formulation may potentially have a faster onset of action than an oral form and may be easier to tolerate than swallowing a pill when patients are experiencing nausea. Under the terms of the Benuvia License Agreement, Benuvia will be responsible for the manufacturing and supply of the Spray Formulations, but we will have exclusive, worldwide rights to develop, commercialize and distribute the Spray Formulations and we will purchase the Spray Formulations exclusively from Benuvia, pursuant to a marketing and supply agreement to be negotiated in the future (the "Benuvia Supply Agreement"). The initial sale price per unit for each Spray Formulation payable by us to Benuvia pursuant to the Benuvia Supply Agreement shall be subject to good faith negotiations; provided that the initial price for each Spray Formulation and the price for each Spray Formulation during the term of the Benuvia License Agreement in no event shall be less than Benuvia's cost of manufacturing the respective Spray Formulation plus a gross margin to Benuvia. The price for each Spray Formulation shall be subject to an annual increase in amounts equal to the percentage change in the Producer Price Index, Pharmaceutical Preparations as published by the U.S. Department of Labor, Bureau of Labor Statistics.

In connection with the Benuvia License Agreement, we agreed to pay Benuvia a six and one-half percent (6.5%) royalty on net sales of the Spray Formulations for a period of up to 15 years from the date of the first commercial sale of any of the Spray Formulations. To date, we have paid $0 to Benuvia as royalty on net sales of the Spray Formulations. In addition, on December 23, 2023, we entered into the Benuvia Stock Issuance Agreement pursuant to which we issued to Benuvia 3,458,033 shares (384,226 shares, after giving effect to the Reverse Stock Split) of our Common Stock, which may be offered and sold pursuant to the Resale Prospectus.

While we currently do not have strategy and development plans for the Spray Formulations licensed from Benuvia, beginning in the third quarter of 2024, we plan to develop clinical programs for each of the Spray Formulations, determine the labelling strategy that would be obtained from completion of these programs and discuss with the FDA the requirements for bringing each of the Spray Formulations to market. We anticipate bringing the Spray Formulations to market through the FDA 505(b)(2) regulatory pathway for new drug applications; however, the exact details will require further consultation with the FDA.

Our Strategy

We are a clinical-stage pharmaceutical company focused on non-opioid pain blockers in the NaV space. Our development programs are initially designed to address the underlying condition and mitigate the burning pain symptoms in EM. Based on genetic studies, several academic and clinical scientists have suggested that NaV1.7 could be a promising target to address EM. Studies presented in the Journal of Clinical Investigation show a correlation between a genetic mutation (SCN9A) and the expression of the disease phenotype in EM patients. The study assessed the pattern of pain, natural history, somatosensory profile, psychosocial status and olfactory testing of 13 subjects with primary inherited erythromelalgia with mutations of SCN9A, the gene encoding Na(v)1.7. All subjects reported pain and heat in the extremities (usually feet and/or hands), with pain attacks triggered by heat or exercise and relieved mainly by non-pharmacological maneuvers such as cooling. Quantitative sensory testing revealed significantly increased detection thresholds for cold and warm stimuli at affected, compared to unaffected sites of the body. By contrast, significantly decreased cold and heat pain thresholds were found at unaffected sites of the body. The NIH database of rare diseases specifically mentions the genetic causation of EM in patients with the SCN9A gene, which encodes for the NaV1.7 sodium channel. Our first aim is to assess CC8464's potential as a drug for EM patients that have a genetic disposition to develop the phenotype.

The therapeutic benefit of CC8464 will, among other factors, be determined by its potency and selectivity. The potency reflects the compound's effect in blocking the NaV1.7 channel. The selectivity is the absence of effects in blocking other, similar channels (e.g. NaV1.5) that could cause undesirable side effects. We conducted *in vitro* and *in vivo* studies described in more detail below that showed both a high potency and selectivity of CC8464. While positive results of *in vitro* and *in vivo* studies do not necessarily translate into human studies, we believe that the consistency of results in various *in vivo* models (rat, mouse, mini-pig) supports the projection of a potential positive outcome in clinical studies.

CC8464 is a potent inhibitor of the inactivated state of the human NaV1.7. We measured with our electrophysiology equipment the difference in affinity between cells with and without CC8464 added *in vitro*. The results showed that the compound preferentially inhibits the inactivated state of the channel with 1000-fold higher affinity as compared to the resting state. Injury or chronic inflammation is associated with persistent neuronal depolarization that shifts hNaV1.7 channels to the inactivated state. Therefore, CC8464 may preferentially affect injured or inflamed tissues while having minimal effect on the hNaV1.7 channels in uninjured/healthy tissues. CC8464 displays high target selectivity and a favorable in vitro cardiac safety profile (*in vitro* electrophysiology experiments where we measured differences between cells with and without CC8464 added showed a>1,000-fold selectivity for human NaV1.7 over human NaV1.5, hERG and human CaV1.2 ion channel receptors). Further, a canine cardiovascular and respiratory *in vivo* study where vital signs of canines were monitored after administering CC8464 showed no adverse findings. CC8464 demonstrated minimal activity against a broad array of potential targets and off-targets with only one confirmed IC50 less than 10 μM (κ-opioid receptor agonist). At predicted therapeutic doses, there is >100-fold selectivity for hNaV1.7 over the κ-opioid receptor. In vivo, CC8464 selectivity may be augmented by a lack of exposure in the central nervous system. In an *in vivo* tissue distribution study in rats all of the tissues in the central nervous system did not have measurable concentrations of CC8464-derived radioactivity at any time point post-dose. Behavioral effects potentially attributable to the CNS have not been observed in animals. There were no CC8464 related effects on any parameter in the functional observational battery evaluation conducted as a part of the 28-day repeat dose study in rats. In a streptozotocin-induced diabetic neuropathy model, wherein rats self-administered CC8464, there was no increase in intake in up to 8 weeks of dosing. There was no evidence of motor/balance impairments on observational measurements in the foot-fault test, where motoric/balance impairments are monitored *in vivo* after administering CC8464. Also, no immobility or lethargy observations were reported in cage side observations in any of the nonclinical efficacy studies performed. CC8464 has shown statistically significant efficacy in reversing pain in several nonclinical neuropathic and inflammation induced pain models, where motoric/balance impairments were monitored *in vivo* by comparing results from animal cohorts and preventing the emergence of neuropathic pain in neuropathic pain models. CC8464 has been shown to reverse thermal and mechanical hyperalgesia, spontaneous pain and tactile allodynia in these models. The reversal of hyperalgesia endpoints follows the pharmacokinetics of CC8464 in plasma. The reversal of tactile allodynia in rats was more gradual and disassociated from the pharmacokinetics, but the therapeutic effect is comparable to the effect on hyperalgesia endpoints and is sustained for some time after the cessation of treatment. There was no tachyphylaxis observed on efficacy parameters after repeated dose administration in the partial sciatic nerve ligation ("PSNL") and streptozotocin-induced diabetic neuropathy models.

The Phase 2a results will have significance beyond EM and provide important insights about NaV1.7 as a potential target to find novel pain medications as an alternative to opioids, the continuing primary standard of care in analgesics. Despite the societal cost of opioids, no fundamental commercially available breakthroughs have been achieved in pain management over the past decades. We believe that positive results from the Phase 2a study could not only act as support for CC8464's potential in EM but may also provide guidance of its potential for other indications of peripheral neuropathic pain. The key elements of our strategy to achieve our mission are:

- ***Advance the development of our lead candidate, CC8464, towards FDA approval for treating EM.*** Based on its pre-clinical profile, the target validation and trends seen with other NaV1.7 blockers in clinical studies, if approved by the FDA, we believe that CC8464 has the potential to become a drug for treatment of EM patients, potentially delivering meaningful clinical benefits over the currently available standard of care.

- ***Conduct in vivo and toxicology studies of CC8464 for the treatment of eye pain.*** According to a presentation at the Association for Research in Vision and Ophthalmology, with the abstract published in the publication, Investigative Ophthalmology and Visual Science in June 2020, there is evidence that the NaV1.7 receptor is present on the cornea and may be a viable biological target for treating eye pain. As such, we intend to conduct in vivo and toxicology studies on the treatment of eye pain with CC8464 as a topical agent. We have commenced development of a topical ophthalmic formulation of CC8464 that would initially be utilized for toxicology and in vivo studies and then followed by a proof-of-concept trial in patients suffering from various conditions including severe dry eye disease, trauma and surgery. We expect the trials for this ophthalmic formulation of CC8464 to start in the third quarter of 2024.

- ***Leverage our differentiated research and discovery approach to expand our pipeline.*** We plan to build a pipeline of potential pain blockers acting against sodium-channels related to NaV1.7. Pain modulation is complex, and a multitude of physiological mechanisms are involved in transmitting pain signals. Other than NaV1.7, we believe that several related sodium channels, e.g., NaV1.8 or NaV1.6, may be involved in pain sensation. While NaV1.7 is the most validated pain receptor, we believe that blockers against other sodium channels may complement CC8464 as our primary pain blocking candidate.

- ***Build a leading, fully integrated pharmaceutical company to maximize the clinical impact and value of our pipeline and deliver value to stockholders.*** We plan to build an experienced team to rapidly advance compounds in a capital-efficient manner. We intend to retain the commercialization rights to lead compounds; however, we may opportunistically enter into strategic collaborations in certain geographic or clinical settings to maximize the value of our pipeline.

We believe our strategy will allow us to minimize risk and expenses by maintaining an initial focus on CC8464 and EM.

While we currently do not have strategy and development plans for the Spray Formulations licensed from Benuvia, beginning in the third quarter of 2024, we plan to develop clinical programs for each of the Spray Formulations, determine the labelling strategy that would be obtained from completion of these programs and discuss with the FDA the requirements for bringing each of the Spray Formulations to market. We anticipate bringing the Spray Formulations to market through the FDA 505(b)(2) regulatory pathway for new drug applications; however, the exact details will require further consultation with the FDA.

Our Lead compound: CC8464 for the Treatment of EM

CC8464 is our lead compound for the treatment of EM.

Background on EM

EM is a condition characterized by episodes of pain, redness, and swelling in various parts of the body, particularly the hands and feet. These episodes are usually triggered by increased body temperature, which may be caused by exercise or entering a warm room. Ingesting alcohol or spicy foods may also trigger an episode. Wearing warm socks, tight shoes, or gloves can cause a pain episode so debilitating that it can impede everyday activities such as wearing shoes and walking. Pain episodes can prevent an affected person from going to school or work regularly. Strong cases are debilitating for patients and suicidal tendencies in these patients emphasize the urgent medical need in this field.

The signs and symptoms of EM typically begin in childhood, although mildly affected individuals may have their first pain episode later in life. As individuals with EM get older and the disease progresses, the hands and feet may be constantly red, and the affected areas can extend from the hands to the arms, shoulders and face, and from the feet to the entire legs.

EM is often considered a form of peripheral neuropathy because it affects the peripheral nervous system, which connects the brain and spinal cord to muscles and to cells that detect sensations such as touch, smell and pain.

Prevalence

According to Transparency Market Research:

- EM is a rare condition that primarily affects feet and hands. It is characterized by intense, burning pain of affected extremities, severe redness (erythema), and increased skin temperature that may be episodic or almost continuous in nature.

- The specific cause of EM remains unknown. EM is caused by a mutation of the NaV1.7 gene and may also result of vasomotor abnormalities or dysfunction in the normal narrowing and widening of the diameter of certain blood vessels, leading to abnormalities of blood flow to the extremities.

- Females are more affected than males. Disorder onset occurs most commonly in middle age; however, associated symptoms may develop at any age. Terminology is not uniform in EM, but certain terms have gained a certain level of general acceptance. With this caveat, EM is of two types: primary EM and secondary EM. Primary EM is caused by a genetic mutation, while secondary EM is likely caused by another disease, such as diabetes or myelodysplasia. Also relevant is the difference between EM cases where a known genetic variation has at least partially caused the illness and cases where it is unknown what underlying genetic variation, if any, caused EM.

Existing Treatment Options

The current standard-of-care for patients with EM is limited to symptom management. However, according to a case report published in the Journal of Pain Medicine, more than 50% of EM patients report that over-the-counter medications did not effectively address the symptoms. In severe cases, opioids may be the only available treatment option and are accompanied by well-known risks and liabilities. Further, there is a lack of guidelines available on how it should be optimally managed. Current EM treatments are regarded as ineffective, risky, or both.

CC8464's Unknown Mechanism of Action

The mechanism of action for EM is unknown. According to the National Institutes of Health, mutations of NaV1.7 are a leading cause for EM but it remains unclear why this defect leads to the observed phenotype. It is also unclear whether other sodium-channels or causes other than genetic mutations influence the development of EM.

Our initial focus for CC8464 is evaluating its potential therapeutic benefit to treat EM patients. While we do not know the mechanism of action, we believe the empirical correlation between the SCN9A genetic mutation and disease is a hypothesis to develop CC8464 as a potential drug to mitigate EM for patients with a genetic disposition, however, we will also evaluate CC8464 for secondary EM patients as part of our study.

CC8464 Current Study Results

CC8464 has undergone a Phase 1 study. The study was not powered for statistical significance and no p-values are available. The result showed that CC8464 has a good overall tolerability but may cause rashes in certain patients. The occurrence of rashes is not uncommon in the class of molecules to which CC8464 belongs. A dose-escalation-regime is a standard method used in pharmaceutical drug development to mitigate rashes as a side effect. We believe that a dose-escalation-regime could reduce the occurrence of rashes to a tolerable level for CC8464. We plan to conduct a dose-escalation-study to potentially validate the concept and establish a prescription regime for patients that minimizes the risk of rashes. Even though the FDA has in the past approved drugs that listed rashes as a potential side effect, we do not know if CC8464 will be approved by the FDA (or any foreign authority) in view of its potential to cause rashes.

Currently a total of 207 healthy subjects have been dosed in four Phase 1 studies (CC8464-1001, CC8464-1002, CC8464-1003, and 1807-CL-0102) with study treatment. The studies were sponsored by Chromocell Holdings. A Phase 1 study investigating safety, tolerability and pharmacokinetics of single and multiple ascending doses of CC8464 in healthy volunteers has been conducted and the data base has been locked (Study Protocol CC8464-1001). CC8464-1002 and CC8464-1003 were relative bioavailability studies in healthy volunteers to support new formulations. CC8464 was, in general, well tolerated in these Phase 1 studies (CC8464-1001, CC8464-1002, CC8464-1003) when administered to healthy volunteers as a single dose up to 1800 mg or over 14 days of once a day dosing up to 1200 mg. Skin rash, the only clinically relevant safety finding, was seen in a total of six (6) out of the 159 subjects dosed with CC8464 in these Phase 1 studies (CC8464-1001, CC8464-1002, CC8464-1003).

Following clinical completion of the studies CC8464-1001, CC8464-1002, and CC8464-1003, the drug-drug interaction (DDI) study 1807-CL-0102 was initiated to examine the effect of CC8464 on the PK and Pharmacodynamics (PD) of warfarin, a CYP2C9 substrate. This was the first study with a BID dosing regimen (CC8464 400 mg BID daily for two weeks) which had greater accumulation than expected. Thirteen out of eighteen (13/18) subjects dosed with CC8464 reported rash in this open label drug-drug interaction study. Clinical presentation and resolution of the rashes reported in study 1807-CL-0102 were consistent with the rash cases from CC8464-1001 except for a single case of a severe skin reaction requiring IV corticosteroid therapy (SAE). All reported skin rashes in study 1807-CL-0102 resolved within days of treatment discontinuation without sequalae.

Overview of Studies – CC8464

Study ID/ Location	Study Title	Study Design	Dosing Regimen	Study Population	FPFV*	Planned Enrollment	Subject exposure
CC8464-1001 (USA)	A Randomized, Double Blind, Placebo Controlled, Single Ascending Dose and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of Oral Doses of CC8464 in Normal Healthy Subjects with Food Effect Assessment	SAD/MAD	SAD: 30, 120, 300, 600, 1200, 1800, or 2400 mg QD on Day 1. MAD: 120, 300, 600, 1200, 1800 or 2400 mg QD on Days 1-14.	Healthy Volunteers	September 13, 2016	206	125
CC8464-1002 (USA)	A Phase 1 Crossover Study to Assess the Relative Bioavailability of CC8464 following a Single Dose of Melt Granulation Capsule Compared to a Single Dose of Encapsulated Suspension in Normal Healthy Subjects with a Food Effect Assessment	Cross-over	200 mg Melt Granulation Capsule (fed and fasted) vs 200 mg Suspension Capsule (fasted)	Healthy Volunteers	July 31, 2017	24	24
CC8464-1003 (USA)	A Single-Dose, Open-Label, Five-Period, Randomized, Crossover Study to Compare the Relative Bioavailability and Dose Proportionality Between Two Formulations and 3 Dosage Strengths of CC8464 in Healthy Volunteers	Cross-over	50 mg, 100 mg and 400 mg of CC8464 Melt Granulation Tablet (Fed and Fasted) vs 2x200 mg of Melt Granulation Capsules	Healthy Volunteers	February 5, 2018	40	40
1807-CL-0102 (USA)	A Phase 1 Study to Evaluate the Effect of Multiple Doses of CC8464 (ASP1807) on the Pharmacokinetics and Pharmacodynamics of Warfarin in Healthy Subjects	Drug-Drug Interaction	Single doses of 5mg Warfarin tablets will be taken on days 1 and 15. 400mg of CC8464 BID will begin on Day 8 and continue until 6 days after the second dose of Warfarin is taken, for a total of 14 days	Healthy Volunteers	May 16, 2018	18	18

* FPFV = first patient first visit

CC8464 Phase 2a Trials

Genetic studies have established a correlation between a mutation in the SCN9A gene and the expression of the EM phenotype in EM patients. Our initial focus in the development plan for CC8464 is assessing its therapeutic use for EM patients with such genetic disposition. We plan to conduct two key studies as part of our Phase 2a clinical trials. First, we will conduct a dose escalation study ("DES") with healthy volunteers, where we determine the maximum tolerated dose ("MTD") for CC8464 and the pace of increasing the dosage towards MTD and minimal risk of rashes. Second, we will conduct a proof of concept ("POC") study, where we induce mild to moderate flares by exposing patients' hands to cold water and record the self-assessment of patients regarding perception of pain on the 1-10 pain scale. The POC will be conducted as a double-blinded, placebo-controlled study with 20 patients.

Our Addressable Market

Based on a study published in the *International Journal of Vascular Medicine*, our lead product for the treatment of EM, CC8464, may be relevant for approximately 50,000 patients in the US today. Similarly, according to studies quoted by the Erythromelalgia Association, estimates of the incidence rate for EM vary from 1.3 to 15 per 100,000 persons, reflecting a potential EM patient population up to 50,000 in the U.S.

According to Transparency Market Research, Key Drivers of Global Erythromelalgia Treatment Market include:

- Increase in number of patients with EM, strong product pipeline, and increasing research and development activity for developing new innovative drugs for treatment of EM are likely to drive the EM market during the forecasted period. In addition, high demand for disease specific novel treatment to the patients as quickly as possible is enhancing the growth of the market.

- According to the National Organization for Rare Disorders, the prevalence rate of EM is approximately 1.3 people in every 100,000 people in the U.S.
- On the other hand, limited treatment options and low healthcare budget in some developing countries are likely to restrain the growth of the market.

While we have not conducted an analysis nor can we point to studies which indicate the incidence of EM in other countries, we have issued patents (as set forth in greater detail below) in countries representing an additional population of approximately 2.0 billion people.

The three Spray Formulations licensed from Benuvia are currently indicated for acute pain, migraine and the prevention of nausea and vomiting associated with chemotherapy or surgical anesthesia. All three of these conditions have a relatively high number of potential patients who may be candidates for the medication; however, we have performed no further market assessment and the performance of any such market assessment would be pre-mature. We plan to assess the addressable markets for the three Spray Formulations after we have collected further pharmacokinetic data and we have developed a strategy and development plan for the Spray Formulations in connection with our discussions with the FDA.

Our Lead Drug Candidate and Pipeline

We intend to focus our efforts on the development of CC8464, our lead compound, towards approval in the United States and other jurisdictions. While CC8464 is the focus of our efforts, we may also allocate future resources towards the discovery and development of other compounds that could potentially modulate NaV1.7 or related sodium-channels. We believe that these molecules could represent alternatives in case we encounter challenges in the further development of CC8464 or, in particular, if blocking channels other than NaV1.7 (e.g., NaV1.8) become a complementary therapeutic to CC8464. Pain perception is complex and, given its essential function for human physiology, modulated through a variety of receptors. Hence, we believe that different NaV blockers may provide an additive or even synergistic effect on patients with neuropathic pain.

CC8464's FDA Orphan Drug Designation

We are considering submitting a request to the FDA for Orphan Drug Designation, which could lead to approval for such designation. Orphan Drug Designation provides for a seven-year window of exclusivity and potential 25% tax credit on qualified clinical trials, as well as reduced FDA review periods and regulatory fees. We may apply for similar orphan drug designations in additional jurisdictions, including India, Japan and Mexico, as well as additional regulatory classifications, such as FDA Breakthrough Therapy Designation, that confer an advantage during development. As of the date of this prospectus, we have not submitted an application for orphan drug designation for CC8464.

CC8464 Manufacturing

We plan to manufacture the clinical and eventual commercial supply through CROs in the U.S. and potentially other jurisdictions. We have rights to two proprietary methods to produce CC8464. We have not yet decided which production process we will use for subsequent clinical trials and eventual commercial supply, but both appear suitable for further use and optimization.

Both manufacturing processes employ common methods of organic synthesis used in the production drug substance. We do not intend to file patents for these processes but will keep the detailed protocols (e.g. the selected crystallization solvent or the particular salt) as trade secrets.

We do not produce drug substance in house. External CROs have produced enough drug substance (based on both processes) to conduct the planned Phase 2a trials.

Benuvia Spray Formulations

On December 23, 2023, we entered into the Benuvia License Agreement for the Spray Formulations, diversifying our pipeline of non-opioid pain treatment therapies, while adding therapeutic options for related conditions. The Diclofenac Spray Formulation is patented and has started clinical development in human volunteers. Preliminary pharmacokinetics suggest that this formulation may have a faster onset of action than oral Diclofenac tablets. Diclofenac is an NSAID that is also marketed under additional brand names including Voltaren and Cataflam in its pill form. A single Phase 1 trial of the Diclofenac spray formulation was completed in 24 healthy volunteers wherein a single dose of 50mg diclofenac-potassium was compared to 25 mg of sublingual Diclofenac spray. In this trial, the blood plasma concentrations of Diclofenac rose more quickly with the Diclofenac spray formulation than with the diclofenac administered orally by approximately 15 minutes. This suggests that the Diclofenac spray formulation may have a faster onset of analgesia; however, additional trials may be needed to confirm this effect. Additionally, the initial pharmacokinetic study demonstrated that a 25mg dose of sublingual Diclofenac spray resulted in lower systemic exposure to Diclofenac than the oral dose of 50mg diclofenac-potassium which means that an additional Phase I pharmacokinetic study exploring additional higher doses of the sublingual diclofenac spray will likely be necessary to determine the appropriate dose.

Rizatriptan, whose brand name is Maxalt, is used for the acute treatment of Migraines as a pill. By a number of clinical measures it is thought to be superior to Sumatriptan. Both Rizatriptan and Sumatriptan belong to a family of tryptamine-based medications named "triptans" that work as serotonin 1A receptor (or 5-HT1A-receptor) agonists and are indicated for the treatment of migraine. A sublingual formulation of Rizatriptan may potentially have a faster onset of action than an oral form and may be easier to tolerate than swallowing a pill when patients are experiencing nausea as a result of the migraine headache. According to a study that was reported in 2001, Rizatriptan has a higher bioavailability and a more rapid onset of action which may be responsible for better results in resolving migraines as well as better results in patients reporting that they are "pain free" after 2 hours. We believe both Sumatriptan and Rizatriptan are competitors for the same indication, though neither are widely marketed because they are generic drugs.

Ondansetron is an anti-emetic that is available in oral and intravenous form. An Ondansetron sublingual spray formulation may potentially have a faster onset of action than an oral form and may be easier to tolerate than swallowing a pill when patients are experiencing nausea. Under the terms of the Benuvia License Agreement, Benuvia will be responsible for the manufacturing and supply of the Spray Formulations, but we will have exclusive, worldwide rights to develop, commercialize and distribute the Spray Formulations.

While we currently do not have strategy and development plans for the Spray Formulations licensed from Benuvia, beginning in the third quarter of 2024, we plan to develop clinical programs for each of the Spray Formulations, determine the labelling strategy that would be obtained from completion of these programs and discuss with the FDA the requirements for bringing each of the Spray Formulations to market. We anticipate bringing the Spray Formulations to market through the FDA 505(b)(2) regulatory pathway for new drug applications; however, the exact details will require further consultation with the FDA.

Intellectual Property

Protection of our intellectual property is an important part of our business. We seek patent protection in the United States and in other countries for our inventions and discoveries, and we develop and protect our key know-how and trade secrets relating to our platform technology and the products we are developing using our platform.

We have adopted a strategy of seeking patent protection in the United States and in other jurisdictions globally that we deem appropriate with respect to certain of our technologies relating to our products and process. As of February 21, 2024, we have received an issued patent from the USPTO directed to the composition of matter and use of CC8464. We have also obtained patents in France, Japan, India and other smaller markets (Mexico, Israel and South Korea). Our U.S. patent for CC8464 will expire in 2035. The Company owns the patent and has not licensed any portion to third parties. In addition, we have an additional pending patent application in India. While the eventual issuance of a patent in India cannot be guaranteed, we believe that we have a good chance to obtain comprehensive composition of matter protection for CC8464 during 2024.

The Diclofenac Spray Formulation is covered by U.S. Patent 9,855,234. The patent was issued in January 2018 to Benuvia and is a composition-of-matter patent that will expire, barring a patent term adjustment, in April 2036. The patent coverage applies to the United States. The Ondansetron Spray Formulation is covered by U.S. Patent

9,566,233 and U.S. Patent 10,172,833. Both patents are composition-of-matter patents that will expire, barring a patent term adjustment, in May 2034 and August 2036, respectively. The patent coverages apply to the United States. The U.S. and international patents relating to the Rizatriptan Spray Formulation have either expired or have been abandoned.

In addition to patents and licenses, we rely on trade secrets and know-how to develop and maintain technologies and methods that provide us a meaningful competitive advantage. However, trade secrets can be difficult to defend and maintain. We seek to protect our proprietary technology and processes, and maintain ownership of certain technologies, in part, through confidentiality agreements and invention assignment agreements with our employees, consultants and commercial partners.

Our Competition

The biotechnology and pharmaceutical industries are highly competitive. Several pharmaceutical companies that are developing either topical applications for EM or other molecules that modulate NaV1.7 and therefore have the potential to mitigate EM. These companies and new entrants may potentially compete with our products in the future with novel delivery technologies. To the best of our knowledge, CC8464 is currently the most advanced NaV1.7 blocker in clinical development because other programs that modulate NaV1.7 are in pre-clinical development, which makes CC8464 more advanced in comparison as CC8464 has entered clinical trials and completed a Phase 1 study. However, we may be unaware of unpublished development efforts in the NaV1.7 space. The market exclusivity associated with a potential future Orphan Drug Designation plus the CC8464 market exclusivity associated with our issued patent are key elements of our commercialization strategy; however, we have not currently applied and may not receive orphan drug designation for CC8464. Competition in this space will remain strong and we do not know if we will be successful to obtain orphan designation from the FDA, encounter challenges to our issued patents and continue to advance CC8464 throughout clinical development towards approval.

In connection with this offering, we have entered into a side letter with Chromocell Holdings, pursuant to which Chromocell Holdings agreed not to (i) directly or indirectly engage in the business of owning, licensing, developing, marketing, manufacturing, producing, selling or distributing products, technologies, therapies, or services in any way related to our business, including all patents, pre-clinical and Phase I study results and data, and trade secrets related to the CC8464 compound, transferred by Chromocell Holdings to us further to the Contribution Agreement, (ii) directly or indirectly, hire, engage or employ (as an employee, consultant or otherwise) any of our employees; provided that Chromocell Holdings shall not, directly or indirectly, prevent any of our employees from serving on the board of directors of Chromocell Holdings, and (iii) through any director or officer of Chromocell Holdings, directly or indirectly, solicit for employment or the engagement of services of any of our employees or induce or attempt to induce any of our employees to leave his or her employment with us, or in any way intentionally interfere with the employment relationship between any of our employees and us, for the purpose of employing or engaging the services of such employee or soliciting such employee to become an employee or consultant of Chromocell Holdings or any other person.

Our Facilities

Our office is located at 4400 Route 9 South, Suite 1000, Freehold, NJ 07728. We are considering lab options commensurate with the start of the Phase II trials and dose escalation study.

Employees and Human Capital Resources

As of January 1, 2024, we had three full-time employees and four consultants on a part-time basis. None of our employees is subject to a collective bargaining agreement or represented by a trade or labor union. We consider our relationship with our employees to be good.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and additional employees. The principal purposes of our equity incentive plans are to attract, retain and motivate selected employees, consultants and directors through the granting of stock-based compensation awards and cash-based performance bonus awards.

In addition, we have a three person Scientific Advisory Board ("SAB") led by Dr. Stephen Waxman, who is the Bridget M. Flaherty Professor of Neurology and of Neuroscience and the Director of the Center For Neuroscience and Regeneration Medicine at Yale University School of Medicine.

Legal Proceedings

From time to time, we may be involved in legal proceedings arising in the ordinary course of our business. We are not presently a party to any legal proceedings that, in the opinion of management, would have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on us due to defense and settlement costs, diversion of management resources, negative publicity and reputation harm, and other factors.

Government Regulation

The FDA and other regulatory authorities at federal, state and local levels, as well as outside the United States, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, recordkeeping, approval, advertising, promotion, marketing, post-approval monitoring and post-approval reporting of drugs and biologics. We, along with our vendors, CROs, clinical investigators, clinical trial sites and CMOs, will be required to navigate the various preclinical, clinical, manufacturing and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek marketing approval of compounds. The process of obtaining regulatory approvals of drugs and biologics and ensuring subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources.

In the United States where we are initially focusing our drug commercialization, we believe compounds, as small molecule drugs, would be regulated as new drugs rather than biologics. The FDA regulates new drug products under the Federal Food, Drug, and Cosmetic Act, as amended (the "FDCA") and its implementing regulations. New drug products are also subject to other federal, state and local statutes and regulations. If we fail to comply with applicable FDA or other requirements at any time with respect to product development, clinical testing, approval or any other regulatory requirements relating to product manufacture, processing, handling, storage, quality control, safety, marketing, advertising, promotion, packaging, labeling, export, import, distribution, or sale, we may become subject to administrative or judicial sanctions or other legal consequences. These sanctions or consequences could include, among other things, the FDA's refusal to approve pending applications, issuance of clinical holds for proposed or ongoing studies, suspension or revocation of approvals, warning or untitled letters, product withdrawals or recalls, product seizures, relabeling or repackaging, total or partial suspensions of manufacturing or distribution, injunctions, fines, civil penalties or criminal prosecution.

Compounds must be approved for therapeutic indications by the FDA before they may be marketed in the United States. For new drug products regulated under the FDCA such as our lead compound, a sponsor must submit an NDA to the FDA for review and approval. The NDA review and approval process may take multiple years and involves the following steps:

- completion of extensive preclinical studies in accordance with applicable regulations, including studies conducted in accordance with GLP requirements;
- completion of the manufacture, under cGMP conditions of the drug substance, drug product, and labeling and packaging that the sponsor intends to use in human clinical trials along with required analytical and stability testing;
- submission to the FDA of an IND, which must become effective before clinical trials may begin and must be updated annually and amended when certain changes are made;
- approval by an institutional review board ("IRB") or independent ethics committee ("IEC") at each clinical trial site before each trial may be initiated;
- performance of adequate and well-controlled clinical trials in accordance with applicable IND regulations, GCP requirements, including informed consent, financial disclosure by investigators and other clinical trial-related regulations, to establish maximum tolerable dose and efficacy of the investigational product for each proposed indication and other condition of use;
- preparation and submission to the FDA of an NDA;
- a determination by the FDA within 60 days of its receipt of an NDA to file the application for review;
- satisfactory completion of one or more FDA pre-approval inspections of the manufacturing facility or facilities where the drug will be produced to assess compliance with cGMP requirements to assure that the facilities, methods and controls are adequate to preserve the drug product's identity, strength, quality and purity;
- satisfactory completion of FDA inspection of select clinical trial sites involved in conducting pivotal studies that generated the data in support of the NDA;
- payment of user fees for FDA review of the NDA; and
- FDA review and approval of the NDA, including of the proposed prescribing information and, where applicable, consideration of the views of any FDA advisory committee, prior to any commercial marketing or sale of the drug in the United States.

Preclinical Studies and Clinical Trials for Drugs

Before testing any drug in humans, compound must undergo rigorous preclinical testing. Preclinical studies include laboratory evaluations of product chemistry, formulation and stability, as well as in vitro and animal studies to assess maximum tolerable dose and in some cases to establish the rationale for therapeutic use. The conduct of preclinical studies is subject to federal and state regulation and requirements, including GLP requirements under 21 C.F.R. Part 58 and animal testing requirements under the Animal Welfare Act Amendments of 1976 (7 U.S.C. 2131 et seq.). The results of the preclinical studies, together with manufacturing information and analytical data, must be submitted to the FDA as part of an IND.

An IND is a submission to the FDA under which a sponsor proposes to administer an investigational product to humans. An IND must become effective before the proposed clinical trials may begin. The central focus of an IND submission is on the general investigational plan and the protocol(s) for clinical studies. The IND also includes the results of animal and in vitro studies assessing the toxicology, pharmacokinetics, pharmacology, and pharmacodynamic characteristics of the product; chemistry, manufacturing, and controls information; and any available human data or literature to support the use of the investigational product. Some long-term preclinical testing may continue after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the proposed clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks, refuses to allow the IND to take effect until the FDA's concerns and questions have been addressed and/or imposes a full or partial clinical hold. The FDA must notify the sponsor of the grounds for the hold, and any identified deficiencies must be resolved before the clinical trial can begin. Submission of an IND may result in the FDA not allowing clinical trials to commence or not allowing clinical trials to commence on the terms originally specified in the IND. A clinical hold can also be imposed once a trial has already begun, thereby halting the trial until the deficiencies articulated by FDA are corrected.

The clinical stage of development involves the administration of the compounds to healthy volunteers or patients under the supervision of qualified investigators, who generally are physicians not employed by or under the trial sponsor's control, in accordance with GCP requirements, which include the requirements that all research subjects 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 and criteria to be used in monitoring safety and evaluating effectiveness. 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 or IEC 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 compared to the anticipated benefits. The IRB or IEC 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. The FDA, the IRB or IEC, or the sponsor may suspend or discontinue a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk. There also are requirements governing the reporting of ongoing clinical trials and completed clinical trials to public registries. Information about clinical trials, including results for clinical trials other than phase 1 investigations, must be submitted within specific timeframes for publication on www.ClinicalTrials.gov, a clinical trials database maintained by the National Institutes of Health.

A sponsor who wishes to conduct a clinical trial outside of the United States are subject to the requirements of the applicable jurisdiction and may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. If a foreign clinical trial is not conducted under an IND, the FDA will nevertheless accept the results of the study in support of an NDA if the study was conducted in accordance with GCP requirements, and the FDA is able to validate the data through an onsite inspection if deemed necessary.

Clinical trials to evaluate therapeutic indications to support NDAs for marketing approval are typically conducted in three sequential phases, which may overlap.

- Phase 1 — Phase 1 clinical trials involve initial introduction of the investigational product in a limited population of healthy human volunteers or patients with the target disease or condition. These studies are typically designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, evaluate the side effects associated with increasing doses, and, if possible, to gain early evidence of effectiveness.

- Phase 2 — Phase 2 clinical trials typically involve administration of the investigational product to a limited patient population with a specified disease or condition to evaluate the drug's potential efficacy, to determine the optimal dosages and dosing schedule, and to identify possible adverse side effects and safety risks.

- Phase 3 — Phase 3 clinical trials typically involve administration of the investigational product to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy, and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended, with the other available evidence, to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval and physician labeling. Generally, two adequate and well-controlled phase 3 trials are required by the FDA for approval of an NDA. Under certain circumstances, FDA can conclude that one adequate and well-controlled clinical investigation plus confirmatory evidence is sufficient to establish effectiveness.

Post-approval trials, sometimes referred to as phase 4 clinical trials or post-marketing studies, may be conducted after initial marketing approval. These trials are used to gain additional evidence from the treatment of study subjects in the intended therapeutic indication and are commonly intended to generate additional safety data regarding use of the product in a clinical setting, or in some cases to confirm clinical benefit. In certain instances, the FDA may mandate the performance of phase 4 clinical trials as a condition of NDA approval.

Progress reports detailing the results of the clinical trials, among other information, must be submitted at least annually to the FDA. Written IND safety reports must be submitted to the FDA and the investigators fifteen days after the trial sponsor determines the information qualifies for reporting for serious and unexpected suspected adverse events, findings from other studies or animal or in vitro testing that suggest a significant risk for human volunteers, and any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must also notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction as soon as possible but in no case later than seven calendar days after the sponsor's initial receipt of the information.

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

Expanded Access

Expanded access, sometimes called "compassionate use," is the use of investigational products outside of controlled clinical trials to treat patients with serious or immediately life-threatening diseases or conditions when there are no comparable or satisfactory alternative treatment options. FDA regulations allow access to investigational products under an IND by the sponsor or the treating physician for treatment purposes on a case-by-case basis for the following groups: individual patients (single-patient IND applications for treatment in emergency settings and non-emergency settings); intermediate-size patient populations; and larger populations for use of the investigational product under a treatment protocol or treatment IND.

A clinical trial sponsor is not obligated under the law to provide expanded access to its investigational product. However, if a sponsor decides to make its investigational product available for expanded access, FDA reviews each request for expanded access and determines if treatment may proceed. Expanded access may be appropriate when all of the following criteria apply: the patient has a serious or immediately life-threatening disease or condition, and there is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition; the potential patient benefit justifies the potential risks of the treatment and the potential risks are not unreasonable in the context of the disease or condition to be treated; and providing the investigational product for the requested use will not interfere with the initiation, conduct, or completion of clinical investigations that could support marketing approval of the expanded access use or otherwise compromise the potential development of the expanded access use.

In addition, on May 30, 2018, the Right to Try Act was signed into law. The law, among other things, provides an additional mechanism for patients with a life-threatening condition who have exhausted approved treatments and are unable to participate in clinical trials to access certain investigational products that have completed a phase 1 clinical trial, are the subject of an active IND, and are undergoing investigation in a clinical trial that is intended to form the primary basis of a claim of effectiveness in support of FDA approval. Unlike the expanded access framework described above, the Right to Try Act does not require FDA to review or approve requests for use of the investigational product, although the law requires sponsors to report annually to the FDA on use of the pathway and require the FDA to post certain annual summaries. There is no obligation for a sponsor to make its investigational products available to eligible patients under the Right to Try Act.

Under the 21st Century Cures Act, the manufacturer or distributor of one or more investigational products for the diagnosis, monitoring and treatment of a serious disease or condition must make publicly available their policy for evaluating and responding to requests for expanded access for individual patients. The manufacturer or distributor is required to make such policies publicly available upon the earlier of initiation of a phase 2 or phase 3 study, or as applicable, 15 days after the investigational drug receives designation as a breakthrough therapy, fast track product, or regenerative medicine advanced therapy. The posting of the expanded access policies by manufacturers and distributors does not serve as a guarantee of access to any specific investigational drug by any individual patient, but the sponsor must develop a policy and respond to patient requests according to that policy.

U.S. Marketing Approval for Drugs

Assuming successful completion of the required clinical testing, the results of the preclinical 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 package requesting approval to market the drug product for one or more indications. An NDA is an application to FDA for approval to market a new drug for one or more specified indications and must contain proof of the drug's maximum tolerable dose and efficacy for the requested indication(s). An NDA is required to include both negative and ambiguous results of preclinical studies and clinical trials, as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. Data may come from company-sponsored clinical trials intended to test the maximum tolerable dose and efficacy of a product's use or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the maximum tolerable dose and efficacy of the investigational drug, to the satisfaction of the FDA. The FDA must approve an NDA before a drug may be marketed in the United States.

The FDA reviews all submitted NDAs to ensure they are sufficiently complete to permit substantive review before it accepts them for filing and may request additional information rather than accepting the NDA for filing. The FDA must make a decision on accepting an NDA for filing within 60 days of receipt, and such decision could include a "refuse-to-file" decision by the FDA. Once the submission is accepted for filing, the FDA begins an in-depth substantive review of the NDA. The FDA reviews an NDA to determine, among other things, whether the product is safe and effective for the indications sought and whether the facility in which it is manufactured, processed, packaged or held meets standards designed, including cGMP requirements, designed to assure and preserve the product's continued identity, strength, quality and purity. Under the goals and polices agreed to by the FDA under the Prescription Drug User Fee Act, as amended (the "PDUFA"), the FDA targets ten months, from the filing date, in which to complete its initial review of a new molecular entity NDA and respond to the applicant, and six months from the filing date of a new molecular entity NDA for priority review. The FDA does not always meet its PDUFA goal dates for standard or priority NDAs, and the review process is often extended by FDA requests for additional information or clarification.

Further, under PDUFA, each NDA must be accompanied by a substantial user fee. For fiscal year 2023, the application fee for each application containing clinical data is $3,242,026. PDUFA also imposes an annual program fee for each approved prescription drug, which has been set at $393,933 for fiscal year 2023. The FDA adjusts the PDUFA user fees on an annual basis. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on applications for products designated as orphan drugs, unless the product also includes a non-orphan indication.

The FDA also may require submission of a Risk Evaluation and Mitigation Strategy ("REMS") if it believes that a risk evaluation and mitigation strategy is necessary to ensure that the benefits of the drug outweigh its risks. A REMS can include use of risk evaluation and mitigation strategies like medication guides, physician communication plans, assessment plans, and/or elements to assure safe use ("ETASU") such as restricted distribution methods, patient registries, special monitoring 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, which reviews, evaluates and provides advice and recommendations to FDA 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 are adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA may inspect one or more select clinical trial sites involved in conducting pivotal studies to assure compliance with GCP and other requirements and the integrity of the clinical data submitted to the FDA.

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 indicates that the review cycle of the application is complete, and the application is not ready for approval. A Complete Response Letter generally contains a statement of specific conditions that must be met in order to secure final approval of the NDA, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the Complete Response Letter without first conducting required inspections, testing submitted product lots, and/or reviewing proposed labeling. In issuing the Complete Response Letter, the FDA may require additional clinical or preclinical testing or recommend other actions, such as requests for additional information or clarification, that the applicant might take in order for the 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 product with specific prescribing information for specific indication(s).

Even if the FDA approves a product, depending on the specific risk(s) to be addressed it may limit the approved indications for use of the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including phase 4 clinical trials, be conducted to further assess a product's maximum tolerable dose and efficacy after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution and use restrictions or other risk management mechanisms under a REMS, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-marketing studies or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes, and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Orphan Drug Designation and Exclusivity

Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug intended to treat a rare disease or condition, which is a disease or condition with either a patient population of fewer than 200,000 individuals in the United States, or a patient population greater than 200,000 individuals in the United States when there is no reasonable expectation that the cost of developing and making the product available in the United States for the disease or condition will be recovered from sales of the product. Orphan drug designation must be requested before submitting a marketing application. After the FDA grants orphan drug designation, the generic identity of the therapeutic agent and its designated orphan use are disclosed by the FDA on its website. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process, though companies developing orphan products are eligible for certain incentives, including tax credits for qualified clinical testing and waiver of application fees.

If a product that has orphan drug designation subsequently receives the first FDA approval for the use for which it has such designation, the product is entitled to a seven-year period of marketing exclusivity from the date of FDA approval during which the FDA may not approve any other applications to market the "same drug" for the same use, except in limited circumstances, such as a subsequent product's showing of "clinical superiority" over the product with orphan exclusivity or where the original applicant cannot produce sufficient quantities of product. The FDA defines "same drug" with respect to small molecule drugs as a drug that contains the same active moiety as a previously approved drug and is intended for the same use as the previously approved drug. To demonstrate a drug is "clinically superior" to the previously approved orphan drug, a sponsor must show that the drug provides a significant therapeutic advantage over and above the previously already approved drug in terms of greater efficacy, greater safety, or by providing a major contribution to patient care. Since the enactment of the FDA Reauthorization Act of 2017, the FDA publishes clinical superiority findings on its website for those drugs approved on or after August 18, 2017. Competitors, however, may receive approval of different therapeutic agents for the indication for which the orphan product has exclusivity or obtain approval for the same therapeutic agent for a different indication than that for which the orphan product has exclusivity. If an orphan designated product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan exclusivity. Further, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or the manufacturer of the approved product is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition, or if the manufacturer chooses to provide consent to approval of other applications.

Expedited Development and Review Programs for Drugs

The FDA maintains several programs intended to facilitate and expedite development and review of new drugs to address unmet medical needs in the treatment of serious or life-threatening diseases or conditions. These programs include Fast Track designation, Breakthrough Therapy designation, Priority Review and Accelerated Approval, and the purpose of these programs is to either expedite the development or review of important new drugs and biologics to get them to patients more quickly than standard FDA review timelines typically permit. We intend to apply for these programs for compounds, as applicable.

A new drug is eligible for Fast Track designation if it is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address unmet medical needs for such disease or condition. Fast Track designation applies to the compound and the specific indication for which it is being studied. The sponsor of a new drug product may request the FDA to designate the drug as a Fast Track product at any time during the clinical development of the product, but ideally no later than the pre-NDA meeting because many of the features of Fast Track designation will not apply after that time. Fast Track designation provides increased opportunities for sponsor interactions with the FDA during preclinical and clinical development, in addition to the potential for rolling review once a marketing application is filed. Rolling review means that the FDA may review portions of the marketing application before the sponsor submits the complete application.

In addition, a new drug may be eligible for Breakthrough Therapy designation if it is intended to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug, alone or in combination with one or more other drugs, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. A sponsor may request that a drug product be designated as a Breakthrough Therapy at any time during the clinical development of the product and ideally before initiation of the pivotal clinical trial intended to serve as the primary basis for demonstration of efficacy to obtain the full benefits of the designation. Breakthrough Therapy designation provides all the features of Fast Track designation, in addition to intensive guidance on an efficient product development program beginning as early as phase 1 and FDA organizational commitment to expedited development, including involvement of senior managers and experienced review staff in a cross-disciplinary review, where appropriate.

Any product submitted to the FDA for approval, including a product with Fast Track or Breakthrough Therapy designation, may also be eligible for additional FDA programs intended to expedite the review and approval process, including Priority Review and Accelerated Approval. A product is eligible for Priority Review, once an NDA is submitted, if the product that is the subject of the marketing application has the potential to provide a significant improvement in safety or effectiveness in the treatment, diagnosis or prevention of a serious disease or condition. Significant improvement may be illustrated by the following examples: evidence of increased effectiveness in treatment, prevention, or diagnosis of a condition, elimination or substantial reduction of a treatment-limiting adverse reaction, documented enhancement of patient compliance that is expected to lead to an improvement in serious outcomes, and evidence of safety and effectiveness in a new subpopulation. Under Priority Review, the FDA's goal date to take action on the marketing application is six months compared to ten months for a standard review.

The FDA may grant Accelerated Approval to a product for a serious or life-threatening condition that provides meaningful therapeutic advantage to patients over existing treatments based upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant Accelerated Approval for such a condition when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality ("IMM") and that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. Products granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

For the purposes of Accelerated Approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign or other measure that is thought to predict clinical benefit but is not itself a measure of clinical benefit. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. An intermediate clinical endpoint is a measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a drug, such as an effect on IMM. The FDA has limited experience with accelerated approvals based on intermediate clinical endpoints but has indicated that such endpoints generally may support Accelerated Approval where the therapeutic effect measured by the endpoint is not itself a clinical benefit and basis for traditional approval, if there is a basis for concluding that the therapeutic effect is reasonably likely to predict the ultimate clinical benefit of a product.

The Accelerated Approval pathway is most often used in settings in which the course of a disease is long, and an extended period of time is required to measure the intended clinical benefit of a product, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly. Thus, Accelerated Approval has been used extensively in the development and approval of products for treatment of a variety of cancers in which the goal of therapy is generally to improve survival or decrease morbidity and the duration of the typical disease course requires lengthy and sometimes large trials to demonstrate a clinical or survival benefit. Thus, the benefit of Accelerated Approval derives from the potential to receive approval based on surrogate endpoints sooner than possible for trials with clinical or survival endpoints, rather than deriving from any explicit shortening of the FDA approval timeline, as is the case with priority review.

The Accelerated Approval pathway is usually contingent on a sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the product's clinical benefit. As a result, a compound approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, would allow the FDA to initiate expedited proceedings to withdraw approval of the product. All promotional materials for compounds approved under accelerated regulations are subject to prior review by the FDA. In addition, the FDA generally requires, as a condition for Accelerated Approval, that all advertising and promotional materials intended for dissemination or publication within 120 days of marketing approval be submitted to the agency for review during the pre-approval review period. After the 120-day period has passed, all advertising and promotional materials must be submitted at least 30 days prior to the intended time of initial dissemination or publication.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or the time period for FDA review or approval may not be shortened. Furthermore, Fast Track designation, Breakthrough Therapy designation, Priority Review and Accelerated Approval do not change the scientific or medical standards for approval or the quality of evidence necessary to support approval, though they may expedite the development or review process.

Pediatric Study Plan and Pediatric Exclusivity

Under the Pediatric Research Equity Act, as amended (the "PREA"), certain NDAs and certain NDA supplements must contain data that can be used to assess the safety and efficacy of the compound for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. For a cancer drug directed at a molecular target, the pediatric testing requirement extends to pediatric cancers involving the molecular target even if different than the claimed adult cancer in the NDA. The FDA may grant deferrals for submission of pediatric data or full or partial waivers. The PREA requires that a sponsor who is planning to submit a marketing application for a compound that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit an initial Pediatric Study Plan (the "PSP"), within 60 days of an end-of-phase 2 meeting or, if there is no such meeting, as early as practicable before the initiation of the phase 3 or phase 2/3 study. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA and the sponsor must reach an agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from preclinical studies, early phase clinical trials and/or other clinical development programs. Unless otherwise required by regulation, the PREA does not apply to a drug for an indication for which orphan drug designation has been granted, except that the PREA will apply to an original NDA for a new active ingredient that is orphan-designated if the drug is a molecularly targeted cancer product intended for the treatment of an adult cancer and is directed at a molecular target that the FDA determines to be substantially relevant to the growth or progression of a pediatric cancer.

A drug can also obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study.

U.S. Post-Approval Requirements for Drugs

Drugs approved by FDA are subject to continuing regulation by the FDA, including, among other things, requirements relating to manufacturing establishment registration and product listing, recordkeeping, periodic reporting, product sampling and distribution, reporting of adverse experiences with the product, field alerts regarding issues with distributed product, promotion and advertising compliance, which include restrictions on promoting products for unapproved uses or patient populations (known as "off-label use") and limitations on industry-sponsored scientific and educational activities. Although physicians may prescribe approved products for off-label uses, manufacturers may not market or promote such uses. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, as well as other advertising and promotion requirements, including not only by company employees but also by agents of the company or those speaking on the company's behalf, and a company that is found to have improperly promoted may be subject to significant liability, including investigation by federal and state authorities. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, untitled letters, corrective advertising, and potential civil and criminal penalties, including liabilities under the FCA where products obtain reimbursement under federal health care programs. Promotional materials for approved drugs must be submitted to the FDA in conjunction with their first use or first publication, and for products approved under accelerated approval prior to their first use. Further, if there are any modifications to the drug, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new NDA or NDA supplement, which may require the development of additional data or preclinical studies and clinical trials.

The FDA may withdraw approval of a product if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information, requirements for post-market studies or clinical trials to assess new safety risks, or imposition of distribution or other restrictions under a REMS. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve applications or supplements to approved applications, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- injunctions or the imposition of civil or criminal penalties; and
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs; or mandated modification of promotional materials and labeling and issuance of corrective information.

United States Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of FDA approval of future lead compounds, some of our United States patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Amendments"). The Hatch-Waxman Amendments permit restoration of the patent term of up to five years as compensation for patent term lost during the FDA regulatory review process for a drug that has not been previously approved for commercial marketing. Patent-term restoration, however, cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date and only those claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. The patent-term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA plus the time between the submission date of an NDA and the approval of that application, except that the review period is reduced by any time during which the applicant failed to exercise due diligence. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may apply for restoration of patent term for our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant NDA.

Regulatory exclusivity provisions under the FDCA also can delay the submission or the approval of certain applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to gain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an ANDA, or a 505(b)(2) NDA, submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement.

The FDCA also provides three years of exclusivity for an NDA, 505(b)(2) NDA, or supplement to an existing NDA, if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions of use associated with the new clinical investigations and prevents FDA approval of an ANDA or 505(b)(2) NDA for such conditions of use, but does not prevent FDA acceptance for filing and review of an ANDA or 505(b)(2) NDA. The three-year exclusivity does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for drugs containing the original active agent for other conditions of use outside those protected by the exclusivity. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to evaluate maximum tolerated dose and effectiveness.

Other Regulatory Matters

Manufacturing, sales, promotion and other activities of products following product approval, where applicable, or commercialization are also subject to regulation by numerous regulatory authorities in the United States in addition to the FDA, which may include the CMS, other divisions of the U.S. Department of Health and Human Services ("HHS"), the Department of Justice, the Drug Enforcement Administration, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency and state and local governments and governmental agencies.

Healthcare Laws

Healthcare providers, physicians, and third-party payors will play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. Our business operations and any current or future arrangements with third-party payors, healthcare providers, and physicians may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we develop, market, sell and distribute any drugs for which we obtain marketing approval. In the United States, these laws include federal and state anti-kickback, false claims, physician transparency, and patient data privacy and security laws and regulations, including those described below.

- The federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Violations are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from federal health care programs. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, but the exceptions and safe harbors are drawn narrowly and require strict compliance in order to offer protection.

- The federal civil and criminal false claims laws, including the FCA, which can be enforced through civil "whistleblower" actions, and civil monetary penalty laws, impose criminal and civil penalties against individuals or entities for, among other things, knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid, or other federal health care programs that are false or fraudulent; knowingly making or causing a false statement material to a false or fraudulent claim or an obligation to pay money to the federal government; or knowingly concealing or knowingly and improperly avoiding or decreasing such an obligation. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. When an entity is determined to have violated the federal civil FCA, the government may impose civil fines and penalties for each false claim, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs.

- The federal civil monetary penalties laws impose civil fines for, among other things, the offering or transfer or remuneration to a Medicare or state healthcare program beneficiary, if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state health care program, unless an exception applies.

- HIPAA, which created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (including, public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating HIPAA without actual knowledge of the statute or specific intent to violate it.

- HIPAA, as amended by HITECH, and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses and their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information as well as their covered subcontractors, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions.

- The federal Physician Payments Sunshine Act, enacted as part of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the "ACA"), imposed annual reporting requirements for certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, for certain payments and "transfers of value" provided to physicians (currently defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Effective January 1, 2022, these reporting obligations will extend to include transfers of value made in the previous year to certain non-physician providers such as physician assistants and nurse practitioners.

- Federal consumer protection and unfair competition laws broadly regulate marketplace activities and activities that potentially harm consumers.

- Analogous state and foreign laws and regulations, such as state and foreign anti-kickback, false claims, consumer protection and unfair competition laws which may apply to pharmaceutical business practices, including but not limited to, research, distribution, sales and marketing arrangements as well as submitting claims involving healthcare items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government that otherwise restricts payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to file reports with states regarding pricing and marketing information, such as the tracking and reporting of gifts, compensations and other remuneration and items of value provided to healthcare professionals and entities; state and local laws requiring the registration of pharmaceutical sales representatives; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current regulatory and healthcare environment, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry.

Insurance Coverage and Reimbursement

In the United States and markets in other countries, patients who are prescribed treatments for their conditions and providers performing healthcare services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Thus, even if a compound is approved, sales of the product will depend, in part, on the extent to which third-party payors, including government healthcare programs in the United States such as Medicare and Medicaid, private health insurers, managed care organizations and other third-party payors, provide coverage, and establish adequate reimbursement levels for, the product. In the United States, principal decisions about Medicare reimbursement for new products are typically made by CMS and regional contractors responsible for administering the Medicare program. CMS and these contractors decide whether and to what extent a new product will be covered and reimbursed under Medicare, and private third-party payors often follow CMS's decisions regarding coverage and reimbursement to a substantial degree.

Reimbursement by a third-party payor may depend upon a number of factors, including, but not limited to, the third-party payor's determination that use of a product is (1) a covered benefit under its health plan; (2) safe, effective and medically necessary; (3) appropriate for the specific patient; (4) cost-effective; and (5) neither experimental nor investigational. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. However, one third-party payor's determination to provide coverage for a compound does not assure that other payors will also provide coverage for the compound. No uniform policy of coverage and reimbursement for products exists among third-party payors, and coverage and reimbursement levels for products can differ significantly from payor to payor.

Third-party payors are increasingly challenging the prices charged, examining the medical necessity, reviewing the cost-effectiveness of medical products and services and imposing controls to manage costs. In order to secure coverage and reimbursement for any product that might be approved for sale, a company may need to conduct expensive pharmaco-economic studies in order to demonstrate the cost effectiveness of the product, which will require additional expenditure above and beyond the costs required to obtain FDA or other comparable regulatory approvals. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the FDA-approved products for a particular indication. Moreover, the containment of healthcare costs has become a priority of federal, state and foreign governments, and the prices of products have been a focus in this effort. Governments have shown significant interest in implementing cost-containment programs, including price controls or price increase penalties, restrictions on reimbursement and requirements for substitution of generic products.

In addition, companion diagnostic tests require coverage and reimbursement separate and apart from the coverage and reimbursement for their companion pharmaceutical products. Similar challenges to obtaining coverage and reimbursement, applicable to pharmaceutical products, will apply to companion diagnostics.

Current and Future Healthcare Reform Legislation

In the United States and certain foreign jurisdictions, there have been, and likely will continue to be, a number of proposed and adopted legislative and regulatory changes regarding the healthcare system directed at broadening the availability of healthcare, improving the quality of healthcare, and containing or lowering the cost of healthcare. For example, in March 2010, the United States Congress enacted the ACA, which, among other things, includes changes to the coverage and payment for products under government health care programs. The ACA includes provisions of importance to our potential lead compounds that:

- created an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drug products, apportioned among these entities according to their market share in certain government healthcare programs;

- expanded eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;

- expanded manufacturers' rebate liability under the Medicaid Drug Rebate Program by increasing the minimum rebate for both branded and generic drugs and revising the definition of "average manufacturer price," or AMP, for calculating and reporting Medicaid drug rebates on outpatient prescription drug prices;

- addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;

- expanded the types of entities eligible for the 340B drug discount program;

- established the Medicare Part D coverage gap discount program by requiring manufacturers to provide point-of-sale-discounts off the negotiated price of applicable brand drugs to eligible beneficiaries during their coverage gap period as a condition for the manufacturers' outpatient drugs to be covered under Medicare Part D; and

- created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. For example, various portions of the ACA have faced legal and constitutional challenges, including in the United States Supreme Court; the Trump administration issued various Executive Orders which eliminated cost sharing subsidies and various provisions that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices; and Congress introduced several pieces of legislation aimed at significantly revising or repealing the ACA. It is unclear whether the ACA will be overturned, repealed, replaced, or further amended in the future, and we cannot predict what effect further changes to the ACA would have on our business.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. For example, in August 2011, the Budget Control Act of 2011, among other things, included reductions of Medicare payments to providers of 2%, which went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030 unless additional Congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, including bundled payment models. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their commercial products, which has resulted in numerous Congressional inquiries and proposed and enacted state and federal legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for pharmaceutical products. At the federal level, former President Trump used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders, and policy initiatives. It is unclear whether the Biden administration will work to reverse those measures or pursue similar or other policy initiatives, for example related to an independent review board or other mechanisms that would impact drug pricing and reimbursement.

On November 20, 2020, CMS and the HHS Office of the Inspector General issued two final rules implementing changes to the Physician Self-Referral Law, or Stark Law, and the Anti-Kickback Statute. These new rules provide new value-based enterprise exceptions and safe harbors to the Stark Law and the Anti-Kickback Statute, as well as offer additional clarification in the form of updated definitions.

Compliance with Other Federal and State Laws or Requirements; Changing Legal Requirements

If any products that we may develop are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, labeling, packaging, distribution, sales, promotion and other activities also are potentially subject to federal and state consumer protection and unfair competition laws, among other requirements to which we may be subject. The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive recordkeeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products, and state licensure.

The failure to comply with any of these laws or regulatory requirements may subject firms to legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in criminal prosecution, fines or other penalties, injunctions, exclusion from federal healthcare programs, requests for recall, seizure of products, total or partial suspension of production, denial or withdrawal of product approvals, relabeling or repackaging, or refusal to allow a firm to enter into supply contracts, including government contracts. Any claim or action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Prohibitions or restrictions on marketing, sales or withdrawal of future products marketed by us could materially affect our business in an adverse way.

Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (1) changes to our manufacturing arrangements; (2) additions or modifications to product labeling or packaging; (3) the recall or discontinuation of our products; or (4) additional recordkeeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

Government Regulation of Drugs Outside of the United States

To market any product outside of the United States, we would need to comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy and governing, among other things, clinical trials, marketing authorization, manufacturing, commercial sales and distribution of our products. These regulatory requirements may be similarly complex and even more stringent in certain regards than those described above. If we fail to comply with applicable regulatory requirements in the jurisdiction where we conduct clinical trials or seek regulatory approvals, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

For instance, in the European Economic Area (the "EEA") (comprising the 27 EU member states plus Iceland, Liechtenstein and Norway), medicinal products must be authorized for marketing by using either the centralized authorization procedure or national authorization procedures.

- Centralized procedure—The centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid throughout the EEA. Pursuant to Regulation (EC) No. 726/2004, the centralized procedure is compulsory for specific products, including for medicines produced by certain biotechnological processes, products designated as orphan medicinal products, advanced therapy products (gene therapy, somatic cell therapy and tissue engineered products) and products with a new active substance indicated for the treatment of certain diseases, which includes products for the treatment of cancer. For medicines that do not fall within one of the mandatory categories, an applicant still has the option of submitting an application for a centralized marketing authorization to the EMA, as long as the medicine concerned contains a new active substance not authorized in the EEA prior to May 20, 2004, is a significant therapeutic, scientific or technical innovation, or if its authorization would be in the interest of public health in the EEA. If pursuing marketing authorization of a lead compound for a therapeutic indication under the centralized procedure, the EMA's Committee for Medicinal Products for Human Use (the "CHMP"), is responsible for conducting an initial assessment of whether a product meets the required quality, safety and efficacy requirements, and whether a product has a positive benefit/risk ratio. Under the centralized procedure the maximum timeframe for the evaluation of a marketing authorization application (the "MAA"), by the EMA is 210 days, excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP. Clock stops may extend the timeframe of evaluation of a MAA considerably beyond 210 days. Where the CHMP gives a positive opinion, it provides the opinion together with supporting documentation to the European Commission, who make the final decision to grant a marketing authorization, which is issued within 67 days of receipt of the EMA's recommendation. Accelerated assessment might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of major public health interest, particularly from the point of view of therapeutic innovation. The timeframe for the evaluation of a MAA under the accelerated assessment procedure is 150 days, excluding clock stops, but it is possible that the CHMP may revert to the standard time limit for the centralized procedure if it determines that the application is no longer appropriate to conduct an accelerated assessment.

- National authorization procedures—There are also two other possible routes to authorize products for therapeutic indications in several countries, which are available for products that fall outside the scope of the centralized procedure:

    - Decentralized procedure—Using the decentralized procedure, an applicant may apply for simultaneous authorization in more than one EEA Member State for a medicinal product that has not yet been authorized in any EEA Member State and that does not fall within the mandatory scope of the centralized procedure.

    - Mutual recognition procedure—In the mutual recognition procedure, a medicine is first authorized in one EEA Member State, in accordance with the national procedures of that country. Following this, additional marketing authorizations can be sought from other EEA Member States in a procedure whereby the countries concerned recognize the validity of the original, national marketing authorization.

In both cases, as with the centralized procedure, the competent authorities of the EEA Member States assess the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy before granting the marketing authorization.

In the EEA, new products for therapeutic indications that are authorized for marketing (so called "references products") qualify for eight years of data exclusivity and an additional two years of market exclusivity upon marketing authorization. The data exclusivity period prevents generic or biosimilar applicants from referencing the preclinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar marketing authorization in the EEA during a period of eight years from the date on which the reference product was first authorized in the EEA. The additional two-year period of market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the EEA until ten years have elapsed from the initial authorization of the reference product in the EU. The overall ten-year period can be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. Even if a compound is considered to be a new active substance so that the innovator gains the prescribed period of data exclusivity, another company may market another version of the product if such company obtained marketing authorization based on a MAA with a complete independent data package of pharmaceutical tests, preclinical tests and clinical trials.

The criteria for designating an "orphan medicinal product" in the EEA are similar in principle to those in the United States. Under Article 3 of Regulation (EC) 141/2000, in the EEA a medicinal product may be designated as orphan if it meets the following criteria (1) it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition; and (2) either (a) such condition affects no more than five in 10,000 persons in the EEA when the application is made, or (b) it is unlikely that the product, without the benefits derived from orphan status, would generate sufficient return in the EEA to justify the investment needed for its development; and (3) there exists no satisfactory method of diagnosis, prevention or treatment of such condition, or if such a method exists, the product will be of significant benefit to those affected by the condition. Orphan medicinal products are eligible for financial incentives such as reduction of fees or fee waivers and are, upon grant of a marketing authorization, entitled to ten years of market exclusivity for the approved therapeutic indication. During this ten-year orphan market exclusivity period, no marketing authorization application shall be accepted, and no marketing authorization shall be granted for a similar medicinal product for the same indication, although similar, is safer, more effective or otherwise clinically superior than the authorized product; (ii) the marketing authorization holder of the authorized product consents to a second orphan medicinal product application; or (iii) the marketing authorization holder of the authorized product cannot supply enough orphan medicinal product. An orphan product can also obtain an additional two years of market exclusivity in the EEA for pediatric studies. The ten-year market exclusivity may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan drug designation, for example, if the product is sufficiently profitable not to justify maintenance of market exclusivity. The application for orphan drug designation must be submitted before the application for marketing authorization. The applicant will receive a fee reduction for the MAA if the orphan drug designation has been granted, but not if the designation is still pending at the time the marketing authorization is submitted. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

Similar to the United States, the various phases of non-clinical and clinical research in the European Union are subject to significant regulatory controls.

The Clinical Trials Directive 2001/20/EC, the Directive 2005/28/EC on GCP and the related national implementing provisions of the individual EU member states govern the system for the approval of clinical trials in the European Union. Under this system, an applicant must obtain prior approval from the national competent authority (the "NCA"), of the EU member states in which the clinical trial is to be conducted. Furthermore, the applicant may only start a clinical trial at a specific study site after the competent ethics committee (the "EC"), has issued a favorable opinion. The clinical trial application must be accompanied by, among other documents, an investigational medicinal product dossier (the Common Technical Document) with supporting information prescribed by Directive 2001/20/EC, Directive 2005/28/EC, and the provisions of the individual EU member states' legislation implementing the Clinical Trials Directive. Under the current regime (the EU Clinical Trials Directive 2001/20/EC and corresponding national laws) all suspected unexpected serious adverse reactions to the investigated drug that occur during the clinical trial have to be reported to the NCA and ECs of the Member State where they occurred.

In April 2014, the new Clinical Trials Regulation, (EU) No 536/2014 (the "Clinical Trials Regulation") was adopted, which is expected to apply following confirmation of full functionality of the Clinical Trials Information System, the centralized European Union portal and database for clinical trials foreseen by the regulation, through an independent audit. The regulation becomes applicable six months after the European Commission publishes notice of this confirmation, which it has not yet done. The Clinical Trials Regulation will be directly applicable in all the EU member states, repealing the current Clinical Trials Directive 2001/20/EC. Conduct of all clinical trials performed in the European Union will continue to be bound by the Clinical Trials Directive and the Member States' national implementing legislation until the new Clinical Trials Regulation becomes applicable. The extent to which ongoing clinical trials will be governed by the Clinical Trials Regulation will depend on when the Clinical Trials Regulation becomes applicable and on the duration of the individual clinical trial. If a clinical trial continues for more than three years from the day on which the Clinical Trials Regulation becomes applicable the Clinical Trials Regulation will at that time begin to apply to the clinical trial. The new Clinical Trials Regulation aims to simplify and streamline the approval of clinical trials in the European Union. The main characteristics of the regulation include: a streamlined application procedure via a single-entry point, the "EU portal"; a single set of documents to be prepared and submitted for the application as well as simplified reporting procedures for clinical trial sponsors; and a harmonized procedure for the assessment of applications for clinical trials, which is divided in two parts. Part I is assessed by the competent authorities of all EU member states in which an application for authorization of a clinical trial has been submitted (Member States concerned). Part II is assessed separately by each Member State concerned. Strict deadlines have been established for the assessment of clinical trial applications. The role of the relevant ethics committees in the assessment procedure will continue to be governed by the national law of the concerned EU member state. However, overall related timelines will be defined by the Clinical Trials Regulation.

Outside the United States, ensuring coverage and adequate payment for a product also involves challenges. Pricing of prescription pharmaceuticals is subject to government control in many countries. Pricing negotiations with government authorities can extend well beyond the receipt of regulatory approval for a product and may require a clinical trial that compares the cost-effectiveness of a product to other available therapies. The conduct of such a clinical trial could be expensive and result in delays in commercialization. For example, in the European Union, pricing and reimbursement schemes vary widely from country to country. Some countries provide that products may be marketed only after a reimbursement price has been agreed upon. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular compound to currently available therapies or so-called health technology assessments, in order to obtain reimbursement or pricing approval. For example, the European Union provides options for its member states to restrict the range of products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. European Union member states may approve a specific price for a product or may instead adopt a system of direct or indirect controls on the profitability of the company placing the product on the market. Other member states allow companies to fix their own prices for products, but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. Recently, many countries in the European Union have increased the amount of discounts required on pharmaceuticals and these efforts could continue as countries attempt to manage healthcare expenditures, especially in light of the severe fiscal and debt crises experienced by many countries in the European Union. The downward pressure on healthcare costs in general, particularly prescription products, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various European Union member states, and parallel trade, in other words, arbitrage between low- priced and high-priced member states, can further reduce prices. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any products, if approved in those countries.

Government Regulation of Data Collection Outside of the United States

In the event we conduct clinical trials in the European Union, we will be subject to additional privacy restrictions. The collection and use of personal health data in the EEA is governed by the General Data Protection Regulation (the "GDPR"), which became effective on May 25, 2018. The GDPR applies to the processing of personal data by any company established in the EEA and to companies established outside the EEA to the extent they process personal data in connection with the offering of goods or services to data subjects in the EEA or the monitoring of the behavior of data subjects in the EEA. The GDPR enhances data protection obligations for data controllers of personal data, including stringent requirements relating to the consent of data subjects, expanded disclosures about how personal data is used, enhanced requirements for securing personal data, requirements to conduct privacy impact assessments for "high risk" processing, limitations on retention of personal data, mandatory data breach notification and "privacy by design" requirements, and creates direct obligations on service providers acting as processors. The GDPR also imposes strict rules on the transfer of personal data outside of the EEA to countries that do not ensure an adequate level of protection, like the United States. Failure to comply with the requirements of the GDPR and the related national data protection laws of the EEA Member States, which may deviate slightly from the GDPR, may result in fines of up to 4% of a company's global revenue for the preceding financial year, or €20 million, whichever is greater. Moreover, the GDPR grants data subjects the right to claim material and non-material damages resulting from infringement of the GDPR. Given the breadth and depth of changes in data protection obligations, maintaining compliance with the GDPR will require significant time, resources and expense, and we may be required to put in place additional controls and processes ensuring compliance with the new data protection rules. There has been limited enforcement of the GDPR to date, particularly in biopharmaceutical development, so we face uncertainty as to the exact interpretation of the new requirements on any future trials and we may be unsuccessful in implementing all measures required by data protection authorities or courts in interpretation of the new law. Further, the United Kingdom's decision to leave the European Union, means that it has in force its own legislation, which is aligned with the GDPR, known as the Data Protection Act 2018. The requirements are similar except that the United Kingdom is now regarded as a "third country" for the purposes of transfers of personal data from the EEA. Transfers continue to flow freely from the UK to the EEA following an adequacy decision from the European Commission adopted on June 28, 2021 and valid for four years.

Data protection authority activity differs across the EU, with certain authorities applying their own agenda which shows there is uncertainty in the manner in which data protection authorities will seek to enforce compliance with GDPR. For example, it is not clear if the authorities will conduct random audits of companies doing business in the EU, or if the authorities will wait for complaints to be filed by individuals who claim their rights have been violated. Enforcement uncertainty and the costs associated with ensuring GDPR compliance are onerous and may adversely affect our business, financial condition, results of operations and prospects.

Should we utilize third-party distributors, compliance with such foreign governmental regulations would generally be the responsibility of such distributors, who may be independent contractors over whom we have limited control.

MANAGEMENT

Executive Officers and Directors

The following table provides information regarding our current executive officers and directors:

Name	Age	Position
Executive Officers		
Francis Knuettel II	57	Interim Chief Executive Officer, Chief Financial Officer, Treasurer and Secretary
Eric Lang	62	Chief Medical Officer
Directors		
Todd Davis	62	Director (Chairman of the Board)
Ezra Friedberg	53	Director
Richard Malamut	64	Director
Chia-Lin Simmons	50	Director

Biographic Information - Executive Officers

Francis Knuettel II has served as our Interim Chief Executive Officer since July 2023, and as our Chief Financial Officer, Treasurer and Secretary since June 2022. Prior to that, from December 2020 to April 2022, he served as Chief Executive Officer and director of Unrivaled Brands, a California-based operator of cannabis assets in California and Oregon, where he helped grow revenue from an annualized rate of $10 million to $100 million in six quarters by acquiring three companies in the sector. He also served as Chief Financial Officer of ONE Cannabis Group from June 2019 to January 2021 and held various roles at MJardin Group, including Chief Strategy Officer, from August 2018 to January 2019. Prior to MJardin Group, Mr. Knuettel served as Chief Financial Officer of Aqua Metals in 2018 and held the same position at Marathon Patent Group from 2014 to 2018. During Mr. Knuettel's career, he has helped raise more than $300 million via venture equity and debt, public equity and debt offerings in the United States and Canada, convertible debt, PIPEs, bridge loans and other instruments. In addition, he has managed more than 15 mergers and acquisition transactions of companies as both buyer and seller and has handled large-scale licensing transactions with fortune 50 companies. Mr. Knuettel also holds numerous board positions at both public and private companies, including ECOM Medical since 2019, Relativity Acquisition Corp. (Nasdaq: RACY) since 2022, and Capstone Technologies Group Inc (OTC: CATG) since 2023. Mr. Knuettel received his BA with honors in Economics from Tufts University and holds an MBA in Finance and Entrepreneurial Management from The Wharton School at the University of Pennsylvania.

Eric Lang has served as our Chief Medical Officer since June 2023. Prior to that, from September 2018 to May 2023, Dr. Lang served at Nevakar Inc, initially as Vice President of Clinical Development and later as its Chief Medical Officer. From January 2018 to September 2018, Dr. Lang served as the Chief Medical Officer at Entera Bio Ltd. (Nasdaq: ENTX). From February 2012 to November 2017, he served at Covance (now Labcorp Drug Development), heading an international team that assisted smaller biotech companies in moving their programs through the various phases of pre-clinical and clinical development. From August 2010 to January 2012, Dr. Lang served at Grunenthal USA, Inc. as their head of clinical development. Prior to that, Dr. Lang led the clinical development team at Javelin Pharmaceuticals, Inc. from October 2008 to August 2010, which was acquired by Hospira (now Pfizer Inc.) in 2010. Dr. Lang worked for Novartis Consumer Health from October 2006 to October 2008 and he began his career with Johnson & Johnson (NYSE: JNJ) where he worked from 1999 to 2006. Dr. Lang is an Anesthesiologist and Pain Management Specialist with over 26 years of experience in the pharmaceutical industry. During his pharmaceutical career, he has had both broad-based drug and device development expertise in a variety of therapeutic areas. Dr. Lang has experience in designing development programs from early translational stages through phase III including the successful filing of several recent INDs and NDAs. He has experience with Regulatory interactions and negotiations with FDA and various European and Asian Authorities. Dr. Lang received his Doctor of Medicine from Ben-Gurion University of the Negev and completed post graduate training at Emory University in Atlanta, GA.

Biographical Information - Directors

Todd Davis has served as a member of our board of directors since January 2023. He is the founder and has served as the managing partner of RoyaltyRx Capital, LLC, a special opportunities investment firm, since 2018. Since November 2019, he has also served as Chairman and CEO of Benuvia Holdings, LLC, a pharmaceutical holding company. From 2006 to 2018, Mr. Davis was a founder and managing partner of Cowen/HealthCare Royalty Partners, a global healthcare investment firm. From 2004 to 2006, Mr. Davis was a partner at Paul Capital Partners, where he co-managed its royalty investments as a member of the Royalty Management Committee. From 2001 to 2004, he served as a partner responsible for biopharmaceutical growth equity investments at Apax Partners. Mr. Davis began his business career in sales at Abbott Laboratories where he held several commercial roles of increasing responsibility. He subsequently held general management, business development, and licensing roles at Elan Pharmaceuticals. Mr. Davis is a navy veteran and received a B.S. from the U.S. Naval Academy and an M.B.A. from the Harvard Business School. He currently serves on the board of directors of Palvella Therapeutics Inc., BioDelivery Sciences International, Inc., and Ligand Pharmaceuticals Incorporated. He is also a board member of the Harvard Business School Healthcare Alumni Association. We believe Mr. Davis is qualified to serve on the board of directors because of his extensive experience within the life sciences industry, including as a founder and managing partner of a special opportunities investment firm.

Ezra Friedberg has served as a member of our board of directors since May 2021. Since September 2011, Mr. Friedberg has served as co-founder and general partner of Multiplier Capital, a fund focused on lending opportunities to sponsor-backed growth companies. He is also a member of the fund's credit committee. Mr. Friedberg is a seasoned investor with more than twenty years of investing experience in both public and private companies. He invests actively in the biotech space and has served on the board of directors of Humanigen (Nasdaq: HGEN), a clinical-stage biopharmaceutical company which develops monoclonal antibodies. His other investments include private equity, venture capital, and property across the United States, Canada and overseas. Separately, Mr. Friedberg manages and owns other investments and businesses through Liberty Peak Capital, Key Recovery Group, and related companies. Mr. Friedberg is a graduate of Johns Hopkins University. He has founded and is an active board member of several community and civic organizations, including a non-profit mentoring agency. Mr. Friedberg serves and has served on several for-profit and non-profit boards. He was selected to serve on our board of directors due to his investment experience and his knowledge of our industry.

Dr. Richard Malamut has served as a member of our board of directors since January 2023. Dr. Malamut is currently Chief Medical Officer at MedinCell Inc. He was most recently Chief Medical Officer and Executive Vice President at Collegium Pharmaceuticals from April 2019 to May 2022 and has also served as Chief Medical Officer for Braeburn Pharmaceuticals, Inc. from 2018 to 2019 where he was responsible for the company's medical affairs, non-clinical and clinical development, clinical operations, research and development quality assurance, and pharmacovigilance functions. Prior to that, Dr. Malamut had similar responsibilities as Chief Medical Officer at Avanir Pharmaceuticals from 2016 to 2018 and was Senior Vice President of Global Clinical Development at Teva Pharmaceutical Industries Ltd from 2013 to 2016 where he was responsible for Pain, Neuropsychiatry, Oncology, and New Therapeutic Entities. His experience also includes roles of increasing responsibility focusing on early clinical development and translational medicine in Neurology, Psychiatry and Analgesia at Bristol-Myers Squibb and AstraZeneca. Dr. Malamut earned his medical degree from Hahnemann University in Philadelphia and completed both a residency in Neurology and a fellowship in Neuromuscular disease. He worked as a board-certified academic and clinical neurologist for 17 years and has more than 50 publications in the fields of pain medicine, neuromuscular disease, autonomic disease, and neurodegenerative disease. He was selected to serve on our board of directors due to his experience and knowledge of our industry.

Chia-Lin Simmons has served as a member of our board of directors since March 2023. Since June 2021, Ms. Simmons has served as Chief Executive Officer and as a director of LogicMark, Inc. (Nasdaq: LGMK), a company that develops medical alert devices and related technologies. Ms. Simmons currently also serves as a member of the board of directors for Servco Pacific Inc., a global automotive and consumer goods company with businesses in mobility, automotive distribution and sales, and entertainment, and for New Energy Nexus, an international organization that supports clean energy entrepreneurs with funds, accelerators, and networks. From 2016 to June 2021, Ms. Simmons served as the Chief Executive Officer and co-founder of LookyLoo, Inc., an artificial intelligence social commerce company. From 2014 to 2016, Ms. Simmons served as Head of Global Partner Marketing at Google Play, prior to which, between 2010 and 2014, she served as VP of Marketing & Content for Harman International. Ms. Simmons received her B.A. in Communications, Magna cum Laude, and Phi Beta Kappa, from the University of California, San Diego in 1995. She also received her M.B.A. from Cornell University in 2002, where she was a Park Leadership Fellow, and her J.D. from George Mason University in 2005, and is currently a licensed attorney in the State of New York. She was selected to serve on our board of directors due to her experience serving on the boards of directors of public companies.

Board Composition

Board of Directors

Upon completion of the IPO, our board of directors will consist of four members. The primary responsibilities of our board of directors are to provide oversight, strategic guidance, counseling and direction to our management. Our board of directors meets on a regular basis and additionally as required.

Director Independence

Applicable NYSE American rules require a majority of a listed company's board of directors to be comprised of independent directors within one year of listing. In addition, NYSE American rules require that, subject to specified exceptions, each member of a listed company's audit, compensation and nominating and corporate governance committees be independent and that audit committee members also satisfy independence criteria set forth in Rule 10A-3 under the Exchange Act. The NYSE American independence definition includes a series of objective tests, such as that the director is not, and has not been for at least three years, one of our employees and that neither the director nor any of his family members has engaged in various types of business dealings with us. In addition, under applicable NYSE American rules, a director will only qualify as an "independent director" if, in the opinion of the listed company's board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

Our board of directors has determined that all of our non-employee directors, other than Mr. Todd Davis, are independent, as defined under applicable NYSE American rules. In making such determination, our board of directors considered the relationships that each such non-employee director has with our company and all other facts and circumstances that our board of directors deemed relevant in determining his or her independence, including the beneficial ownership of our capital stock by each non-employee director and the transactions involving them described in the section entitled "Certain Relationships and Related-Party Transactions."

Audit committee members must also satisfy the independence criteria set forth in Rule 10A-3 under the Exchange Act. In order to be considered independent for purposes of Rule 10A-3 of the Exchange Act, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors or any other board committee: (i) accept, directly or indirectly, any consulting, advisory or other compensatory fee from the listed company or any of its subsidiaries; or (ii) be an affiliated person of the listed company or any of its subsidiaries.

Our executive officers are elected by, and serve at the discretion of, our board of directors. There are no family relationships among any of our directors and officers.

Committees of Our Board of Directors

Our board of directors has an audit committee, a compensation committee and a nominating and corporate governance committee, each of which have the composition and responsibilities described below. Members serve on these committees until their resignation or until otherwise determined by our board of directors. Each committee operates under a charter approved by our board of directors. Copies of each committee's charter are posted on the investor relations section of our website at www.chromocell.com.

Audit Committee

Our audit committee is composed of Ezra Friedberg and Chia-Lin Simmons. Ezra Friedberg is the chairperson of our audit committee. The composition of our audit committee meets the requirements for independence under the current NYSE American listing standards and SEC rules and regulations. Each member of our audit committee is financially literate. In addition, our board of directors has determined that Ezra Friedberg is an "audit committee financial expert" as defined in Item 407(d)(5)(ii) of Regulation S-K promulgated under the Securities Act. This designation does not impose any duties, obligations or liabilities that are greater than are generally imposed on members of our audit committee and our board of directors. Our audit committee is responsible for, among other things:

- our accounting and financial reporting processes, including our financial statement audits and the integrity of our financial statements;
- our compliance with legal and regulatory requirements;
- reviewing and approving related person transactions;
- selecting and hiring our registered independent public accounting firm;
- the qualifications, independence and performance of our independent auditors; and
- the preparation of the audit committee report to be included in our annual proxy statement.

Compensation Committee

Our compensation committee is composed of Richard Malamut and Chia-Lin Simmons. Richard Malamut is the chairperson of our compensation committee. The composition of our compensation committee meets the requirements for independence under the current NYSE American listing standards and SEC rules and regulations. Each member of this committee is: (i) an outside director, as defined pursuant to Section 162(m) of the Internal Revenue Code of 1986, as amended (the "Code"); and (ii) a non-employee director, as defined in Rule 16b-3 promulgated under the Exchange Act. Our compensation committee is responsible for, among other things:

- evaluating, recommending, approving and reviewing executive officer and director compensation arrangements, plans, policies and programs;
- administering our cash-based and equity-based compensation plans; and
- making recommendations to our board of directors regarding any other board of director responsibilities relating to executive compensation.

Nominating and Corporate Governance Committee

Our nominating and corporate governance committee is composed of Chia-Lin Simmons and Richard Malamut. Chia-Lin Simmons is the chairperson of our nominating and corporate governance committee. The composition of our nominating and corporate governance committee meets the requirements for independence under the current NYSE American listing standards and SEC rules and regulations. Our nominating and corporate governance committee is responsible for, among other things:

- identifying, considering and recommending candidates for membership on our board of directors;
- overseeing the process of evaluating the performance of our board of directors; and
- advising our board of directors on other corporate governance matters.

Code of Business Conduct and Ethics

We have adopted a Code of Business Conduct and Ethics (the "Code of Conduct"), applicable to all of our employees, executive officers and directors, which is available on our website at www.chromocell.com. The reference to our website address in this prospectus does not include or incorporate by reference the information on our website into this prospectus. The nominating and corporate governance committee of our board of directors is responsible for overseeing the Code of Conduct and must approve any waivers of the Code of Conduct for employees, executive officers and directors. In addition, we intend to post on our website all disclosures that are required by law or the listing standards of the applicable stock exchange concerning any amendments to, or waivers from, any provision of the Code of Conduct, to the extent required by the applicable rules and exchange requirements.

Non-Employee Director Compensation

We have not implemented a formal policy with respect to equity awards granted to our non-employee directors. From time to time, we have granted equity awards to attract individuals to join our board of directors and for their continued service thereon. We did not pay any compensation to any of our non-employee directors in 2022 and 2023. We plan to reimburse our directors for expenses associated with attending meetings of our board of directors and its committees although we have not previously done so.

On March 9, 2023, our board of directors approved cash compensation in the amount of $10,000.00 per quarter for all non-employee directors who serve and will serve on the board of directors, so long as they serve on the board of directors, effective beginning immediately following the IPO.

EXECUTIVE COMPENSATION

Our named executive officers for 2023 were Mr. Christian Kopfli, our former Chief Executive Officer and former Chief Strategy Officer, Mr. Francis Knuettel II, our Interim Chief Executive Officer, Chief Financial Officer, Treasurer and Secretary, and Mr. Eric Lang, our Chief Medical Officer. Mr. Knuettel was first appointed in June 2022, and Mr. Lang was first appointed in May 2023. The number of equity awards issued presented below does not give effect to the 1-for-9 Reverse Stock Split in connection with the IPO Transactions.

Summary Compensation Table

The following table provides information regarding the compensation of our named executive officers during the years ended December 31, 2023 and 2022.

Name and Principal Position	Year	Salary	Bonus	Option Awards	Non-Equity Incentive Plan Compensation	All Other Compensation	Total
Christian Kopfli Former Chief Executive Officer, Former Chief Strategy Officer, and Former Vice Chairman [2]	2023	$ 11,280[1]	$ --	$ 149,633	$ --	$ --	$ 160,913
	2022	$ 158,654[1]	$ --	$ 49,578	$ --	$ --	$ 208,232
Francis Knuettel II Interim Chief Executive and Chief Financial Officer	2023	$ 100,000	$ --	$ 199,510	$ --	$ --	$ 299,510
	2022	$ 30,000	$ --	$ 49,878	$ --	$ --	$ 79,878
Eric Lang[3] Chief Medical Officer	2023	$ 166,767	$ --	$ 120,735	$ --	$ --	$ 287,502
	2022	$ --	$ --	$ --	$ --	$ --	$ --

(1) Represents the portion of Mr. Kopfli's salary attributable to his services to the Company during the years ended December 31, 2023 and 2022.

(2) Mr. Kopfli stepped down as Chief Financial Officer with the hiring of Mr. Knuettel, effective June 10, 2022. In addition, in July 2023, Mr. Knuettel assumed the role of Interim Chief Executive Officer and stepped down as Chief Strategy Officer, and Mr. Kopfli was appointed Vice Chairman and Chief Strategy Officer. On December 1, 2023, the Company terminated Mr. Kopfli as Vice Chairman and Chief Strategy Officer.

(3) Represents the portion of Mr. Lang's salary attributable to his services to the Company during the year ended December 31, 2023. Mr. Lang was appointed Chief Medical Officer of the Company, effective May 15, 2023.

Employment Agreements and Arrangements

Christian Kopfli

We were a party to an amended and restated employment agreement with Christian Kopfli, dated July 28, 2023. Pursuant to such agreement, Mr. Kopfli agreed to serve as our Vice Chairman and Chief Strategy Officer, in consideration for an annualized salary of $275,000, payable in cash at the rate of $5,000 per month (a minimum of $1,125 per week), with the remainder accrued and paid as of the earliest of a sale or liquidation of the Company, the Company's bankruptcy or three days after the approval by the Board of a funded budget with appropriately established milestones subsequent to the effective date of a Form S-1 registration statement ("Post-registration Approval"). Mr. Kopfli also agreed, as of Post-registration Approval, to resign as Chief Executive Officer of Chromocell Corporation although he could continue to serve on the board of directors of Chromocell Corporation, including as its Board Chair. The employment agreement provided that Mr. Kopfli receive an option to acquire 200,000 shares of our Common Stock, vesting quarterly over 10 quarters and beginning October 1, 2022. This option shall have an exercise price equal to the fair market value of our Common Stock on the date of grant and shall expire on the 10th anniversary of the date of grant. The option was awarded as of January 10, 2023. The employment agreement contemplated an annual bonus, as determined by the Board. The target bonus was 50% of Mr. Kopfli's annualized salary and was to be based on achievement of performance goals and objectives agreed to by Mr. Kopfli and the Board in January of each year. The Board was to increase the bonus in recognition of performance in excess of the performance objectives. Any bonus would have only been paid if Mr. Kopfli remained employed on the date of payment, which would have been no later than March 15 of the year following the year to which the bonus relates. Any bonus for 2022 would have been payable solely in the Board's discretion.

Pursuant to Mr. Kopfli's employment agreement, in the event he was involuntarily terminated by the Company other than for "Cause" or if he resigns for "Good Reason," he was entitled to receive (i) six months of salary at the same rate existing immediately prior to his termination, (ii) his target bonus, if performance goals and objectives had been established for the year and prorated for the period of service, and (iii) six months of additional vesting credit with respect to any outstanding time-based equity awards. "Cause" and "Good Reason" are each defined in the employment agreement.

Finally, Mr. Kopfli agreed to certain non-solicitation and non-competition provisions for a period of 12 months following termination and to certain confidentiality obligations. Additional terms and conditions are set forth in the employment agreement.

On November 27, 2023, Mr. Kopfli was removed from our Board by our stockholders having a majority of the number of votes necessary to take such action. Mr. Kopfli was then terminated from his position as Vice Chairman and Chief Strategy Officer by the Company for "Cause", as defined in the employment agreement, effective December 1, 2023.

Camden Capital LLC

We entered into a Consultant Agreement with Camden Capital LLC, dated January 10, 2023 (the "Consultant Agreement"). This Consultant Agreement replaced an agreement with Mr. Francis Knuettel II dated June 2, 2022 and pursuant to which, Camden Capital LLC agreed to provide the services of Mr. Knuettel, who was to serve as our Chief Financial and Strategy Officer, Treasurer and Secretary.

Under the Consultant Agreement, Camden Capital LLC accrued a consulting fee for the period June 6, 2022 through August 31, 2022 of $10,000 per month and effective September 1, 2022, began to accrue a consulting fee of $20,000 per month, payable in cash at the rate of $5,000 per month (a minimum of $1,125 per week), with the remainder accrued. All accrued consulting fees are payable as of the earliest of a sale or liquidation of the Company, the Company's bankruptcy or three days after Post-registration Approval. The Consultant Agreement provides for the following equity awards to Camden Capital LLC: (i) an option, awarded as of January 10, 2023, to acquire 200,000 shares of our Common Stock, vesting quarterly over 10 quarters and beginning October 1, 2022, with the option having an exercise price equal to the fair market value of our Common Stock on the date of grant and expiring on the 10th anniversary of the date of grant; (ii) an option, awarded as of January 10, 2023, to acquire 25,000 shares of our Common Stock, vesting 100% upon the sooner of the sale of the Company or Post-registration Approval, with the option having an exercise price equal to the fair market value of our Common Stock on the date of grant and expiring on the 10th anniversary of the date of grant; and (iii) a restricted stock unit ("RSU"), awarded as of January 10, 2023, of 150,000 shares of our Common Stock, vesting 100% on the day after the first trading window that opens after Post-registration Approval.

The Consultant Agreement contemplates an additional consulting fee, as determined by the Board. The potential additional consulting fee is 50% of the annualized consulting fee and will be based on achievement of performance goals and objectives established by the Board in concert with Mr. Knuettel in January of each year. The Board may increase the potential additional consulting fee in recognition of performance in excess of the performance objectives. Any amount shall only be paid if Camden Capital LLC continues to provide consulting services to the Company as of the date of payment, which will be no later than March 15 of the year following the year to which the additional

consulting fee relates. Any additional consulting fee for 2022 is payable solely in the Board's discretion.

Pursuant to the Consultant Agreement, in the event the relationship with Camden Capital LLC is involuntarily terminated by the Company other than for "Cause" or if Camden Capital LLC terminates the relationship for "Good Reason," Camden Capital LLC is entitled to receive (i) six months of consulting fees at the same rate existing immediately prior to termination, (ii) a potential additional consulting fee, if performance goals and objectives have been established for the year and prorated for the period of service, and (iii) six months of additional vesting credit with respect to any outstanding time-based equity awards. "Cause" and "Good Reason" are each defined in the Consultant Agreement.

Finally, Camden Capital LLC and Mr. Knuettel agree to certain non-solicitation and non-competition provisions for a period of 12 months following termination of the relationship and to certain confidentiality obligations. Additional terms and conditions are set forth in the Consultant Agreement.

On June 23, 2023, we amended and restated the Consultant Agreement by entering into an Amended and Restated Consultant Agreement with Camden Capital LLC whereby the RSU for 150,000 shares of Common Stock was cancelled, and we agreed to grant Camden Capital LLC an option to acquire 250,000 shares of Common Stock within 30 days of the closing of the IPO. As of June 23, 2023, such RSU for 150,000 shares of our Common Stock had not vested, and no expense was recorded on the Company's financial statements. In addition, from and after June 1, 2023, the consulting fee will be paid in cash by the Company. No other material changes were made to the Consultant Agreement.

Eric Lang

We are a party to an employment agreement with Eric Lang, effective May 15, 2023. Pursuant to such agreement, Mr. Lang agreed to serve as our Chief Medical Officer, in consideration for an annualized salary of $400,000. The employment agreement provides that Mr. Lang receive an option to acquire 218,000 shares of our Common Stock, vesting quarterly over 12 quarters and beginning August 15, 2023. This option shall have an exercise price equal to the fair market value of our Common Stock on the date of grant and shall expire on the 10th anniversary of the date of grant. The option was awarded as of May 15, 2023. The employment agreement contemplates an annual bonus, as determined by the Board. The target bonus is 50% of Mr. Lang's annualized salary and will be based on achievement of performance goals and objectives determined by our Chief Executive Officer. The Chief Executive Officer may increase the bonus in recognition of performance in excess of the performance objectives. Any bonus will be paid if Mr. Lang remains employed on the date of payment, which will be no later than March 15 of the year following the year to which the bonus relates. In addition, the employment agreement contemplates annual equity bonus. The Board may, in its sole discretion, and for so long as Mr. Lang remains an employee, make an annual discretionary bonus award of an option to acquire up to 32,000 additional shares of Common Stock of the Company. Any such option shall vest in equal increments on a quarterly basis, beginning one quarter after the date of grant, with the final vesting date on the third anniversary of the date of grant. The option shall have an exercise price equal to the fair market value of our Common Stock on the date of grant and shall expire on the 10th anniversary of the date of grant.

Pursuant to Mr. Lang's employment agreement, in the event he is involuntarily terminated by the Company other than for "Cause" or if he resigns for "Good Reason," he is entitled to receive (i) six months of salary at the same rate existing immediately prior to his termination, (ii) 50% of his annualized salary, prorated from January 1 of the year of termination and through the date of termination, (iii) vesting of all outstanding options with time-based vesting, and (iv) coverage of 18 months of group medical, dental and/or vision benefits under the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended, if he elects to continue such benefits. "Cause" and "Good Reason" are each defined in the employment agreement.

Finally, Mr. Lang agreed to certain non-solicitation and non-competition provisions for a period of 12 months following termination and to certain confidentiality obligations. Additional terms and conditions are set forth in the employment agreement.

Equity and Equity-Based Plans

Outstanding Equity Awards at Fiscal Year-End

The following table provides information regarding the outstanding equity awards of our named executive officers during the year ended December 31, 2023.

	Option Awards					Stock Awards			
Name and Principal Position	**Number of Securities Underlying Unexercised Options Exercisable**	**Number of Securities Underlying Unexercised Options Unexercisable**	**Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options**	**Option Exercise Price**	**Option Expiration Date**	**Number of shares of Common Stock Unvested**	**Market Value of shares of Common Stock Unvested**	**Equity Incentive Plan Awards: Number of Unearned Unvested Shares**	**Equity Incentive Plan Awards: Market or Payout Value of Unearned Unvested Shares**
Christian Kopfli Former Chief Executive Officer [1]	100,000	100,000	---	$ 2.52	09/30/2032	---	$ ---	---	$ ---
Francis Knuettel II, Interim Chief Executive Officer and Chief Financial Officer	100,000	375,000	---	$ 2.52	09/30/2032	---	$ ---	---	$ ---
Eric Lang, Chief Medical Officer	36,333	181,667	---	$ 2.52	05/15/2033	---	$ ---	---	$ ---

(1) Mr. Kopfli stepped down as Chief Financial Officer with the hiring of Mr. Knuettel, effective June 10, 2022. In addition, in July 2023, Mr. Knuettel assumed the role of Interim Chief Executive Officer and stepped down as Chief Strategy Officer, and Mr. Kopfli was appointed Vice Chairman and Chief Strategy Officer. On December 1, 2023, the Company terminated Mr. Kopfli as Vice Chairman and Chief Strategy Officer.

Equity Incentive Plans

The Chromocell Therapeutics Corporation 2023 Equity Incentive Plan (the "2023 Plan")

On January 10, 2023, our board of directors adopted and submitted for stockholder approval the 2023 Plan, which 2023 Plan was later approved by the Company's stockholders. On February 15, 2023, we amended the 2023 Plan to increase the number of shares available for issuance thereunder to 444,444 (after giving effect to the Reverse Stock Split). The following summary of the material features of the 2023 Plan is qualified in its entirety by reference to the complete text of the 2023 Plan, a copy of which is filed with the registration statement of which this prospectus forms a part. The 2023 Plan will terminate on January 10, 2033, in accordance with its terms, although, awards outstanding under the 2023 Plan will continue to be governed by their existing terms after the 2023 Plan's expiration.

Share Reserve. We have reserved 444,444 shares of our Common Stock for issuance under the 2023 Plan (after giving effect to the 1-for-9 Reverse Stock Split in connection with the IPO Transactions). Unissued shares of Common Stock subject to awards that fail to settle, vest or be fully exercised prior to expiration or other termination shall again become available for grant under the terms of the 2023 Plan.

Administration. Our board of directors currently administers the 2023 Plan. The compensation committee of our board of directors administers the 2023 Plan. The administrator has complete discretion to make all decisions relating to the 2023 Plan and outstanding awards.

Eligibility. Key employees, non-employee members of our board of directors and other persons who render services of special importance to our management, operation or development are eligible to participate in the 2023 Plan.

Types of Awards. The 2023 Plan provides for the following types of awards granted with respect to shares of our Common Stock:

- incentive and nonqualified stock options to purchase shares of our Common Stock;
- stock appreciation rights, whether settled in cash or our Common Stock;
- direct awards or sales of shares of our Common Stock, with or without restrictions; and
- restricted stock units.

The recipient of an award under the 2023 Plan is referred to as a participant.

Options. The administrator may grant incentive stock options (ISOs) and nonqualified stock options (NSOs) under the 2023 Plan. The administrator determines the number of shares of our Common Stock subject to each option, its exercise price, its duration and the manner and time of exercise; provided, however, that no option may be issued under the 2023 Plan with an exercise price that is less than the fair market value of our Common Stock as of the date the option is granted, and no option issued as an ISO will have a duration that exceeds ten years. ISOs may be issued only to our employees or employees of our corporate subsidiaries, and in the case of a more than ten percent stockholder, must have an exercise price that is at least 110% of the fair market value of our Common Stock as of the date the option is granted, and may not have a duration of more than five years.

The administrator, in its discretion, may provide that any option is subject to vesting limitations that make it exercisable during its entire duration or during any lesser period of time.

The exercise price of an option may be paid in cash, by delivery of a recourse promissory note secured by the Common Stock acquired upon exercise of the option (except that such a loan would not be available to any of our executive officers or directors), by means of a "cashless exercise" procedure in which a broker transmits to us the exercise price in cash, either as a margin loan or against the optionee's notice of exercise and confirmation by us that we will issue and deliver to the broker stock certificates for that number of shares of Common Stock having an aggregate fair market value equal to the exercise price, or agrees to pay the exercise price to us in cash upon our receipt of stock certificates, by delivery of shares of our Common Stock already owned by the optionee, by a "net exercise" in the case of an NSO or by any combination of the methods listed.

Stock Appreciation Rights (SARs). The administrator may also grant SARs to participants on such terms and conditions as it may determine. SARs may be granted separately or in connection with an option. No SAR may be issued under the 2023 Plan with an exercise price that is less than the Fair Market Value of our Common Stock as of the date the SAR is granted, and no SAR will have a duration that exceeds ten years. Upon the exercise of an SAR, the participant is entitled to receive payment equal to the excess of the fair market value, on the date of exercise, of the number of shares of Common Stock for which the SAR is exercised over the exercise price for the Common Stock under a related option or, if there is not a related option, over an amount per share stated in the agreement setting forth the terms and conditions of the SAR.

Payment to the participant may be made in cash or other property, including Common Stock, in accordance with the provisions of the SAR agreement.

Stock Grants. The administrator may make an award in one or more of the following forms of stock grant. Stock grants (including restricted stock units and performance units after settlement) generally will provide the participant with all of the rights of a stockholder of ours, including the right to vote and to receive payment of dividends.

Stock grant without restriction. The administrator may make a stock grant without any restrictions.

Restricted stock and restricted stock units ("RSUs"). The administrator may issue shares of our Common Stock with restrictions determined by the administrator in its discretion. Restrictions could include conditions that require the participant to forfeit the shares in the event that the participant ceases to provide services to us or any of our affiliates thereof before a stated time. RSUs are similar to restricted stock except that no shares are actually issued to the participant on the RSU grant date. Rather, and provided all applicable restrictions are satisfied, shares of Common Stock are generally delivered at settlement of the award. The period of restriction, the number of shares of restricted stock or the number of RSUs granted, the purchase price, if any, and such other conditions and/or restrictions as the administrator may establish will be set forth in an award agreement. Participants holding RSUs will not have voting rights or other rights as a stockholder until any shares related to the RSU are issued. After all conditions and restrictions applicable to restricted shares and/or RSUs have been satisfied or have lapsed, shares of restricted stock will become freely transferable and RSUs may be settled in cash, in shares of our Common Stock or in some combination of cash and shares of our Common Stock, as determined by the administrator and stated in the award agreement.

Performance shares and performance share units ("PSUs"). With respect to an award of performance shares and/or PSUs, the administrator will establish performance periods and performance goals. The extent to which a participant achieves their performance goals during the applicable performance period will determine the value and/or the number of performance shares and/or PSUs earned by such participant. Payment of earned performance shares and/or PSUs will be in cash, shares of our Common Stock or some combination of cash and shares of our Common Stock, as determined by the administrator and stated in the award agreement.

Other awards. The administrator may issue other types of equity-based or equity-related awards under the 2023 Plan, on such terms and conditions as the administrator shall determine in its discretion.

Dividends. Participants holding restricted stock and performance shares will be entitled to receive dividends on our shares, provided that in the discretion of the administrator, participants will not be entitled to dividends with respect to unvested restricted stock and performance shares until the stock or shares vest, respectively. Dividend equivalent units may, but are not required to, be issued with respect to RSUs or PSUs and may be paid in cash, additional shares of our Common Stock or a combination on the date the shares are delivered, all as determined by the administrator and stated in the award agreement.

Effect of certain corporate transactions. In the event of a stock split, reverse stock split, stock dividend, recapitalization, combination of shares, reclassification of shares, spin-off or other similar change in capitalization or event, or any dividend or distribution on our Common Stock other than an ordinary cash dividend, the administrator shall make equitable adjustments to awards as it, in its sole discretion, deems appropriate. In the case of (1) a merger or consolidation of the Company with or into another entity pursuant to which all of our Common Stock is cancelled or converted into or exchanged for the right to receive cash, securities or other property, (2) any transfer or disposition of all of our Common Stock for cash, securities or other property pursuant to a share exchange or other transaction, (3) the sale or other disposition of all or substantially all of the Company's assets or (4) any liquidation or dissolution of the Company, the administrator may take any of a number of actions including providing for the assumption of awards, the termination of awards (with advance notice permitting exercise), Awards to become exercisable at or prior to the event, the liquidation of awards or any combination of the foregoing.

Amendments to the 2023 Plan. Our board of directors may amend, suspend or terminate the 2023 Plan in whole or in part at any time provided that stockholder approval shall be required to the extent necessary under the rules applicable to ISOs or under NYSE American or other applicable securities exchange rules.

The administrator may, without stockholder approval, amend the 2023 Plan as necessary to enable awards to qualify for favorable foreign tax, securities or other treatment in the case of a participant who is subject to a jurisdiction outside the United States.

Amendments or Termination. The administrator may at any time amend, suspect or terminate the 2023 Plan, subject to stockholder approval in the case of an amendment if the amendment increases the number of shares available for issuance or materially changes the class of persons eligible to receive incentive stock options. The 2023 Plan will terminate automatically ten years after the later of the date when our board of directors adopted the plan or the date when our board of directors most recently approved an increase in the number of shares of Common Stock reserved thereunder which was also approved by our stockholders, and as noted above, any awards outstanding under the 2023 Plan upon termination will remain outstanding and will continue to be governed by their existing terms.

On January 10, 2023, pursuant to the 2023 Plan, we granted: (a) options to purchase up to an aggregate of 1,275,000 shares of Common Stock to employees and directors and (b) 150,000 RSUs to employees. On March 9, 2023, pursuant to the 2023 Plan, we granted an option to purchase up to 135,000 shares of Common Stock to a director. On June 23, 2023, we granted options to acquire 468,000 shares of Common Stock to employees (inclusive of options that have not yet been granted but the Company has agreed to grant in connection with the closing of the IPO) and canceled an RSU for 150,000 shares issued to an employee on January 10, 2023. The number of equity awards in the preceding sentences does not give effect to the 1-for-9 Reverse Stock Split in connection with the IPO Transactions.

The offers and sales of the above securities were deemed to be exempt from registration under the Securities Act in reliance upon Section 4(a)(2) of the Securities Act or Regulation D promulgated thereunder, or Rule 701 promulgated under Section 3(b) of the Securities Act, as transactions by an issuer not involving any public offering or pursuant to benefit plans and contracts relating to compensation as provided under Rule 701. The recipients of the above securities represented their intentions to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof.

Limitations on Liability and Indemnification Matters

Our certificate of incorporation contains provisions that limit the liability of our current and former directors for monetary damages to the fullest extent permitted by Delaware law. Delaware law provides that directors of a corporation will not be personally liable for monetary damages for any breach of fiduciary duties as directors, except liability for:

- any breach of the director's duty of loyalty to the corporation or its stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the DGCL; or
- any transaction from which the director derived an improper personal benefit.

These limitations of liability do not apply to liabilities arising under federal securities laws and does not affect the availability of equitable remedies such as injunctive relief or rescission.

Our certificate of incorporation and our bylaws provide that we are required to indemnify our directors to the fullest extent permitted by Delaware law. Our bylaws will also provide that, upon satisfaction of certain conditions, we are required to advance expenses incurred by a director in advance of the final disposition of any action or proceeding, and permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in that capacity regardless of whether we would otherwise be permitted to indemnify him or her under the provisions of Delaware law. Our bylaws will also provide our board of directors with discretion to indemnify our officers and employees when determined appropriate by the board.

We have entered into indemnification agreements with each of our executive officers and directors. With certain exceptions, these agreements provide for indemnification for related expenses including, among other things, attorneys' fees, judgments, fines and settlement amounts incurred by any of these individuals in any action or proceeding. We believe that these bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and executive officers. We also maintain customary directors' and officers' liability insurance.

The limitation of liability and indemnification provisions in our certificate of incorporation and bylaws may discourage stockholders from bringing a lawsuit against our directors for breach of their fiduciary duty. They may also reduce the likelihood of derivative litigation against our directors and officers, even though an action, if successful, might benefit us and other stockholders. Further, a stockholder's investment may be adversely affected to the extent that we pay the costs of settlement and damage awards against directors and officers as required by these indemnification provisions. At present, there is no pending litigation or proceeding involving any of our directors, officers or employees for which indemnification is sought and we are not aware of any threatened litigation that may result in claims for indemnification.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted for our directors, executive officers or persons controlling us, we have been informed that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

Rule 10b5-1 Sales Plans

Our directors and executive officers may adopt written plans, known as Rule 10b5-1 plans, in which they will contract with a broker to buy or sell shares of our Common Stock on a periodic basis. Under a Rule 10b5-1 plan, a broker executes trades pursuant to parameters established by the director or officer when entering into the plan, without further direction from them. The director or officer may amend a Rule 10b5-1 plan in some circumstances and may terminate a plan at any time. Our directors and executive officers also may buy or sell additional shares outside of a Rule 10b5-1 plan when they are not in possession of material nonpublic information subject to compliance with the terms of our insider trading policy. Prior to 180 days after the effective date of the registration statement of which this prospectus forms a part, subject to early termination, the sale of any shares under such plans would be prohibited by the lock-up agreement that the director or officer has entered into with the underwriters.

CERTAIN RELATIONSHIPS AND RELATED PARTY AND OTHER TRANSACTIONS

The following is a summary of transactions among related parties that occurred since the Company's incorporation, and any ongoing related party relationships:

In May 2021, Chromocell Holdings, the Company and Flamands International Holdings LLC ("Flamands") commenced negotiations regarding a three-party agreement whereby Chromocell Holdings would spin off assets and liabilities associated with its therapeutics operations to the Company and Flamands would provide funding to the Company. As the parties contemplated various transactional structures, an agreement was never effectuated because significant details concerning the assumption of liabilities were never finalized. Chromocell Holdings instead provided multiple advances to the Company for its operations from May 2021 through August 2022. At December 31, 2021, all amounts previously received from Chromocell Holdings by the Company were recorded as advances payable on the Company's financial statements.

On August 10, 2022, the Company and Chromocell Holdings entered into the Contribution Agreement effecting (1) the contribution by Chromocell Holdings to the Company of assets related to Chromocell Holding's Therapeutics Business, including all intellectual property related to Chromocell Holding's NaV1.7 program and its clinical-stage CC8464 lead compound, (2) assumption by the Company of direct liabilities related to Chromocell Holding's historical Therapeutics Business in the amount of $1,556,323 as well as a cash payment by the Company to Chromocell Holdings of $597,038 within three business days of the closing of the IPO and (3) the issuance by the Company to Chromocell Holdings of 10,000,000 shares of its common stock and 600,000 shares of its Series A Preferred Stock.

On August 2, 2023, we entered into the Holdings Side Letter to the Contribution Agreement. Pursuant to the Holdings Side Letter, upon closing of the IPO: (a) Chromocell Holdings will re-assume all $1.6 million in direct liabilities previously assumed by the Company in accordance with the Contribution Agreement, (b) Chromocell Holdings will waive the Company's obligations to make a cash payment in the amount of $0.6 million to Chromocell Holdings, and (c) in consideration thereof, we will issue to Chromocell Holdings 2,600 shares of Series C Preferred Stock.

On April 17, 2023, Chromocell Holdings forfeited 1,203,704 shares of Common Stock (133,745 shares of Common Stock after giving effect to the Reverse Stock Split) as Chromocell Holdings did not fund its pro rata allocation in the April Bridge Financing, per the terms governing the April Bridge Financing.

On December 6, 2022, the Company and Mr. Todd Davis, one of our directors, entered into the Director Note with a face amount of $175,000 and purchase price of $100,000. The Director Note matured on December 31, 2023 or, if earlier to occur, upon the closing of an underwritten offering of securities resulting in at least $15 million in gross proceeds. Mr. Davis, as lender, has the right but not the obligation to subscribe to the underwritten offering by presenting the Director Note in whole or in part to purchase such securities as legal tender therefor, on a dollar-for-dollar basis based upon the offering price of such securities to the public. The Director Note bears no interest except in the case of certain events of default. On December 28, 2023, we entered into an amendment to the Director Note, which extended the maturity date to February 29, 2024.

On April 17, 2023, we entered into a April Bridge Financing for working capital purposes with various accredited investors, all of whom are pre-existing stockholders, including Chromocell Holdings, Boswell Prayer Ltd., Motif Pharmaceuticals Ltd, Aperture Healthcare Ventures Ltd., MDB Merchants Park LLC, Balmoral Financial Group LLC and AME EQUITIES LLC (each a related party based on share ownership in excess of 5% or resulting from a principal at one of the entities being on the Company's board of directors) in the aggregate principal amount of $389,757, after giving effect to the Representative Affiliate Transactions. During the nine months ended September 30, 2023, the Company received $166,903 in Advances from certain participating investors. Such Advances accrued interest at a rate of eight percent (8%) per annum until close of the April Bridge Financing on April 17, 2023, for a total of $1,870 in aggregate interest on all Advances during the nine months ended September 30, 2023. The April Bridge Financing consists of senior secured convertible notes that had a maturity date of October 17, 2023. On October 12, 2023, we entered into a first amendment to the senior secured convertible notes in the April Bridge Financing, which extended the maturity of the notes to November 1, 2023. On October 24, 2023, we entered into a second amendment to the senior secured convertible notes in the April Bridge Financing, which extended the maturity of the notes to November 14, 2023. On November 13, 2023, we entered into a third amendment to the senior secured convertible notes in the April Bridge Financing, which further extended the maturity of the notes to February 29, 2024. Such notes accrue interest on the unpaid principal amount at a rate of eight percent (8%) per annum and will automatically convert into shares of Common Stock at the IPO at a twenty percent (20%) discount to the price per IPO Share (87,109 shares, based on the initial public offering price of $6.00 per IPO Share).

On September 1, 2023, we entered into the September Bridge Financing with various accredited investors, certain of which are pre-existing stockholders, including Aperture Healthcare Ventures Ltd., MDB Merchants Park LLC, Balmoral Financial Group LLC and AME EQUITIES LLC (each a related party based on share ownership in excess of 5% or resulting from a principal at one of the entities being on the Company's board of directors) in the aggregate principal amount of $197,421, after giving effect to the Representative Affiliate Transactions. The September Bridge Financing consists of senior secured convertible notes that have a maturity date of March 1, 2024. Such notes accrue interest on the unpaid principal amount at a rate of eight percent (8%) per annum and will automatically convert into shares of Common Stock in connection with the IPO at a twenty percent (20%) discount to the price per IPO Share plus 549 Bonus Shares (43,385 shares, based on the initial public offering price of $6.00 per IPO Share). The senior secured convertible notes issued in the September Bridge Financing are secured by a security interest in all of our assets (including our patents and intellectual property licenses). In connection with the September Bridge Financing, on September 1, 2023, we also entered into a securities purchase agreement with holders of the notes, pursuant to which we are required to file a registration statement within 180 calendar days after consummation of the IPO, providing for the resale of Common Stock received by holders of the notes upon conversion of such notes. Additionally, entered into a subordination and intercreditor agreement, effective September 1, 2023, with the holders of the senior secured convertible notes issued in the April Bridge Financing, pursuant to which those notes and certain liens of the Company would be subordinated to the rights of the holders of the notes issued in the September Bridge Financing.

On October 12, 2023, we and four existing investors entered into the October Promissory Notes with an aggregate face amount of $210,000 and an aggregate purchase price of $175,000. The October Promissory Notes mature on November 12, 2023 or, if earlier to occur, upon the closing of this IPO. The October Promissory Notes bear no interest except in the case of certain events of default. On November 7, 2023, we amended and restated the October Promissory Notes to extend the maturity dates of the October Promissory Notes to November 17, 2023. On November 13, 2023, we amended and restated the October Promissory Notes to further extend the maturity dates of the Promissory Notes to February 29, 2024.

On November 22, 2023, we commenced the Rights Offering pursuant to which we distributed Subscription Rights to each holder of our Common Stock held as of the Rights Offering Record Date. The Subscription Rights expired at 5:00 p.m., Eastern Standard Time, on December 1, 2023. The Subscription Rights were offered to all of our pre-existing stockholders, including Aperture Healthcare Ventures Ltd., MDB Merchants Park LLC, Balmoral Financial Group LLC and AME EQUITIES LLC (each a related party based on share ownership in excess of 5%, or resulting from a principal at one of the entities being on the Company's board of directors), and each participated and exercised their Subscription Rights to purchase an aggregate of 10,902,036 shares of Common Stock at the Subscription Price. In addition, we distributed to Mr. Knuettel, our Interim Chief Executive Officer and Chief Financial Officer, and Mrs. Lara Knuettel c/o The Lara H. Knuettel Revocable Trust, a trust for which Mr. Knuettel and his wife are co-trustees (the "Knuettel Trust"), and at no charge to them, additional non-transferable Subscription Rights to purchase up to an aggregate 1,428,571 shares of our Common Stock in the Rights Offering at the same Subscription Price. On December 27, 2023, the Knuettel Trust made a charitable donation of 250,000 of those shares (prior to giving effect to the Reverse Stock Split) to Temple Israel of the City of New York. Also on December 27, 2023, AME EQUITIES LLC made a charitable donation of 790,000 of its shares (prior to giving effect to the Reverse Stock Split) to Ballantyne Jewish Center, Inc. Upon the closing of the Rights Offering, we issued an aggregate of 21,982,216 shares (2,442,468 shares, after giving effect to the Reverse Stock Split) of our Common Stock and received aggregate net proceeds of $246,201, after giving effect to the Representative Affiliate Transactions, which we intend to use primarily for general corporate purposes and expenses associated with our initial public offering.

On December 23, 2023, we entered into the Benuvia License Agreement for the Spray Formulations, diversifying our pipeline of non-opioid pain treatment therapies, while adding therapeutic options for related conditions. The Diclofenac Spray Formulation is patented and has started clinical development in human volunteers. Preliminary pharmacokinetics suggest that this formulation may have a faster onset of action than oral Diclofenac tablets. Diclofenac is an NSAID that is also marketed under additional brand names including Voltaren and Cataflam in its pill form. Rizatriptan, whose brand name is Maxalt, is used for the acute treatment of Migraines as a pill. By a number of clinical measures it is thought to be superior to Sumatriptan. A sublingual formulation of Rizatriptan may potentially have a faster onset of action than an oral form and may be easier to tolerate than swallowing a pill when patients are experiencing nausea as a result of the migraine headache. Ondansetron is an anti-emetic that is available in oral and intravenous form. An Ondansetron sublingual spray formulation may potentially have a faster onset of action than an oral form and may be easier to tolerate than swallowing a

pill when patients are experiencing nausea. Under the terms of the Benuvia License Agreement, Benuvia will be responsible for the manufacturing and supply of the Spray Formulations, but we will have exclusive, worldwide rights to develop, commercialize and distribute the Spray Formulations and we will purchase the Spray Formulations exclusively from Benuvia, pursuant to the Benuvia Supply Agreement. The initial sale price per unit for each Spray Formulation payable by us to Benuvia pursuant to the Benuvia Supply Agreement shall be subject to good faith negotiations; provided that the initial price for each Spray Formulation and the price for each Spray Formulation during the term of the Benuvia License Agreement in no event shall be less than Benuvia's cost of manufacturing the respective Spray Formulation plus a gross margin to Benuvia. The price for each Spray Formulation shall be subject to an annual increase in amounts equal to the percentage change in the Producer Price Index, Pharmaceutical Preparations as published by the U.S. Department of Labor, Bureau of Labor Statistics.

Under the terms of the Benuvia License Agreement, we obtained exclusive, worldwide rights to develop, commercialize and distribute the Spray Formulations. In connection with the Benuvia License Agreement, we agreed to pay Benuvia a six and one-half percent (6.5%) royalty on net sales of the Spray Formulations for a period of up to 15 years from the date of the first commercial sale of the Spray Formulations. To date, we have paid $0 to Benuvia as royalty on net sales of the Spray Formulations. Pursuant to the Benuvia Stock Issuance Agreement, we issued to Benuvia 3,458,033 shares (384,226 shares, after giving effect to the Reverse Stock Split) of our Common Stock, which may be offered and sold pursuant to the Resale Prospectus. Benuvia will be responsible for the manufacturing and supply of the Spray Formulations, which is capped not to exceed a specific gross margin for Benuvia, and we have a most favored nation rate on development and regulatory services.

Under the Benuvia License Agreement, we will have exclusive, worldwide rights to develop, commercialize and distribute the Spray Formulations. Further, we have the right to request a bid from a third party to manufacture the Spray Formulations once each year.

The Benuvia License Agreement contains standard termination provisions. The Benuvia License Agreement may be terminated in its entirety, on a Spray Formulation by Spray Formulation basis, and by country by county for a material breach not cured within sixty (60) days after written notice thereof. If we breach any of our payment obligations under the terms of the Benuvia License Agreement that are not the subject of a good faith dispute and are not cured within twenty (20) business days following notice thereof, Benuvia may terminate the Agreement upon written notice to us. We also have the right to terminate the Benuvia License Agreement in the event we determine, in our reasonable business judgment, that (i) any of the Spray Formulations will not be differentiated from oral tablets to result in a financially viable product or (ii) after having discussed a Spray Formulations with the FDA, we determine in our reasonable business judgment, that the cost of development of such Spray Formulation would exceed any reasonable forecast of a positive financial return. In the event we terminate the License Agreement, the parties will negotiate in good faith a license agreement to any improvements we made to the Spray Formulations, including any clinical trial data, and Benuvia will pay us a pre-determined royalty for such license. Mr. Davis, one of our directors, serves as the Chairman and Chief Executive Officer of Benuvia Holdings, LLC, which is the ultimate parent company of Benuvia.

On February 8, 2024, we and certain affiliates of the Representative entered into the Bridge Financing Note Amendments. Under the Bridge Financing Note Amendments, both notes issued in the April Bridge Financing and the September Bridge Financing have a maturity date of March 1, 2024, and the full principal amount of both notes and any accrued interest thereon shall be payable solely in cash upon the consummation of this IPO. Both notes have an annual interest rate of eight percent (8%), which accrues daily, and is calculated on the basis of a 360-day year (consisting of twelve 30 calendar day periods).

On February 10, 2024, we entered into the Stock Rescission Agreement with certain affiliates of the Representative, pursuant to which we rescinded 111,129 shares of our Common Stock (after giving effect to the Reverse Stock Split) held by such affiliates of the Representative and agreed to refund an aggregate of $91,512.53 paid by such affiliates of the Representative in consideration therefor within 30 days of the effective date of the Stock Rescission Agreement.

Review, Approval or Ratification of Transactions with Related Parties

In connection with the IPO, we adopted a written related-person transactions policy that provides that our executive officers, directors, nominees for election as a director, beneficial owners of more than 5% of our Common Stock and any members of the immediate family of the foregoing persons, are not permitted to enter into a material related-person transaction with us without the review and approval of our audit committee, or a committee composed solely of independent directors in the event it is inappropriate for our audit committee to review such transaction due to a conflict of interest. The policy provides that any request for us to enter into a transaction with an executive officer, director, nominee for election as a director, beneficial owner of more than 5% of our Common Stock or with any of their immediate family members or affiliates, in which the amount involved exceeds the lesser of (i) $120,000 or (ii) one percent of the average of the Company's total assets at year-end for the last two completed fiscal years will be presented to our audit committee for review, consideration and approval. In approving or rejecting any such proposal, we expect that our audit committee will consider the relevant facts and circumstances available and deemed relevant to the audit committee, including, but not limited to, whether the transaction is on terms no less favorable than terms generally available to an unaffiliated third party under the same or similar circumstances and the extent of the related person's interest in the transaction.

PRINCIPAL STOCKHOLDERS

The following table sets forth information regarding beneficial ownership of our voting securities as of February 21, 2024, by:

- each person or group of affiliated persons known by us to be the beneficial owner of more than 5% of our Common Stock;
- each of our named executive officers;
- each of our directors; and
- all of our executive officers and directors as a group.

We have determined beneficial ownership in accordance with the rules of the SEC and the information is not necessarily indicative of beneficial ownership for any other purpose. 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 of Common Stock that they beneficially own, subject to community property laws where applicable. In computing the number of shares of our Common Stock beneficially owned by a person and the percentage ownership of that person, we deemed outstanding shares of our Common Stock subject to convertible securities, options or warrants held by that person that are currently convertible or exercisable or convertible or exercisable within 60 days of February 21, 2024. We did not deem these shares outstanding, however, for the purpose of computing the percentage ownership of any other person.

Percentage computations prior to the IPO are based on approximately4,667,525 shares of our Common Stock outstanding as of February 21, 2024 (after giving effect to the IPO Transactions and the issuance of the Leak-Out Shares not yet issued as of February 21, 2024). Percentage computations after the IPO are based on approximately 5,767,525 shares of our Common Stock outstanding immediately following the IPO, and assume no exercise of the Underwriter's option to purchase additional IPO Shares. Beneficial ownership representing less than 1% is denoted with an asterisk (*).

Unless otherwise indicated, the address of each beneficial owner listed on the table below is c/o Chromocell Therapeutics Corporation, 4400 Route 9 South, Suite 1000, Freehold, NJ 07728.

	Shares Beneficially Owned Prior to the IPO		Shares Beneficially Owned After the IPO	
	Common Stock		Common Stock	
Name of Beneficial Owner	Number	Percentage	Number	Percentage
Named Executive Officers and Directors				
Francis Knuettel II[1]	177,070	3.8%	177,070	3.0%
Ezra Friedberg[2]	529,054	11.3%	529,054	9.2%
Todd Davis[3]	45,837	1.0%	45,837	*%
Richard Malamut[4]	8,335	*%	8,335	*%
Chia-Lin Simmons[5]	8,335	*%	8,335	*%
Eric Lang[6]	5,592	*%	5,592	*%
All executive officers and directors as a group (6 persons)	**774,223**	**16.6%**	**774,223**	**13.4%**
5% Stockholders				
Chromocell Corporation[7]	1,093,854	23.4%	1,093,854	19.0%
Boswell Prayer Ltd[8]	471,592	10.1%	471,592	8.2%
Motif Pharmaceuticals Ltd.[9]	483,406	10.4%	483,406	8.4%
Balmoral Financial Group LLC[10]	520,719	11.2%	520,719	9.0%
AME Equities LLC[11]	369,177	7.9%	369,177	6.4%
Aperture Healthcare Ventures Ltd.[12]	443,070	9.5%	443,070	7.7%
MDB Merchants Park LLC[13]	273,776	5.9%	273,776	4.7%
Benuvia Operations, LLC[14]	384,226	8.2%	384,226	6.7%

[1] For Mr. Knuettel, includes 15,561 shares of Common Stock underlying stock options that are currently exercisable or exercisable within 60 days of February 21, 2024 and, immediately following the IPO, includes an additional 2,778 shares of Common Stock underlying stock options exercisable upon the closing of the IPO and 27,778 shares of Common Stock underlying stock options that will be issued and will become exercisable within 30 days of the close of the IPO. All reported securities are held of record by Camden Capital LLC ("Camden"). Mr. Knuettel serves as Managing Member of Camden and, accordingly, may be deemed to beneficially own the shares of Common Stock owned directly by Camden. Mr. Knuettel has sole voting and dispositive power over such shares of Common Stock issuable to Camden.

[2] For Mr. Friedberg, includes 8,335 shares of Common Stock underlying stock options that are currently exercisable or exercisable within 60 days of February 21, 2024. In addition, Mr. Friedberg serves as a manager of Balmoral Financial Group LLC ("Balmoral"), which also manages a retirement account for Mr. Friedberg, and, accordingly, Mr. Friedberg may also be deemed to beneficially own the shares of Common Stock held by Balmoral (or managed by Balmoral, in respect of the retirement account).

[3] For Mr. Davis, includes 16,670 shares of Common Stock underlying stock options that are currently exercisable or exercisable within 60 days of February 21, 2024 and, immediately following the IPO, includes an additional 29,167 shares of Common Stock issued in a private placement in full satisfaction of the Company's obligations under the Director Note.

[4] For Mr. Malamut, includes 8,335 shares of Common Stock underlying stock options that are currently exercisable or exercisable within 60 days of February 21, 2024.

[5] For Ms. Simmons, includes 8,335 shares of Common Stock underlying stock options that are currently exercisable or exercisable within 60 days of February 21, 2024.

[6] For Mr. Lang, includes 5,592 shares of Common Stock underlying stock options that are currently exercisable or exercisable within 60 days of February 21, 2024.

[7] For Chromocell Corporation, the shares of Common Stock beneficially owned includes 346,667 shares of Common Stock issuable upon the conversion of 2,600 shares of Series C Preferred Stock at $7.50 per share, or 125% of the price per IPO Share, based on the initial public offering price per IPO Share of $6.00. Christian Kopfli has sole voting and dispositive power over the shares held by Chromocell Corporation. The principal executive office of Chromocell Corporation is 685 US Highway One, North Brunswick, NJ 08902.

[8] Rochelle Gross has sole voting and dispositive power over the shares held by Boswell Prayer Ltd. The principal executive office of Boswell Prayer Ltd. is 145 Adelaide Street West, Toronto ON M5H 4E5, Canada.

[9] Zachary Klein has sole voting and dispositive power over the shares held by Motif Pharmaceuticals Ltd. The principal executive office of Motif Pharmaceuticals Ltd. is 25 and 28 North Wall Quay, Dublin 1, Ireland.

[10] Ezra Friedberg has sole voting and dispositive power over the shares held by Balmoral Financial Group LLC. The principal executive office of Balmoral Financial Group LLC is 106 Court Road, Suite 202, Baltimore, MD 21208.

[11] Ruth Friedman has sole voting and dispositive power over the shares held by AME Equities LLC. The principal executive office of AME Equities LLC is 3012 Luke Crossing Drive, Charlotte, NC 28226.

[12] Avi Wachsman has sole voting and dispositive power over the shares held by Aperture Healthcare Ventures Ltd. The principal executive office of Aperture Healthcare

Ventures Ltd. is 970 Lawrence Ave W. Suite 904, Toronto, ON M6A 3B6, Canada.

(13) Michael Bodner has sole voting and dispositive power over the shares held by MDB Merchants Park LLC. The principal executive office of Merchants Park LLC is 8 The Green Suite A, Dover, DE 19901.

(14) Darwin Richardson has sole voting and dispositive power over the shares held by Benuvia. The principal executive office of Benuvia is 3950 N. Mays Street Round Rock, TX 78665.

DESCRIPTION OF CAPITAL STOCK

Our authorized capital stock consists of 200,000,000 shares of Common Stock and 20,000,000 shares of preferred stock, $0.0001 par value per share (5,000 of which have been designated as Series C Convertible Redeemable Preferred Stock). The following description summarizes the most important terms of our capital stock. Because it is only a summary, it does not contain all the information that may be important to you. For a complete description, you should refer to our certificate of incorporation and bylaws, each as amended, which are included as exhibits to the registration statement of which this prospectus forms a part.

Common Stock

Authorized Shares

The Company has authorized for issuance an aggregate of 200,000,000 shares of Common Stock.

Dividend Rights

The holders of our Common Stock are entitled to receive dividends out of funds legally available if our board of directors, in its discretion, determines to issue dividends and then only at the times and in the amounts that our board of directors may determine. See "Dividend Policy" above.

Voting Rights

Holders of our Common Stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders. We have not provided for cumulative voting for the election of directors.

No Preemptive or Similar Rights

Our Common Stock is not entitled to preemptive rights, and is not subject to conversion, redemption or sinking fund provisions.

Liquidation Rights

Any distribution or payment made to holders of Common Stock in the event of a dissolution, liquidation or winding up of the Company will be made in a pro rata fashion on the basis of the number of shares of Common Stock held by each such holder.

Preferred Stock

Our board of directors has the authority, without further action by our stockholders, to issue up to 20,000,000 shares of preferred stock in one or more classes or series and to fix the designations, rights, preferences, privileges and restrictions thereof, without further vote or action by the stockholder. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting, or the designation of, such class or series, any or all of which may be greater than the rights of Common Stock. The issuance of our preferred stock could adversely affect the voting power of holders of Common Stock and the likelihood that such holders will receive dividend payments and payments upon our liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing a change in control of the Company or other corporate action.

Series C Convertible Redeemable Preferred Stock

We have filed a Certificate of Designation of Series C Redeemable Convertible Preferred Stock with the Secretary of State of the State of Delaware designating 5,000 shares of preferred stock as Series C Preferred Stock.

Dividend Rights

The Series C Preferred Stock has no dividend rights.

Voting Rights

Holders of our Series C Preferred Stock are not entitled to vote, unless otherwise permitted by the DGCL.

Redemption Rights

The Company at its option shall have the right to redeem a portion or all of the outstanding shares of Series C Preferred Stock at any time; provided, however, that we may not redeem any share of Series C Preferred Stock prior to the expiration of the lock-up period associated with this IPO without first obtaining consent of the holder of shares being redeemed. The Company shall pay in cash an amount equal to the Stated Value (as defined in the Certificate of Designation of Series C Preferred Stock) per share of Series C Preferred Stock redeemed.

Conversion

Each share of Series C Preferred Stock is convertible at any time at the holder's option into a number of shares of Common Stock determined by (i) multiplying the Stated Value of the Series C Preferred Stock, and then (ii) dividing the value obtained from the preceding clause (i) by 125% of the price per IPO Share issued to the public in connection with the IPO. If the Common Stock trades for twenty (20) consecutive trading days above 175% of the price per IPO Share issued to the public in connection with the IPO, each share of Series C Preferred Stock shall mandatorily convert into a number of shares of Common Stock equal to the result by multiplying 120% with the quotient obtained by dividing the Stated Value by the price per IPO Share issued to the public in connection with the IPO.

Liquidation Rights

The shares of Series C Preferred Stock are entitled to a liquidation preference of $1,000 per share of Series C Preferred Stock (the "Series C Liquidation Preference"). In the event that we voluntarily or involuntarily liquidate, dissolve, or wind up our affairs, holders of the shares of Series C Preferred Stock are entitled to receive out of our assets available for distribution to stockholders, after satisfaction of liabilities and obligations to creditors, if any, and subject to the rights of holders of any shares of capital stock then outstanding ranking senior to or on parity with the Series C Preferred Stock with respect to distributions upon the voluntary or involuntary liquidation, dissolution, or winding-up of our business and affairs, and before we make any distribution or payment out of our assets to the holders of our Common Stock or any other class or series of our capital stock ranking junior to the Series C Preferred Stock with respect to distributions upon our liquidation, dissolution, or winding-up, an amount per share equal to the Series C Liquidation Preference.

Anti-Takeover Provisions

The provisions of Delaware law, our certificate of incorporation and our bylaws could have the effect of delaying, deferring or discouraging another person from acquiring control of us. These provisions, which are summarized below, may have the effect of discouraging takeover bids. They are also designed, in part, to encourage persons seeking to acquire control of us to negotiate first with our board of directors. We believe that the benefits of increased protection of our potential ability to negotiate with an unfriendly or unsolicited acquirer outweigh the disadvantages of discouraging a proposal to acquire us because negotiation of these proposals could result in an improvement of their terms.

Delaware Law

We are subject to the provisions of Section 203 of the DGCL regulating corporate takeovers. In general, Section 203 of the DGCL prohibits a publicly held Delaware corporation from engaging in a business combination with an interested stockholder for a period of three years following the date on which the person became an interested stockholder unless:

- prior to the date of the transaction, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;

- the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, but not the outstanding voting stock owned by the interested stockholder: (i) shares owned by persons who are directors and also officers; and (ii) shares owned by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or

- at or subsequent to the date of the transaction, the business combination is approved by the board of directors of the corporation and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66.67% of the outstanding voting stock that is not owned by the interested stockholder.

Generally, a business combination includes a merger, asset or stock sale, or other transaction or series of transactions together resulting in a financial benefit to the interested stockholder. An interested stockholder is a person who, together with affiliates and associates, owns or, within three years prior to the determination of interested stockholder status, did own 15% or more of a corporation's outstanding voting stock. We expect the existence of this provision to have an anti-takeover effect with respect to transactions our board of directors does not approve in advance. We also anticipate that Section 203 of the DGCL may also discourage attempts that might result in a premium over the market price for the shares of common stock held by stockholders.

Certificate of Incorporation and Bylaws Provisions

Our certificate of incorporation and our bylaws include a number of provisions that could deter hostile takeovers or delay or prevent changes in control of our company, including the following:

- *Board of Directors Vacancies*. Our certificate of incorporation and bylaws authorize only our board of directors to fill vacant directorships, including newly created seats. In addition, the number of directors constituting our board of directors is permitted to be set only by a resolution adopted by a majority vote of our entire board of directors. These provisions would prevent a stockholder from increasing the size of our board of directors and then gaining control of our board of directors by filling the resulting vacancies with its own nominees. This makes it more difficult to change the composition of our board of directors but promotes continuity of management.

- *Stockholder Action; Special Meetings of Stockholders*. Our certificate of incorporation provides that our stockholders may not take action by written consent but may only take action at annual or special meetings of our stockholders. As a result, a holder controlling a majority of our capital stock would not be able to amend our bylaws or remove directors without holding a meeting of our stockholders called in accordance with our bylaws. Further, our bylaws and certificate of incorporation provide that special meetings of our stockholders may be called only by a majority of our board of directors, the chairman of our board of directors, or our Chief Executive Officer, thus prohibiting a stockholder from calling a special meeting. These provisions might delay the ability of our stockholders to force consideration of a proposal or for stockholders controlling a majority of our capital stock to take any action, including the removal of directors.

- *Advance Notice Requirements for Stockholder Proposals and Director Nominations*. Our bylaws provide advance notice procedures for stockholders seeking to bring business before our annual meeting of stockholders or to nominate candidates for election as directors at our annual meeting of stockholders. Our bylaws also specify certain requirements regarding the form and content of a stockholder's notice. These provisions might preclude our stockholders from bringing matters before our annual meeting of stockholders or from making nominations for directors at our annual meeting of stockholders if the proper procedures are not followed. We expect that these provisions might also discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of the Company.

- *No Cumulative Voting*. The DGCL provides that stockholders are not entitled to the right to cumulate votes in the election of directors unless a corporation's certificate of incorporation provides otherwise. Our certificate of incorporation will not provide for cumulative voting.

- *Directors Removed Only for Cause*. Our certificate of incorporation provides that stockholders may remove directors only for cause and only by the affirmative vote of the holders of at least two-thirds of our outstanding Common Stock.

- *Amendment of Charter Provisions*. Any amendment of the above expected provisions in our certificate of incorporation would require approval by holders of at least two-thirds of our outstanding Common Stock.

- *Issuance of Undesignated Preferred Stock*. Our board of directors has the authority, without further action by the stockholders, to issue up to 20,000,000 shares of undesignated preferred stock with rights and preferences, including voting rights, designated from time to time by our board of directors. The existence of authorized but unissued shares of preferred stock would enable our board of directors to render more difficult or to discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest or other means.

- *Choice of Forum*. Our certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for: any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the DGCL, our certificate of incorporation or our bylaws; any action to interpret, apply, enforce or determine the validity of our certificate of incorporation or our bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. Notwithstanding the foregoing, the exclusive forum provision does not apply to suits brought to enforce any liability or duty created by the Securities Act, the Exchange Act or any other claim for which the federal courts have exclusive or concurrent jurisdiction. Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act of the rules and regulations thereunder, and Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder, and notwithstanding the provisions of our certificate of incorporation and our bylaws, compliance with the federal securities laws and the rules and regulations thereunder may not be waived by our investors. The enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable.

Transfer Agent and Registrar

The transfer agent and registrar for our Common Stock is Nevada Agency and Transfer Company. The transfer agent's address 50 W. Liberty Street, Suite 880, Reno, NV 89501, and its telephone number is (775) 322-0626. Our shares of Common Stock will be issued in uncertificated form only, subject to limited circumstances.

Market Listing

Our Common Stock is listed on NYSE American under the symbol "CHRO".

SHARES ELIGIBLE FOR FUTURE SALE

Prior to the IPO, there has not been a public market for shares of our Common Stock, and we cannot predict the effect, if any, that market sales of shares of our Common Stock or the availability of shares of our Common Stock for sale will have on the market price of our Common Stock prevailing from time to time. Nevertheless, sales of substantial amounts of our Common Stock, including shares issued upon exercise or conversion of outstanding options, warrants and/or convertible securities, in the public market following this offering could adversely affect market prices prevailing from time to time and could impair our ability to raise capital through the sale of our equity securities.

After giving effect to the IPO Transactions, the issuance of the Leak-Out Shares not yet issued as of the date of this prospectus and sale of IPO Shares in the IPO, we will have 5,767,525 outstanding shares of Common Stock. All of the IPO Shares sold in the IPO will be immediately tradable without restriction under the Securities Act of 1933, as amended, or the Securities Act, except for any shares held by "affiliates," as that term is defined in Rule 144 under the Securities Act, or Rule 144.

The remaining outstanding shares of our Common Stock, other than the Selling StockholderShares covered by the Resale Prospectus, will be deemed "restricted securities" as defined in 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 promulgated under the Securities Act, which rules are summarized below.

We have agreed with the underwriters that we will not, without the prior consent of the representative, directly or indirectly sell, offer, contract or grant any option to sell, pledge, transfer, or otherwise dispose of or enter into any transaction which may result in the disposition of any Common Stock or securities convertible into, exchangeable or exercisable for any Common Stock for a period of six (6) months after the closing of this offering, subject to certain exceptions. In addition, we have agreed not to enter into any Variable Rate Transaction for a period of one year following the closing of the IPO as described below. For the avoidance of doubt, the foregoing shall not prevent the Company from entering into or drawing down on the proposed ELOC or issuing the shares of Common Stock issuable pursuant to the proposed ELOC.

All of our directors, executive officers and holders of 5% or more of our capital stock prior to the IPO, have entered into lock-up agreements with the underwriters pursuant to which they have agreed, subject to specific exceptions, not to sell any of shares of Common Stock for at least six (6) months following the effective date of the registration statement of which this prospectus forms a part, as described below.

In addition, pursuant to the securities purchase agreement in connection with the Bridge Financings, we will file a registration statement within 180 calendar days after consummation of the IPO, providing for the resale of Common Stock, which includes 51 Bonus Shares, received by holders of the senior secured convertible notes upon conversion of such notes.

Lock-Up Agreements

All of our directors, executive officers and holders of 5% or more of our capital stock prior to the IPO, are subject to lock-up agreements that, subject to certain exceptions, prohibit them from directly or indirectly offering, pledging, selling, contracting to sell, selling any option or contract to purchase, purchasing any option or contract to purchase, granting any option, right or warrant to purchase or otherwise transferring or disposing of any shares of Common Stock, options to acquire shares of Common Stock or any securities convertible into or exercisable or exchangeable for Common Stock, whether now owned or hereafter acquired, or entering into any swap or any other agreement or any transaction that transfer, in whole or in part, directly or indirectly, the economic consequence of ownership, for a period of six (6) months following the effective date of the registration statement of which this prospectus forms a part, without the prior written consent of the underwriters.

For a period commencing on the ninetieth (90th) day following the effective date of the registration statement of which this prospectus forms a part (the "Leak-Out Period"), all of our directors, executive officers and holders of 5% or more of our capital stock prior to the IPO shall be permitted to sell, dispose or otherwise transfer, directly or indirectly, on any trading day, shares of Common Stock in an amount no more than 5% of the average trading volume of our Common Stock as reported by Bloomberg, LP on such trading day; provided, that, prior to any such sale, disposition or other transfer, directly or indirectly, of shares of Common Stock, the closing price of our Common Stock shall have closed at or above 150% of the price per IPO Share, for each of the prior three trading days (the "Leak-Out Restriction"). These agreements are described in the section entitled "Underwriting."

Rule 144

In general, under Rule 144 as currently in effect, once we have been subject to public company reporting requirements for at least 90 days, a person who is not deemed to have been one of our affiliates for purposes of the Securities Act at any time during the 90 days preceding a sale and who has beneficially owned the shares of Common Stock proposed to be sold for at least six months, including the holding period of any prior owner other than our affiliates, is entitled to sell such shares without complying with the manner of sale, volume limitation or notice provisions of Rule 144, subject to compliance with the public information requirements of Rule 144. If such a person has beneficially owned the shares of Common Stock proposed to be sold for at least one year, including the holding period of any prior owner other than our affiliates, then that person would be entitled to sell such shares without complying with any of the requirements of Rule 144.

In general, under Rule 144, as currently in effect, our affiliates or persons selling shares on behalf of our affiliates are entitled to sell upon expiration of the lock-up agreements described above, within any three-month period, a number of shares of Common Stock that does not exceed the greater of:

- 1% of the number of shares of our Common Stock then outstanding, which will equal approximately 57,675 shares of Common Stock immediately after the IPO; or
- the average weekly trading volume of the Common Stock during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

Sales under Rule 144 by our affiliates or persons selling shares of Common Stock on behalf of our affiliates are also subject to certain manner of sale provisions and notice requirements and to the availability of current public information about us.

Rule 701

Rule 701 generally allows a stockholder who purchased shares of Common Stock pursuant to a written compensatory plan or contract and who is not deemed to have been an affiliate of the Company during the immediately preceding 90 days to sell such shares in reliance upon Rule 144, but without being required to comply with the public information, holding period, volume limitation or notice provisions of Rule 144. Rule 701 also permits affiliates of the Company to sell their Rule 701 shares under Rule 144 without complying with the holding period requirements of Rule 144. All holders of Rule 701 shares, however, are required by that rule to wait until 90 days after the date of this prospectus before selling such shares pursuant to Rule 701 and, subject to the exceptions noted above, are subject to the lock-up agreements described above.

Equity Incentive Awards

We intend to file a registration statement on Form S-8 under the Securities Act covering all of the shares of Common Stock subject to outstanding options and the shares of Common Stock reserved for issuance under our 2023 Plan. We expect to file a registration statement covering such shares issuable under the 2023 Plan as soon as permitted under the Securities Act. Upon effectiveness, the shares of Common Stock covered by a registration statement on Form S-8 will generally be eligible for sale in the public market, subject to the contractual and legal descriptions described above.

MATERIAL U.S. FEDERAL INCOME TAX CONSIDERATIONS

The following is a summary of the material U.S. federal income tax considerations relating to the purchase, ownership and disposition of our shares of common stock, but is for general information purposes only and does not purport to be a complete analysis of all the potential tax considerations. This summary is based upon the provisions of the Internal Revenue Code of 1986, as amended (the "Code"), existing and proposed U.S. Treasury regulations promulgated thereunder, administrative rulings and judicial decisions, all as of the date hereof. These authorities may be changed, possibly retroactively, so as to result in U.S. federal income and estate tax consequences different from those set forth below. There can be no assurance that the Internal Revenue Service (the "IRS") will not challenge one or more of the tax consequences described herein, and we have not obtained, and do not intend to obtain, an opinion of counsel or ruling from the IRS with respect to the U.S. federal income tax considerations relating to the purchase, ownership or disposition of our securities.

This summary does not address any alternative minimum tax considerations, any considerations regarding the tax on net investment income, or the tax considerations arising under the laws of any state, local or non-U.S. jurisdiction, or under any non-income tax laws, including U.S. federal gift and estate tax laws, except to the limited extent set forth below. In addition, this summary does not address tax considerations applicable to an investor's particular circumstances or to investors that may be subject to special tax rules, including, without limitation:

- banks, insurance companies or other financial institutions;
- tax-exempt organizations or governmental organizations;
- regulated investment companies and real estate investment trusts;
- controlled foreign corporations, passive foreign investment companies and corporations that accumulate earnings to avoid U.S. federal income tax;
- brokers or dealers in securities or currencies;
- traders in securities that elect to use a mark-to-market method of accounting for their securities holdings;
- persons that own, or are deemed to own, more than five percent of our capital stock (except to the extent specifically set forth below);
- tax-qualified retirement plans;
- certain former citizens or long-term residents of the United States;
- partnerships or entities or arrangements classified as partnerships for U.S. federal income tax purposes and other pass-through entities (and investors therein);
- persons who hold our securities as a position in a hedging transaction, "straddle," "conversion transaction" or other risk reduction transaction or integrated investment;
- persons who do not hold our securities as a capital asset within the meaning of Section 1221 of the Code; or
- persons deemed to sell our securities under the constructive sale provisions of the Code.

In addition, if a partnership (or entity or arrangement classified as a partnership for U.S. federal income tax purposes) holds our securities, the tax treatment of a partner generally will depend on the status of the partner and upon the activities of the partnership. Accordingly, partnerships that hold our securities, and partners in such partnerships, should consult their tax advisors.

You are urged to consult your own tax advisors with respect to the application of the U.S. federal income tax laws to your particular situation, as well as any tax consequences of the purchase, ownership and disposition of our securities arising under the U.S. federal estate or gift tax laws or under the laws of any state, local, non-U.S., or other taxing jurisdiction or under any applicable tax treaty.

Consequences to U.S. Holders

The following is a summary of the U.S. federal income tax consequences that will apply to a U.S. holder of our securities. For purposes of this discussion, you are a U.S. holder if, for U.S. federal income tax purposes, you are a beneficial owner of our securities, other than a partnership, that is:

- an individual citizen or resident of the United States;
- a corporation or other entity taxable as a corporation created or organized in the United States or under the laws of the United States, any State thereof or the District of Columbia;
- an estate whose income is subject to U.S. federal income tax regardless of its source; or
- a trust (x) whose administration is subject to the primary supervision of a U.S. court and which has one or more "United States persons" (within the meaning of Section 7701(a)(30) of the Code) who have the authority to control all substantial decisions of the trust or (y) which has made a valid election to be treated as a "United States person."

Distributions

As described in the section titled "Dividend Policy," we have never declared or paid cash dividends on our common stock and do not anticipate paying any dividends on our Common Stock in the foreseeable future. However, if we do make distributions on our common stock, those payments will constitute dividends for U.S. tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. To the extent those distributions exceed both our current and our accumulated earnings and profits, the excess will constitute a return of capital and will first reduce your basis in our common stock, but not below zero, and then will be treated as gain from the sale of stock as described below under "Sale, Exchange or Other Taxable Disposition of Common Stock."

Dividend income may be taxed to an individual U.S. holder at rates applicable to long-term capital gains, provided that a minimum holding period and other limitations and requirements are satisfied. Any dividends that we pay to a U.S. holder that is a corporation may qualify for a deduction allowed to U.S. corporations in respect of dividends received from other U.S. corporations equal to a portion of any dividends received, subject to generally applicable limitations on that deduction. U.S. holders should consult their own tax advisors regarding the holding period and other requirements that must be satisfied to qualify for the reduced tax rate on dividends or the dividends-received deduction.

Sale, Exchange or Other Taxable Disposition of Common Stock

A U.S. holder will generally recognize capital gain or loss on the sale, exchange or other taxable disposition of our Common Stock. The amount of gain or loss will equal the difference between the amount realized on the sale and such U.S. holder's tax basis in such Common Stock. The amount realized will include the amount of any cash and the fair market value of any other property received in exchange for such Common Stock. Gain or loss will be long-term capital gain or loss if the U.S. holder has held the Common Stock for more than one year. Long-term capital gains of non-corporate U.S. holders are generally taxed at preferential rates. The deductibility of capital losses is subject to certain limitations.

Consequences to Non-U.S. Holders

Gain on Sale, Exchange or Other Taxable Disposition of Common Stock

Subject to the discussion below regarding backup withholding and foreign accounts, a non-U.S. holder generally will not be required to pay U.S. federal income tax on any gain realized upon the sale, exchange or other taxable disposition of our Common Stock unless:

- the gain is effectively connected with the non-U.S. holder's conduct of a U.S. trade or business (and, if required by an applicable income tax treaty, the gain is attributable to a permanent establishment or fixed base maintained by the non-U.S. holder in the United States);

- the non-U.S. holder is a non-resident alien individual who is present in the United States for a period or periods aggregating 183 days or more during the calendar year in which the sale or disposition occurs and certain other conditions are met; or

- shares of our common stock constitute U.S. real property interests by reason of our status as a "United States real property holding corporation" (a USRPHC) for U.S. federal income tax purposes at any 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.

We believe that we are not currently and will not become a USRPHC for U.S. federal income tax purposes, and the remainder of this discussion so assumes. However, because the determination of whether we are a USRPHC depends on the fair market value of our U.S. real property relative to the fair market value of our other business assets, there can be no assurance that we will not become a USRPHC in the future. Even if we become a USRPHC, however, as long as our common stock is regularly traded on an established securities market, such common stock will be treated as U.S. real property interests only if the non-U.S. holder actually or constructively holds more than five percent of such regularly traded common stock at any time during 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.

If the non-U.S. holder is described in the first bullet above, it will be required to pay tax on the net gain derived from the sale, exchange or other taxable disposition under regular graduated U.S. federal income tax rates, and a corporate non-U.S. holder described in the first bullet above also may be subject to the branch profits tax at a rate of 30%, or such lower rate as may be specified by an applicable income tax treaty. An individual non-U.S. holder described in the second bullet above will be required to pay a flat 30% tax (or such lower rate specified by an applicable income tax treaty) on the gain derived from the sale, exchange or other taxable disposition, which gain may be offset by U.S. source capital losses for the year (provided the non-U.S. holder has timely filed U.S. federal income tax returns with respect to such losses). Non-U.S. holders should consult their own tax advisors regarding any applicable income tax or other treaties that may provide for different rules.

Federal Estate Tax

Common stock beneficially owned by an individual who is not a citizen or resident of the United States (as defined for U.S. federal estate tax purposes) at the time of their death will generally be includable in the decedent's gross estate for U.S. federal estate tax purposes. Such shares, therefore, may be subject to U.S. federal estate tax, unless an applicable estate tax treaty provides otherwise.

Backup Withholding and Information Reporting

Generally, we must report annually to the IRS the amount of dividends paid to you, your name and address and the amount of tax withheld, if any. A similar report will be sent to you. Pursuant to applicable income tax treaties or other agreements, the IRS may make these reports available to tax authorities in your country of residence.

Payments of dividends on or of proceeds from the disposition of our securities made to you may be subject to information reporting and backup withholding at a current rate of 28% unless you establish an exemption, for example, by properly certifying your non-U.S. status on an IRS Form W-8BEN or IRS Form W-8BEN-E or other applicable IRS Form W-8. Notwithstanding the foregoing, backup withholding and information reporting may apply if either we or our paying agent has actual knowledge, or reason to know, that you are a U.S. person.

Backup withholding is not an additional tax; rather, the U.S. federal income tax liability of persons subject to backup withholding will be reduced by the amount of tax withheld. If withholding results in an overpayment of taxes, a refund or credit may generally be obtained from the IRS, provided that the required information is furnished to the IRS in a timely manner.

Foreign Account Tax Compliance

The Foreign Account Tax Compliance Act ("FATCA") generally imposes withholding tax at a rate of 30% on dividends on and gross proceeds from the sale or other disposition of our securities paid to a "foreign financial institution" (as specially defined under these rules), unless such institution enters into an agreement with the U.S. government to, among other things, withhold on certain payments and to collect and provide to the U.S. tax authorities substantial information regarding the U.S. account holders of such institution (which includes certain equity and debt holders of such institution, as well as certain account holders that are foreign entities with U.S. owners) or otherwise establishes an exemption. FATCA also generally imposes a U.S. federal withholding tax of 30% on dividends on and gross proceeds from the sale or other disposition of our securities paid to a "non-financial foreign entity" (as specially defined for purposes of these rules) unless such entity provides the withholding agent with a certification identifying certain substantial direct and indirect U.S. owners of the entity, certifies that there are none or otherwise establishes an exemption. The withholding provisions under FATCA generally apply to dividends paid by us, and under current transitional rules are expected to apply with respect to the gross proceeds from a sale or other disposition of our securities on or after January 1, 2020. Under certain circumstances, a non-U.S. holder might be eligible for refunds or credits of such taxes. An intergovernmental agreement between the United States and an applicable foreign country may modify the requirements described in this paragraph. Non-U.S. holders should consult their own tax advisors regarding the possible implications of this legislation on their investment in our securities.

Each prospective investor should consult its own tax advisor regarding the particular U.S. federal, state and local and non-U.S. tax consequences of purchasing, owning and disposing of our securities, including the consequences of any proposed changes in applicable laws.

SELLING STOCKHOLDERS

A total of up to 2,969,823 shares of Common Stock being registered hereby will be offered and may be sold by the Selling Stockholders pursuant to the Resale Prospectus.

The table below sets forth with respect to each Selling Stockholder:

- the name of such Selling Stockholder;
- the number of shares of Common Stock beneficially owned by such Selling Stockholder as of February 21, 2024 (after giving effect to the IPO Transactions , the issuance of the Leak-Out Shares not yet issued as of February 21, 2024 and the consummation of the IPO);
- the maximum number of shares of Common Stock that may be offered for the account of such Selling Stockholder under this Resale Prospectus (which such maximum number shall equal the number of shares of Common Stock beneficially owned by such Selling Stockholder as of February 21, 2024, after giving effect to the IPO Transactions and the issuance of the Leak-Out Shares not yet issued as of February 21, 2024 (excluding the shares of Common Stock to be received upon conversion of the bridge notes issued in the Bridge Financings)); and
- the number and percentage of shares of Common Stock that would be owned by such Selling Stockholder after completion of the offering of the Selling Stockholder Shares, assuming (i) a sale of all of the Common Stock held by such Selling Stockholder and registered hereby and (ii) the sale of 1,100,000 IPO Shares pursuant to the IPO Prospectus (including the shares of Common Stock issued in a private placement in full satisfaction of our obligations under the Investor Note and Director Note).

Each Selling Stockholder and any other person or entity participating in such distribution of Selling Stockholder Shares will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including, without limitation, to the extent applicable, Regulation M of the Exchange Act, which may limit the timing of purchases and sales of any of the Selling Stockholder Shares by the Selling Stockholders and any other participating person. To the extent applicable, Regulation M of the Exchange Act may also restrict the ability of any person engaged in the distribution of the Selling Stockholder Shares to engage in market-making activities with respect to such Selling Stockholder Shares. All of the foregoing may affect the marketability of the Selling Stockholder Shares and the ability of any person or entity to engage in market-making activities with respect to such Selling Stockholder Shares.

Each Selling Stockholder, who is also an insider or owns 5% or more of our Common Stock, is subject to lock-up agreements that, subject to certain exceptions, prohibit them from directly or indirectly offering, pledging, selling, contracting to sell, selling any option or contract to purchase, purchasing any option or contract to purchase, granting any option, right or warrant to purchase or otherwise transferring or disposing of any shares of Common Stock, options to acquire shares of Common Stock or any securities convertible into or exercisable or exchangeable for Common Stock, whether now owned or hereafter acquired, or entering into any swap or any other agreement or any transaction that transfer, in whole or in part, directly or indirectly, the economic consequence of ownership, for a period of six months following the effective date of the registration statement of which this prospectus forms a part, without the prior written consent of the underwriters.

No material relationships exist between any of the Selling Stockholders and us, nor have any such material relationships existed within the past three years, except, in either case, as identified below this table.

Beneficial ownership is determined under the rules of the SEC and includes investment power with respect to shares of Common Stock. The number of shares beneficially owned by a Selling Stockholder includes shares of Common Stock underlying warrants, stock options and other derivative securities to acquire our Common Stock held by that person that are currently exercisable or convertible within 60 days after February 21, 2024. The shares of Common Stock issuable under these securities are treated as outstanding for computing the percentage ownership of the person holding these securities but are not treated as outstanding for the purposes of computing the percentage ownership of any other person.

The Common Stock beneficially owned by the Selling Stockholders has been determined in accordance with the rules promulgated by the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. The information in the table below is current as of February 21, 2024. All information contained in the table below is based upon information provided to the Company by the Selling Stockholders, and the Company has not independently verified this information.

Except as indicated below, the Selling Stockholders are not the beneficial owners of any additional shares of Common Stock or other equity securities issued by the Company or any securities convertible into, or exercisable or exchangeable for, the Company's equity securities.

The Company may require the Selling Stockholders to suspend the sales of Common Stock offered by this Resale Prospectus upon the occurrence of any event that makes any statement in this Resale Prospectus or the related registration statement untrue in any material respect or that requires the changing of statements in these documents in order to make statements in those documents not misleading.

Selling Stockholder Name	Number of Shares of Common Stock Beneficially Owned Prior to the Offering of the Stockholder Shares (1)	Maximum Number of Shares of Common Stock To Be Sold in the Offering of the Stockholder Shares (2)	Number of Shares of Common Stock Beneficially Owned After the Offering of the Stockholder Shares (2)	Percentage Beneficially Owned After the Offering of the Stockholder Shares (3)
3i, LP(4)	193,823(5)	193,823	—	—
AME Equities LLC	369,177	351,163	18,014	*
Aperture Healthcare Ventures Ltd.	444,070	426,566	17,504	*
Boswell Prayer Ltd	471,592	459,895	11,697	*
H&M Ventures II	56,341	55,564	777	*
Hamilcar Portfolio Inc.	12,220	11,027	1,193	*
MDB Merchants Park LLC	273,766	249,533	24,233	*
Motif Pharmaceuticals Ltd	483,406	470,674	12,732	*
Nobi Investments Limited	57,002	55,487	1,515	*
Sargeant Capital Ventures, LLC	61,222	58,809	2,413	*
Dominion Capital LLC(6)	37,500	37,500	—	—
Scott Sussman	100,000	100,000	—	—
Benuvia Operations, LLC(7)	384,226	384,226	—	—
Ballantyne Jewish Center, Inc.(8)	88,555	87,778	777	*
Temple Israel of the City of New York(9)	27,778	27,778	—	—
TOTAL	3,060,678	2,969,823	90,855	1.58%

* Less than 1%

(1) Unless otherwise indicated herein, represents shares of Common Stock issued by the Company to such Selling Stockholder.
(2) The Company does not have the ability to control how many, if any, of the Selling Stockholder Shares will be sold by the Selling Stockholders listed above will sell, the table above assumes that the Selling Stockholders will sell all of the Selling Stockholder Shares offered herein for purposes of determining how many shares of Common Stock each such Selling Stockholder will own after the offering of the Selling Stockholder Shares and their applicable beneficial ownership percentage following the offering of the Selling Stockholder Shares.
(3) All percentages rounded to the nearest hundredth.
(4) Excludes shares of Common Stock issuable pursuant to the proposed ELOC. Includes shares of Common Stock issued pursuant to the Investor Note.
(5) Includes shares of Common Stock issued pursuant to the Investor Note and the Investor Note Side Letters, including the Leak-Out Shares issuable on February 29, 2024.
(6) Mikhail Gurevich has sole voting and dispositive power over the shares held by Dominion Capital LLC. The principal executive office of Dominion Capital LLC is 256 W. 38th Street, 15th Floor, New York, NY 10018.
(7) Darwin Richardson has sole voting and dispositive power over the shares held by Benuvia. The principal executive office of Benuvia is 3950 N. Mays Street, Round Rock, TX 78665.
(8) Israel Levin has sole voting and dispositive power over the shares held by Ballantyne Jewish Center, Inc. The principal executive office of Ballantyne Jewish Center, Inc. is 8632 Bryant Farms Road, Charlotte, NC 28277.
(9) Andrew Fondiller has sole voting and dispositive power over the shares held by Temple Israel of the City of New York. The principal executive office of Temple Israel of the City of New York is 112 E. 75th Street, New York, NY 10021.

PLAN OF DISTRIBUTION

The shares of Common Stock covered by the Resale Prospectus may be offered and sold from time to time by the Selling Stockholders, subject to the terms of the lock-up agreements.

Registration of the Selling Stockholder Shares covered by the Resale Prospectus does not mean that the Selling Stockholder Shares necessarily will be sold; there is no requirement that the Selling Stockholders sell some or all of their respective Selling Stockholder Shares in connection with the offering of the Selling Stockholder Shares, and, in any event, the Selling Stockholders are not obligated to sell such Selling Stockholder Shares below a price that they believe is fair or at a price that does not align with any other legitimate return objectives that they may have.

We will not receive any proceeds from any sale by the Selling Stockholders of the Stockholder Shares. See "Use of Proceeds." We will pay all costs, expenses and fees in connection with the registration of the Selling Stockholder Shares, including fees of our counsel and accountants, fees payable to the SEC and fees of counsel to the Selling Stockholders. The Selling Stockholders will pay all underwriting discounts and commissions and similar selling expenses, if any, attributable to the sale of the Selling Stockholder Shares covered by the Resale Prospectus.

Subject to the terms of the lock-up agreements, the Selling Stockholders may sell their respective Selling Stockholder Shares covered by the Resale Prospectus from time to time, at market prices prevailing at the time of sale, at prices related to market prices, at a fixed price or prices subject to change or at negotiated prices, or in any manner permitted by the Securities Act, including any one or more of the following ways:

- through one or more underwriters or broker-dealers on a firm commitment or best-efforts basis;
- in privately negotiated transactions;
- through broker-dealers, who may act as agents or principals;
- in a block trade in which a broker-dealer will attempt to sell a block of shares of Common Stock as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- directly to one or more purchasers;
- through selling agents; or
- in any combination of the above.

In effecting sales, brokers or dealers engaged by a Selling Stockholder may arrange for other brokers or dealers to participate. Broker-dealer transactions may include:

- purchases of the shares of Common Stock by a broker-dealer as principal and resales of the shares of Common Stock by the broker-dealer for its account pursuant to the Resale Prospectus;
- ordinary brokerage transactions; or
- transactions in which the broker-dealer solicits purchasers.

Until such time as it is no longer necessary to maintain the registration of the Selling Stockholder Shares due to such securities being permitted to be offered and resold without restriction pursuant to the provisions of Rule 144, at any time a particular offer of the Selling Stockholder Shares covered by the Resale Prospectus is made, a prospectus supplement to such prospectus, if required, will be distributed which will set forth the aggregate amount of shares of Common Stock covered by the Resale Prospectus being offered and the terms of such offering, including the name or names of any underwriters, dealers, brokers or agents, any option under which underwriters may purchase additional shares of Common Stock from the Selling Stockholder(s), any discounts, commissions, concessions and other items constituting compensation from the Selling Stockholder(s) and any discounts, commissions or concessions allowed or reallowed or paid to dealers. Such prospectus supplement, and, if necessary, a post-effective amendment to the registration statement of which the Resale Prospectus is a part, will be filed with the SEC to reflect the disclosure of additional information with respect to the distribution of the Selling Stockholder Shares covered by such prospectus, if applicable.

In connection with the sale of the Selling Stockholder Shares covered by the Resale Prospectus through broker-dealers, such broker-dealers may receive compensation in the form of discounts or commissions and may also receive commissions from purchasers of shares of Common Stock for whom they may act as agent. These broker-dealers may sell to or through other dealers, and such dealers may receive compensation in the form of discounts, concessions or commissions from the underwriters and/or commissions from the purchasers for whom they may act as agent.

Any underwriters, broker-dealers or agents participating in the distribution of the Selling Stockholder Shares covered by the Resale Prospectus may be deemed to be "underwriters" within the meaning of the Securities Act, and any commissions received by any of those underwriters, broker-dealers or agents may be deemed to be underwriting commissions under the Securities Act. The Selling Stockholders may also be deemed to be an underwriter, and any discounts and commissions they receive and any profit they realize on the sale of the Selling Stockholder Shares may be deemed to be underwriting commissions under the Securities Act.

The Selling Stockholders may enter into hedging transactions with broker-dealers or other financial institutions. In connection with such transactions, broker-dealers or other financial institutions may engage in short sales of shares of Common Stock in the course of hedging transactions, broker-dealers or other financial institutions may engage in short sales of shares of Common Stock in the course of hedging the positions they assume with a Selling Stockholder. The Selling Stockholders may also sell the Selling Stockholder Shares short and redeliver the securities to close out such short positions. Selling Stockholders may also enter into option or other transactions with broker-dealers or other financial institutions which require the delivery to such broker-dealer or other financial institution of the Selling Stockholder Shares offered by the Resale Prospectus, which shares such broker-dealer or other financial institution may resell pursuant to such prospectus, as supplemented or amended to reflect such transaction to the extent required. The Selling Stockholders may also pledge the Selling Stockholder Shares offered hereby to a broker-dealer or other financial institution, and, upon a default, such broker-dealer or other financial institution, may effect sales of the pledged Selling Stockholder Shares pursuant to the Resale Prospectus, as supplemented or amended to reflect such transaction to the extent required.

The Selling Stockholders may enter into derivative transactions with third parties or sell their respective Selling Stockholder Shares to third parties in privately negotiated transactions. If the applicable prospectus supplement indicates, in connection with those derivatives, the third parties may sell the Selling Stockholder Shares covered by the Resale Prospectus and the applicable prospectus supplement, including in short sale transactions. If so, the third party may use Selling Stockholder Shares pledged by a Selling Stockholder or borrowed from a Selling Stockholder or others to settle those sales or to close out any related open borrowings of stock and may use such Selling Stockholder Shares received from such Selling Stockholder in settlement of those derivatives to close out any related open borrowings of stock. The third party in such sale transactions will be an underwriter and, if not identified in the Resale Prospectus, will be identified in the applicable prospectus supplement (or a post-effective amendment).

We may authorize underwriters, dealers and agents to solicit from third parties offers to purchase Selling Stockholder Shares under contracts providing for payment and delivery on future dates. The applicable prospectus supplement will describe the material terms of these contracts, including any conditions to the purchasers' obligations, and will include any required information about commissions we may pay for soliciting these contracts.

Agents, underwriters and dealers may be entitled under agreements which may be entered into with us or the Selling Stockholders to indemnify us or such Selling Stockholders against specified liabilities, including liabilities incurred under the Securities Act, or to contribution by us or Selling Stockholders to payments it may be required to make in respect of such liabilities. The applicable prospectus supplement will describe the terms and conditions of such indemnification or contribution. Some of the agents, underwriters or dealers, or their affiliates may be customers of, engage in transactions with or perform services for us or our subsidiaries in the ordinary course of business.

In connection with the offering of the Selling Stockholder Shares, underwriters may purchase and sell shares of Common Stock in the open market. These transactions may include short sales, stabilizing transactions and purchases to cover positions created by short sales. Short sales involve the sale by underwriters of a greater number of shares than they are required to purchase in connection with the offering of the Selling Stockholder Shares. "Covered" short sales are sales made in an amount not greater than the underwriters' option to purchase additional shares of Common Stock from the Selling Stockholders in the offering of the Selling Stockholder Shares. Such underwriters may close out any covered short position by either exercising their option to purchase additional shares of Common Stock or purchasing shares of Common Stock in the open market. In determining the source of shares of Common Stock to close out the covered short position, such underwriters will consider, among other things, the price of shares of Common Stock available for purchase in the open market as compared to the price at which they may purchase shares of Common Stock through an over-allotment option, if any. "Naked" short sales are any sales in excess of such option. Such underwriters must close out any naked short position by purchasing shares of Common Stock in the open market. 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 after pricing that could adversely affect investors who purchase shares of Common Stock in the offering of the Selling Stockholder Shares. Stabilizing transactions consist of various bids for or purchases of Common Stock made by such underwriters in the open market prior to the completion of the offering of the Selling Stockholder Shares.

Such underwriters may also impose a penalty bid. This occurs when a particular underwriter repays to other underwriters a portion of the underwriting discount received by it because the representatives have repurchased shares of Common Stock sold by or for the account of such underwriter in stabilizing or short covering transactions.

Purchases to cover a short position and stabilizing transactions may have the effect of preventing or retarding a decline in the market price of the Common Stock, and together with the imposition of the penalty bid, may stabilize, maintain or otherwise affect the market price of the Common Stock. As a result, the price of the Common Stock may be higher than the price that otherwise might exist in the open market. If these activities are commenced, they may be discontinued at any time.

Certain underwriters, agents or dealers or their affiliates may have provided from time to time, and may provide in the future, investment, commercial banking, derivatives and financial advisory services to the Company, the Selling Stockholders and their respective affiliates in the ordinary course of business, for which they have received or may receive customary fees and commissions.

In addition, a Selling Stockholder that is an entity may elect to make a pro rata in-kind distribution of securities to its members, partners or stockholders pursuant to the registration statement of which the Resale Prospectus forms a part by delivering a prospectus. Such members, partners or stockholders would thereby receive freely tradeable shares of Common Stock pursuant to the distribution through such registration statement. To the extent a distributee is an affiliate of ours (or to the extent otherwise required by law), we may file a prospectus supplement in order to permit the distributees to use such prospectus to resell such shares of Common Stock acquired in such distribution.

The Selling Stockholder Shares covered by the Resale Prospectus may also be sold in private transactions or under Rule 144 under the Securities Act rather than pursuant to such prospectus.

LEGAL MATTERS

Certain legal matters concerning this offering will be passed upon for us by Sullivan & Worcester LLP, New York, New York.

Interests of named experts and counsel

David Danovitch and John Riley, partner and of counsel of Sullivan & Worcester LLP, respectively, own 65,745 and 110,817 shares of our Common Stock (after giving effect to the Reverse Stock Split), respectively, and each holds senior secured convertible notes in the amount of $18,487 and $12,205, including principal and interest, respectively, that will each automatically convert into shares of Common Stock at the initial public offering.

EXPERTS

The financial statements of Chromocell Therapeutics Corporation as of December 31, 2022 and 2021 and for each of the two years in the period ended December 31, 2022, appearing in this prospectus have been audited by Marcum LLP, independent registered public accounting firm, as set forth in their report thereon (which contains an explanatory paragraph relating to substantial doubt about the ability of Chromocell Therapeutics Corporation to continue as a going concern as described in Note 2 to the financial statements and an emphasis of matter paragraph related to the preparation of certain financial statements on a carve-out basis as described in Note 4), appearing elsewhere in this prospectus, and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

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 securities offered by this prospectus. This prospectus, which constitutes a part of the registration statement, does not contain all of 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 these securities, 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, proxy statements and other information about issuers, like us, that file electronically with the SEC. The address of that website is www.sec.gov.

As a result of the IPO, we will become subject to the information and reporting requirements of the Exchange Act and, in accordance with this law, will file periodic reports, proxy statements and other information with the SEC. These periodic reports, proxy statements and other information will be available for inspection and copying at the SEC's public reference facilities and the website of the SEC referred to above. We also maintain a website at www.chromocell.com. Upon completion of the IPO, you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. Information contained on our website is not a part of this prospectus and the inclusion of our website address in this prospectus is an inactive textual reference only.

Chromocell Therapeutics Corporation
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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of Directors of
Chromocell Therapeutics Corporation
Freehold, New Jersey

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Chromocell Therapeutics Corporation (the "Company") as of December 31, 2022 and 2021, the related statements of operations, changes in stockholders' / parent's net deficit and cash flows for each of the two years in the period ended December 31, 2022, 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 December 31, 2022 and 2021, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2022, in conformity with accounting principles generally accepted in the United States of America.

Explanatory Paragraph – Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 2, the Company has incurred significant losses and needs to raise additional funds to meet its obligations and sustain its operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2 The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

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

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

Emphasis of Matter

As discussed in Note 4 the financial statements for the period from January 1, 2022 to August 10, 2022, as of December 31, 2021, and for the year ended December 31, 2021 have been prepared on a "carve-out" basis from the financial statements of Chromocell Holdings to reflect the assets, liabilities, revenues and expenses of Chromocell Therapeutics Corporation as well as allocations deemed reasonable by management to present the results of operations, financial position and cash flows of Chromocell Therapeutics Corporation on a standalone basis and may not reflect Chromocell Therapeutics Corporation results of operations, financial position and cash flows had the Company operated as a standalone company during the periods presented. Our Opinion is not modified with respect to this matter.

/s/ Marcum llp

Marcum llp

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

Houston, Texas
May 1, 2023

CHROMOCELL THERAPEUTICS CORPORATION
BALANCE SHEETS

	December 31, 2022	December 31, 2021
ASSETS		
CURRENT ASSETS		
Cash	$ 55,074	$ -
TOTAL CURRENT ASSETS	55,074	-
TOTAL ASSETS	$ 55,074	$ -
LIABILITIES AND STOCKHOLDERS' / PARENT'S NET DEFICIT		
CURRENT LIABILITIES		
Accounts payable and accrued expenses	$ 2,993,920	$ 2,580,317
Accrued compensation	221,875	-
Bridge loan, net of debt discount	435,630	-
Loan payable - related party, net of debt discount	104,800	-
Due to parent	5,386	-
TOTAL CURRENT LIABILITIES	3,761,611	2,580,317
Advance from Chromocell Corporation	-	1,099,950
TOTAL LIABILITIES	3,761,611	3,680,267
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' / PARENT'S NET DEFICIT		
Preferred stock, $0.001 par value, 700,000 shares authorized, 600,000 and 0 shares issued and outstanding as of December 31, 2022 and 2021, respectively	600	-
Common stock, $0.001 par value, 100,000,000 shares authorized, 10,000,000 and 0 shares issued and outstanding as of December 31, 2022 and 2021, respectively	10,000	-
Additional paid in capital	2,421,719	-
Accumulated / parent's net deficit	(6,138,856)	(3,680,267)
TOTAL STOCKHOLDERS' / PARENT'S NET DEFICIT	(3,706,537)	(3,680,267)
TOTAL LIABILITIES AND STOCKHOLDERS' / PARENT'S NET DEFICIT	$ 55,074	$ -

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

CHROMOCELL THERAPEUTICS CORPORATION
STATEMENTS OF OPERATIONS

	For the Year Ended December 31, 2022	For the Year Ended December 31, 2021
OPERATING EXPENSES		
General and administrative expenses	$ 1,098,848	$ 496,667
Research and development	391,730	209,047
Professional fees	827,581	133,282
Total operating expenses	2,318,159	838,996
NET LOSS FROM OPERATIONS	(2,318,159)	(838,996)
OTHER (EXPENSE) INCOME		
Interest expense	(140,430)	(253)
Gain on forgiveness of PPP loan	-	243,862
Total other (expense) income	(140,430)	243,609
Net loss before provision for income taxes	(2,458,589)	(595,387)
Provision for income taxes	-	-
NET LOSS	$ (2,458,589)	$ (595,387)
Net loss per common share - basic and diluted	$ (0.63)	$ -
Weighted average number of common shares outstanding during the year - basic and diluted	3,917,808	-

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

CHROMOCELL THERAPEUTICS CORPORATION
STATEMENT OF CHANGES IN STOCKHOLDERS' DEFICIT
FOR THE YEAR ENDED DECEMBER 31, 2022

	Common Shares	Par	Preferred Shares	Preferred Shares Par	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
Balance, December 31, 2021	-	$ -	-	$ -	$ -	$ (3,680,267)	$ (3,680,267)
Fair value of shares issued in contribution agreement	10,000,000	10,000	600,000	600	1,889,400	-	1,900,000
Net contributions from Chromocell Corporation	-	-	-	-	422,173	-	422,173
Stock-based compensation	-	-	-	-	110,146	-	110,146
Net loss	-	-	-	-	-	(2,458,589)	(2,458,589)
Balance, December 31, 2022	10,000,000	$ 10,000	600,000	$ 600	$ 2,421,719	$ (6,138,856)	$ (3,706,537)

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

CHROMOCELL THERAPEUTICS CORPORATION
STATEMENT OF CHANGES IN PARENT'S NET DEFICIT

	For the Year Ended December 31, 2021
Parent's net deficit, beginning of year	$ (3,577,941)
Net loss	(595,387)
Net contribution from Chromocell Corporation	493,061
Parent's net deficit, end of period	$ (3,680,267)

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

CHROMOCELL THERAPEUTICS CORPORATION
STATEMENTS OF CASH FLOWS

	For the Year Ended December 31, 2022	For the Year Ended December 31, 2021
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (2,458,589)	$ (595,387)
Adjustments to reconcile net loss to net cash used in operating activities		
Forgiveness of PPP loan	-	(241,793)
Amortization of debt discount	140,430	-
Stock-based compensation	110,146	-
Changes in operating assets and liabilities:		
Security deposit	-	71,872
Accounts payable and accrued expenses	413,603	(827,703)
Accrued compensation	221,875	-
Due to parent	5,386	-
Net Cash Used In Operating Activities	(1,567,149)	(1,593,011)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from loan payable - related party, net of debt discount	100,000	-
Proceeds from bridge loan, net of debt discount	300,000	-
Net contribution from Chromocell Corporation	422,173	493,061
Advance from Chromocell Corporation	800,050	1,099,950
Net Cash Provided By Financing Activities	1,622,223	1,593,011
NET INCREASE (DECREASE) IN CASH	55,074	-
CASH AT BEGINNING OF PERIOD	-	-
CASH AT END OF PERIOD	$ 55,074	$ -
Supplemental cash flow information:		
Cash paid for income taxes	$ -	$ -
Cash paid for interest expense	$ -	$ -
NONCASH INVESTING AND FINANCING ACTIVITIES:		
Fair value of shares issued in contribution agreement	$ 1,900,000	$ -

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

NOTE 1 – ORGANIZATION AND NATURE OF BUSINESS

Company Background

Chromocell Therapeutics Corporation ("Chromocell" or the "Company") was incorporated in the State of Delaware on March 19, 2021. On August 10, 2022, the Company entered into that certain Contribution Agreement (the "Contribution Agreement") with Chromocell Corporation, a Delaware corporation ("Chromocell Holdings"), pursuant to which, effective July 12, 2022 (the "Contribution Date"), Chromocell Holdings contributed all assets and liabilities related to Chromocell Holdings' historical therapeutic business, including all patents, pre-clinical and Phase I study results and data, and trade secrets related to the CC8464 compound to the Company. (See Note 5)

The Company is a development stage life sciences company which improves consumer products and patient lives through breakthrough science and technologies. The Company is focused on the discovery and development of therapeutics through the use of pioneering Chromovert® technology. Chromovert technology enables the Company to use rare cells ideally suited for effective high-throughput screening. The Company's therapeutics pipeline is currently focused on analgesics and rare diseases, where Chromovert technology has proven highly effective in the rapid identification of potential new drug candidates.

The Company has a limited operating history and has not generated revenue from intended operations. The Company's business and operations are sensitive to general business and economic conditions in the U.S. and worldwide along with local, state, and federal governmental policy decisions. A host of factors beyond the Company's control could cause fluctuations in these conditions. Adverse conditions may include changes in the biotechnology regulatory environment, technological advances that render our technologies obsolete, availability of resources for clinical trials, acceptance of technologies into the medical community, and competition from larger, more well-funded companies.

On January 30, 2020, the World Health Organization declared the COVID-19 novel coronavirus outbreak a "Public Health Emergency of International Concern" and on March 10, 2020, declared it to be a pandemic. Actions taken around the world to help mitigate the spread of the coronavirus include restrictions on travel, and quarantines in certain areas, and forced closures for certain types of public places and businesses. The COVID-19 coronavirus and actions taken to mitigate it have had and are expected to continue to have an adverse impact on the economies and financial markets of many countries, including the geographical area in which the Company operates. While it is unknown how long these conditions will last and what the financial impact will be to the Company, it is reasonably possible that future capital raising efforts and additional development of our technologies may be negatively affected.

NOTE 2 – GOING CONCERN ANALYSIS

Management Plans

During the year ended December 31, 2022, the Company had a net loss of $2,458,589 and cash of $55,074 at December 31, 2022. These factors indicate substantial doubt about the Company's ability to continue as a going concern for the twelve months following the issuance of these financial statements. The accompanying financial statements have been prepared assuming that the Company will continue as a going concern.

The financial statements included in this report do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the matters discussed herein. While the Company believes in the viability of our strategy to generate sufficient revenue, control costs, and raise additional funds, when necessary, there can be no assurances to that effect. The Company's ability to continue as a going concern is dependent upon the ability to implement the business plan, generate sufficient revenues and to control operating expenses.

Liquidity and Capital Resources

At December 31, 2022, the Company had $55,074 in cash and cash equivalents and a working capital deficit of approximately $3.7 million, compared to approximately $0 in cash and cash equivalents and a working capital deficit of approximately $2.6 million at December 31, 2021.

Based on the Company's current projections, management believes that due to the lack of cash, revenue and accounts receivables there is substantial doubt about its to ability to continue to operate as a going concern and fund its operations through at least the next twelve months following the issuance of these financial statements, unless the Company can raise additional funds through an initial public offering. While the Company will continue to invest in its business and the development of CC8464, and potentially other molecules, and it is unlikely that the Company will generate product or licensing revenue during the next twelve months, so the Company will need to raise funds though the initial public offering or via private investors or both; However, there is no assurance that the Company will be able to raise such additional funds on acceptable terms, if at all. If the Company raises additional funds by issuing securities, existing stockholders may be diluted.

If adequate funds are not available, the Company may be required to curtail its operations or other business activities or obtain funds through arrangements with strategic partners or others that may require the Company to relinquish rights to certain technologies or potential markets.

NOTE 3 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

Prior to the execution of the Contribution Agreement between Chromocell and Chromocell Holdings (see Note 5), Chromocell did not constitute a separate legal entity or group and as such, stand-alone financial statements were not previously prepared for the Company. As a result, carve-out financial statements for Chromocell were prepared for the year ended December 31, 2021, which include all of Chromocell's operations which have been conducted within Chromocell Holdings, which also has other activities. These financial statements have been prepared on a stand-alone basis derived from the financial statements and related accounting records of Chromocell Holdings. The accompanying carve-out financial statements present the historical financial position, results of operations, changes in net assets and cash flows of the Company as it was historically conducted, as more fully described below in Note 4. The financial information in these financial statements does not necessarily include all the expenses that would have been incurred had the Company operated as a separate stand-alone entity and may not reflect results of operations, financial position and cash flows had the Company been a stand-alone company during the year ended December 31, 2021.

With the execution of the Contribution Agreement on August 12, 2022, effective for the reporting period ended December 31, 2022 and all future reporting periods, the financial statements reflect Chromocell as a stand-alone entity. The financial statements for December 31, 2021 represent the carve-out of the financial actively related to Chromocell Therapeutics out of Chromocell Holdings and does not necessarily represent the actual activity of Chromocell Therapeutics if it had been a separate entity during that period.

For all periods, the Company's financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") and the rules and regulations of the Securities and Exchange Commission ("SEC").

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. Significant estimates made by management include, but are not limited to, estimating the useful lives of patent assets, realization of long-lived assets, valuation of deferred income taxes, unrealized tax positions and business combination accounting.

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of three months or less when purchased to be cash equivalents. As of December 31, 2022 and 2021, the Company did not have any cash equivalents. As of December 31, 2022 and 2021, the Company did not have any deposits in excess of Federally insured limits.

Research and Development

We incur research and development costs during the process of researching and developing our technologies and future offerings. We expense these costs as incurred unless such costs qualify for capitalization under applicable guidance.

Below is a disaggregation of R&D expenses:

Account	For the Year Ended December 31, 2022	For the Year Ended December 31, 2021
Consultant	$ 86,802	$ 120,480
Lab gas	13,871	$ 8,628
Lab cell storage	62,197	$ 65,260
Chemistry Manufacturing and Controls (“CMC”)	3,800	$ -
IP services	225,060	$ 14,679
Total	**$ 391,730**	**$ 209,047**

Fair Value Measurements and Fair Value of Financial Instruments

The Company adopted FASB ASC Topic 820, Fair Value Measurements ("ASC Topic 820"). ASC Topic 820 clarifies the definition of fair value, prescribes methods for measuring fair value, and establishes a fair value hierarchy to classify the inputs used in measuring fair value as follows:

- Level 1 Inputs are unadjusted quoted prices in active markets for identical assets or liabilities available at the measurement date.
- Level 2 Inputs are unadjusted quoted prices for similar assets and liabilities in active markets, quoted prices for identical or similar assets and liabilities in markets that are not active, inputs other than quoted prices that are observable, and inputs derived from or corroborated by observable market data.
- Level 3 Inputs are unobservable inputs which reflect the reporting entity's own assumptions on what assumptions the market participants would use in pricing the asset or liability based on the best available information.

The Company did not identify any assets or liabilities that are required to be presented on the balance sheets at fair value in accordance with ASC Topic 820.

Due to the short-term nature of all financial assets and liabilities, their carrying value approximates their fair value as of the balance sheet dates.

Stock-Based Compensation

The Company accounts for stock-based compensation costs under the provisions of ASC 718, Compensation—Stock Compensation, which requires the measurement and recognition of compensation expense related to the fair value of stock-based compensation awards that are ultimately expected to vest. Stock-based compensation expense recognized includes the compensation cost for all stock-based payments granted to employees, officers, and directors based on the grant date fair value estimated in accordance with the provisions of ASC 718. ASC 718 is also applied to awards modified, repurchased, or cancelled during the periods reported. Stock-based compensation is recognized as expense over the employee's requisite vesting period and over the nonemployee's period of providing goods or services. Pursuant to ASC 718, the Company can elect to either recognize the expenses on a straight-line or graded basis and has elected to do so under the straight-line basis.

Basic and Diluted Net Loss per Common Share

Basic loss per common share is computed by dividing the net loss by the weighted average number of shares of common stock outstanding for each period. Diluted loss per share is computed by dividing the net loss by the weighted average number of shares of common stock outstanding plus the dilutive effect of shares issuable through the common stock equivalents. The weighted-average number of common shares outstanding excludes common stock equivalents because their inclusion would be anti-dilutive. As of December 31, 2022, 450,000 stock options were excluded from dilutive earnings per share as their effects were anti-dilutive.

Income Taxes

The Company accounts for income taxes pursuant to the provision of ASC 740 "Accounting for Income Taxes," which requires, among other things, an asset and liability approach to calculating deferred income taxes. The asset and liability approach requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of temporary differences between the carrying amounts and the tax bases of assets and liabilities. A valuation allowance is provided to offset any net deferred tax assets for which management believes it is more likely than not that the net deferred asset will not be realized.

The Company follows the provision of the ASC 740 related to Accounting for Uncertain Income Tax Position. When tax returns are filed, it is more likely than not that some positions taken would be sustained upon examination by the taxing authorities, while others are subject to uncertainty about the merits of the position taken or the amount of the position that would be ultimately sustained. In accordance with the guidance of ASC 740-10, the benefit of a tax position is recognized in the financial statements in the period during which, based on all available evidence, management believes it is most likely that not that the position will be sustained upon examination, including the resolution of appeals or litigation processes, if any. Tax positions taken are not offset or aggregated with other positions.

Tax positions that meet the more-likely-than-not recognition threshold are measured as the largest amount of tax benefit that is more than 50% likely of being realized upon settlement with the applicable taxing authority. The portion of the benefits associated with tax positions taken that exceeds the amount measured as described above should be reflected as a liability for uncertain tax benefits in the accompanying balance sheet along with any associated interest and penalties that would be payable to the taxing authorities upon examination. The Company believes its tax positions will more likely than not be upheld upon examination. As such, the Company has not recorded a liability for uncertain tax benefits.

The federal and state income tax returns of the Company are subject to examination by the Internal Revenue Service and state taxing authorities, generally for three years after they were filed. The Company is in the process of filing the tax returns for the 2022 year. After review of the prior year financial statements and the results of operations through December 31, 2022, the Company has recorded a full valuation allowance on its deferred tax asset.

Recent Accounting Pronouncements

In December 2019, the FASB issued ASU 2019-12, Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes ("ASU 2019-12"), as part as part of its overall simplification initiative to reduce costs and complexity of applying accounting standards while maintaining or improving the usefulness of the information provided to users of financial statements. Amendments include removal of certain exceptions to the general principles of ASC 740, Income Taxes and simplification in several other areas such as accounting for a franchise tax (or similar tax) that is partially based on income. ASU 2019-12 is effective for public business entities for annual reporting periods beginning after December 15, 2020, and interim periods within those reporting periods. The adoption of this ASU did not have a material effect on the Company's financial statements.

Subsequent Events

The Company has evaluated all transactions through the date the consolidated financial statements were issued for subsequent event disclosure consideration.

NOTE 4 – CARVE-OUT CRITERIA AND ASSUMPTIONS

The carve-out statements of comprehensive income, as set forth above and which was the subject of the statement contained herein, reflect direct revenues and expenses and allocations of indirect expenses related to certain support functions that are provided on a centralized basis by Chromocell Holdings. These expenses, assets, and liabilities have been allocated to the Company on the basis of direct usage when identifiable, with others allocated based on relevant data criteria.

- Employment related expenses – allocated all Chromocell direct salaries and an allocation of headquarters salaries based on headcounts.
- General and administrative expenses and Professional fees – allocated all direct Chromocell related expenses and corporate expense have been allocated to reflect the utilization of those corporate services by the Company.
- Research and development expenses – all Research and development expenses are direct Chromocell expenses.
- Rent and related expenses and security deposits – applied a ratio based on floor space used by Chromocell.
- Long lived assets – long lived assets are owned by Chromocell Holdings Inc. and under shared use by its components including the Company. Operating expenses are allocated that reflect the usage of the long-lived asset by the Company.
- Accounts payable and accrued expenses – allocated all direct Chromocell liabilities and an allocation corporate expense reflecting the utilization of those corporate services by the Company.
- PPP loan and PPP loan forgiveness – allocated to reflect the utilization of the proceeds by the Company.
- Bridge loan – the bridge loan was fully allocated to the Company. (See Note 6)

Chromocell Holdings uses a centralized approach to cash management of its operations. Any cash excess over comprehensive income earned by the Company were transferred to Chromocell Holdings through "net parent investment." Accordingly, none of the Chromocell Holdings cash and cash equivalents, have been assigned to the Company in the carve-out combined financial statements.

As these carve-out financial statements present a portion of the business of Chromocell Holdings, which does not constitute a separate legal entity for the purposes of carve-out financial statements, the net assets of the Chromocell Holdings have been presented as parent's net deficit. Except for the PPP loan, Chromocell Holdings third-party bank loans, related party loans and the related interest expense have not been included in the carve-out financial statements for any of the periods presented. Chromocell is not the legal obligor on those loans, and they were not directly attributable to the Chromocell operations.

As the lease is held by Chromocell Holdings, the Company does not have the right to control the use of the space being leased and only shares the space. As such, there is no lease liability or right of use asset recorded for Chromocell.

Management believes the assumptions underlying the carve-out combined financial statements, including the assumptions regarding allocation of expenses, are reasonable.

For the year ended December 31, 2022, the financial statements reflect Chromocell as a stand-alone entity.

NOTE 5 – RELATED PARTY TRANSACTIONS

In May 2021, Chromocell Holdings Corporation ("Chromocell Holdings"), the Company and Flamands International Holdings LLC ("Flamands") (a related party) commenced negotiations regarding a three-party agreement whereby Chromocell Holdings would spin off assets and liabilities associated with its therapeutics operations to the Company and Flamands would provide funding to the Company. As the parties contemplated various transactional structures, an agreement was never effectuated because significant details concerning the assumption of liabilities were never finalized. Chromocell Holdings instead provided multiple advances to the Company for its operations from May 2021 through August 2022 totaling $1,900,000. At December 31, 2022, all amounts previously received from Chromocell Holdings by the Company were recorded as additional paid in capital on the Company's financial statements.

Following execution of the Contribution Agreement, Chromocell Holdings sold 5,999,667 of the shares it owned in the Company to Flamands, making Flamands the majority stockholder of the Company, and the Managing Member of Flamands is also a member of the Company's board of directors. The agreement provides Flamands an option to acquire an additional 667,000 shares of the common stock Chromocell Holdings owns of the Company prior to the public filing of a registration statement relating to the Company's initial public offering. The Company was not a party to the sale, and the option was exercised on September 22, 2022.

On August 10, 2022, the Company and Chromocell Holdings entered into the Contribution Agreement effecting (1) the contribution by Chromocell Holdings to the Company of assets related to Chromocell Holding's Therapeutics Business, including all intellectual property related to Chromocell Holding's NaV1.7 program and its clinical-stage CC8464 lead compound, (2) assumption by the Company of direct-liabilities related to Chromocell Holding's historical Therapeutics Business in the amount of $1,556,323 as well as a cash payment by the Company to Chromocell Holdings of $597,038 and (3) the issuance by the Company to Chromocell Holdings of 10,000,000 shares of its common stock and 600,000 shares of its Series A Convertible Preferred Stock.

Pursuant to the Series A Convertible Preferred Stock Certificate of Designation, the Series A Convertible Preferred Stock ranks on par with the Company's common stock, will not pay a dividend, has no voting rights and shall be mandatorily converted into shares of Common Stock at the close of the IPO. The Series A Convertible Preferred Stock is convertible into an aggregate number of shares of Common Stock determined by (i) multiplying the number of shares of Series A Convertible Preferred Stock by $4.37 and then (ii) dividing the value in the preceding clause (i) by 87.5% of the price at which the shares of Common Stock are sold to the public in the IPO. The shares of Common Stock received upon conversion of the Series A Convertible Preferred Stock will be subject customary lock-up provisions as requested by the underwriter.

As part of the contribution agreement, Chromocell Holdings transferred to the Company assets related to Chromocell Holding's Therapeutics Business, including all the patents and intellectual property related to Chromocell Holding's NaV1.7 program and its clinical-stage CC8464 lead compound.

The Company analyzed the transaction for common control pursuant to ASC 805-50. While the term "common control" is not defined, there are examples in the Transactions between Entities under Common Control Subsection that, among others, indicates that "an entity [that] charters a newly formed entity and then transfers some or all of its assets to the newly chartered entity" is an example of a transaction involving common control, yielding recordation of assets at the transferors' historical cost basis. This directly mirrors the terms underlying the Contribution Agreement whereby Holdings established the Company as wholly owned subsidiary and transferred the Intangibles in return to 100% of the stock of the Company. Further, Staff Accounting Bulletin ("SAB") Topic 5G dictates that "transfers of nonmonetary assets to a company by its promoters or shareholders in exchange for stock prior to or at the time of the company's initial public offering normally should be recorded at the transferors' historical cost basis determined under GAAP." As a result, pursuant to ASC 805-50 and SAB Topic 5G, the Company recorded the net assets acquired at historical value when the Contribution Agreement was executed.

The following presents the purchase price allocation.

Purchase Price	
Advances from Chromocell Corporation	$ 1,900,000
Total purchase price	$ 1,900,000
Allocation of purchase price	
Cash	$ (42,606)
Accounts payable and accrued expenses	2,463,162
Accrued compensation	63,873
Bridge loan, net of debt discount	360,006
Parent's net deficit	(2,844,435)
Equity	1,900,000
Total allocation of purchase price	$ 1,900,000

Prior to the Contribution Date, the Company had only nominal assets and liabilities. Since this was a spin off transaction in accordance with Accounting Standards Codification ("ASC") 805, "Business Combinations", and SAB Topic 5G, the Company recognized the contributed assets from Chromocell Holdings at their historical carrying amounts on the Contribution Date because the two entities were under common control. Chromocell Holdings had two lines of business, the therapeutics business, which was transferred to the Company (the "Therapeutics Business") and a flavors business, which remains with Chromocell Holdings.

Accordingly, the financial statements presented in this prospectus for periods prior to the Contribution Date, the December 31, 2021 financial statements, have been prepared on a "carve-out" basis from the financial statements of Chromocell Holdings to represent the Company's financial position and performance as if it had existed on a stand-alone basis.

All of the assets, liabilities and results of operations of the Company as of and for the periods prior to the Contribution Date were identified based on the assets contributed to the Company from Chromocell Holdings. Management believes the assumptions underlying the Company's carve-out financial statements are reasonable. Nevertheless, the financial statements may not include all of the actual expenses that would have been incurred had the Company operated as a standalone company during the periods presented,

and may not reflect the Company's results of operations, financial position and cash flows had the Company operated as a standalone company during the periods presented. Actual costs that would have been incurred if the Company had operated as a standalone company would depend on multiple factors, including organizational structure and strategic decisions made in various areas, including information technology and infrastructure.

Contribution Agreement (Unaudited)

As of December 31, 2022, the Company's analysis of the complex provisions contained in the Contribution Agreement were finalized, resulting in changes to the preliminary, unaudited results presented in the financial statements as of and for the nine months ended September 30, 2022.

The results of the changes to the Balance Sheet at September 30, 2022 were:

	Preliminary (as reported)	Change	Final
Intangible assets	$ 44,290,462	$ (44,290,462)	$ -
TOTAL ASSETS	44,290,462	(44,290,462)	-
Additional paid in capital	46,672,705	(44,783,305)	1,889,400
Parent's net deficit	(5,400,550)	492,843	(4,097,707)
TOTAL STOCKHOLDERS' EQUITY / PARENT'S NET DEFICIT	41,282,755	(44,290,462)	(3,007,707)
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY / PARENT'S NET DEFICIT	44,463,702	(44,290,462)	173,240

The results of the changes to the Statement of Operations for the nine months ended September 30, 2022 were:

	Preliminary (as reported)	Change	Final
General and administrative expenses	$ 889,122	$ (517,839)	$ 371,283
Total Operating Expenses	1,621,182	(517,839)	1,103,343
Net loss before provision for income taxes	(1,719,000)	517,839	(1,201,161)
Net loss	(1,719,000)	517,839	(1,201,161)
Net loss per common share - basic and diluted	(0.92)	0.28	(0.64)

The results of the changes to the Statement of Changes in Stockholders' Equity for the nine months ended September 30, 2022 were:

	Preliminary (as reported)						
	Common Shares	Par	Preferred Shares	Preferred Shares Par	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
Balance, December 31, 2021	-	$ -	-	$ -	$ -	$ (3,680,267)	$ (3,680,267)
Fair value of shares issued in contribution agreement	10,000,000	10,000	600,000	600	46,672,705	-	46,672,705
Net contributions from Chromocell Corporation	-	-	-	-		(1,283)	(1,283)
Net loss	-	-	-	-	-	(1,719,000)	(1,719,000)
Balance, September 30, 2022	10,000,000	$ 10,000	600,000	$ 600	$ 46,672,705	$ (5,400,550)	$ 41,282,755

	Common Shares	Par	Preferred Shares	Final Preferred Shares Par	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
Balance, December 31, 2021	-	$ -	-	$ -	$ -	$ (3,680,267)	$ (3,680,267)
Fair value of shares issued in contribution agreement	10,000,000	10,000	600,000	600	1,889,400	-	1,900,000
Net contributions from Chromocell Corporation	-	-	-	-		(26,279)	(26,279)
Net loss	-	-	-	-	-	(1,201,161)	(1,201,161)
Balance, September 30, 2022	10,000,000	$ 10,000	600,000	$ 600	$ 1,889,400	$ (4,907,707)	$ (3,007,707)

The results of the changes to the Statement of Cash Flow for the nine months ended September 30, 2022 were:

	Preliminary (as reported)	Change	Final
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	$ (1,719,000)	$ 517,839	$ (1,201,161)
Amortization of intangible assets	517,839	(517,839)	-
CASH FLOWS FROM FINANCING ACTIVITIES:			
Net contribution from Chromocell Corporation	(1,283)	(24,996)	(26,279)
Funds received from contribution agreement	775,054	24,996	800,050
NONCASH INVESTING AND FINANCING ACTIVITIES:			
Fair value of shares issued in contribution agreement	46,683,305	(46,683,305)	-

NOTE 6 – NOTE PAYABLE

On February 4, 2022, the Company entered into a note for $450,000 with a third party. This note has an original issuance discount of $150,000, representing an implicit interest rate of 50%, a maturity date of February 3, 2023, and accrues no interest beyond the original issuance discount. As of December 31, 2022, there was an unamortized debt discount of $14,370. There was $135,630 in amortization of debt discount included in interest expense on the statement of operations for the year ended December 31, 2022.

On February 27, 2023, the note agreement was amended. The maturity date was extended from its original due date of February 3, 2023 to May 15, 2023, in return for the Company agreeing to pay 2% per month in accrued interest and the third party agreeing to settle its outstanding debt, including accrued interests, in shares of Common Stock at the IPO.

On December 6, 2022, the Company and Mr. Todd Davis, one of the Company's directors, entered into a note payable agreement (the "Director Note") for $175,000. The Director Note has an original issuance discount of $75,000, no other interest and matures on December 31, 2023, or, if earlier to occur, upon the closing of an underwritten offering of securities resulting in at least $15 million in gross proceeds. Mr. Davis, as lender, has the right but not the obligation to subscribe to the underwritten offering by presenting the Director Note in whole or in part to purchase such securities as legal tender therefor, on a dollar-for-dollar basis based upon the offering price of such securities to the public. The Director Note bears no interest except in the case of certain events of default. As of December 31, 2022, there was an unamortized debt discount of $70,200. There was $4,800 in amortization of debt discount included in interest expense on the statement of operations for the year ended December 31, 2022.

On April 22, 2020, Chromocell Holdings entered into a PPP loan of which $241,793 was allocated to the Company. This note accrued interest at a rate of 1% per annum. This loan is due on April 22, 2022. At December 31, 2021 and 2020, the loan had accrued interest of $0 and $1,676. During the year ended December 31, 2021, this loan was fully forgiven, with a total of $241,793 in principal forgiven and $1,929 in interest forgiven being allocated to the Company.

NOTE 7 – STOCKHOLDERS' EQUITY

Common Stock

During the year ended December 31, 2022, the Company issued 10,000,000 shares of common stock under the Contribution Agreement. (See Note 5)

Preferred Stock

During the year ended December 31, 2022, the Company issued 600,000 shares of preferred stock under the Contribution Agreement. (See Note 5)

Stock-Based Compensation

On January 10, 2023, the Company granted a total of 450,000 options to purchase shares of the Company's common stock to employees and consultants of the Company pursuant to their employment or consulting agreements, with such vesting commencing on October 1, 2022. These options had a grant date fair value of $1,122,244. These options have an exercise price of $2.52, a term of 10 years, and vest quarterly over ten quarters.

There were 450,000 options outstanding as of December 31, 2022. The fair value of each stock option granted during the year ended December 31, 2022 was estimated using the Black-Scholes Option Pricing Model and assumptions and or factors as follows:

Exercise price	$ 2.52
Expected dividend yield	0%
Risk free interest rate	3.83%
Expected life in years	10
Expected volatility	158%

The risk-free interest rate assumption for options granted is based upon observed interest rates on the United States Government Bond Equivalent Yield appropriate for the expected term of the options.

The Company determined the expected volatility assumption for options granted using the historical volatility of comparable public companies' common stock. The Company will continue to monitor peer companies and other relevant factors used to measure expected volatility for future option grants, until such time that the Company's common stock has enough market history to use historical volatility.

The dividend yield assumption for options granted is based on the Company's history and expectation of dividend payouts. The Company has never declared nor paid any cash dividends on its common stock, and the Company does not anticipate paying any cash dividends in the foreseeable future.

The Company recognizes option forfeitures as they occur as there is insufficient historical data to accurately determine future forfeitures rates.

The following is an analysis of the stock option grant activity:

	Number	Weighted Average Exercise Price	Weighted Average Remaining Life
Stock Options			
Outstanding December 31, 2021	-	$ -	-
Granted	450,000	$ 2.52	9.76
Expired	-	$ -	-
Exercised	-	$ -	-
Outstanding December 31, 2022	450,000	$ 2.52	9.76
Exercisable December 31, 2022	40,000	2.52	9.76

A summary of the status of the Company's nonvested options as of December 31, 2022, and changes during the years ended December 31, 2022 and 2021, is presented below:

Non-vested Options	Options	Weighted-Average Exercise Price
Non-vested at December 31, 2021	-	$ -
Granted	450,000	$ 2.52
Vested	(40,000)	$ 2.52
Forfeited	-	$ -
Non-vested at December 31, 2022	410,000	$ 2.52

The total number of options granted during the years ended December 31, 2022 and 2021 was 450,000 and 0, respectively. The exercise price for these options was $2.52 per share and there was an intrinsic value of $0.

The Company recognized stock-based compensation expense related to option vesting amortization of $110,146 and $0 for the years ended December 31, 2022 and 2021, respectively, in which is included in general and administrative expenses in the statement of operations.

As of December 31, 2022, the unamortized stock option expense was $1,012,098. As of December 31, 2022, the weighted average period for the unamortized stock compensation to be recognized is 1.54 years.

NOTE 8 – INCOME TAX

The Company follows the asset and liability method of accounting for income taxes under ASC 740, "Income Taxes." Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial statements carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that included the enactment date. Valuation allowances are established, when necessary, to reduce deferred tax assets to the amount expected to be realized.

ASC 740 prescribes a recognition threshold and a measurement attribute for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. For those benefits to be recognized, a tax position must be more likely than not to be sustained upon examination by taxing authorities. The Company recognizes accrued interest and penalties related to unrecognized tax benefits as income tax expense. There were no unrecognized tax benefits and no amounts accrued for interest and penalties as of December 31, 2020. The Company is currently not aware of any issues under review that could result in significant payments, accruals or material deviation

from its position. The Company is subject to income tax examinations by major taxing authorities since inception. The Company used the separate return method for the preparation of the income tax provision.

For the years ended December 31, 2022 and 2021, there was no income tax provision recorded. The tax benefit was added to the net operating loss to which a full valuation allowance was applied.

A reconciliation of income tax expense (benefit) computed at the statutory federal income tax rate to income taxes as reflected in the financial statements is as follows:

	2022	2021
Income taxes at U.S. statutory rate	19.11%	19.11%
Income taxes at state rate	9.00%	9.00%
Change in valuation allowance	(28.11)%	(28.11)%
Total provision for income taxes	-%	-%

Deferred taxes are recognized for temporary differences between the basis of assets and liabilities for financial statement and income tax purposes. The significant components of the Company's deferred tax assets and liabilities as of December 31, 2022 and 2021 are comprised of the following:

	December 31,	
	2022	2021
Deferred tax assets		
Net operating loss carryforwards	$ 4,053,204	$ 2,726,414
Total deferred tax assets	4,053,204	2,726,414
Valuation allowance	(4,053,204)	(2,726,414)
Net deferred tax assets	-	-
Deferred tax liabilities		
Total deferred tax liabilities	-	-
Net deferred taxes	$ -	$ -

For the years ended December 31, 2022 and 2021, the Company recorded a full valuation allowance of its deferred tax assets.

The Company has a net operating loss carryforward for federal tax purposes totaling approximately $6.3 million at December 31, 2022. Approximately $6.3 million net operating losses incurred in fiscal 2018 through fiscal 2022 that do not expire and can be utilized to offset up to 80% of future taxable income under the Tax Cuts and Jobs Act.

Utilization of NOL and tax credit carryforwards may be subject to a substantial annual limitation due to ownership change limitations that may have occurred or that could occur in the future, as required by the Internal Revenue Code (the "Code"), as amended, as well as similar state provisions. In general, an "ownership change" as defined by the Code results from a transaction or series of transactions over a three-year period resulting in an ownership change of more than 50 percent of the outstanding stock of a company by certain stockholders or public groups.

NOTE 9 – SUBSEQUENT EVENTS

Employment Agreement

The Company entered into an employment agreement with Christian Kopfli, dated January 10, 2023. Pursuant to such agreement, Mr. Kopfli has agreed to serve as the Company's Chief Executive Officer and Vice-Chairman of its Board of Directors in consideration for an annualized salary of $275,000, payable in cash at the rate of $5,000 per month (a minimum of $1,125 per week), with the remainder accrued and paid as of the earliest of a sale or liquidation of the Company, the Company's bankruptcy or three days after the approval by the Board of a funded budget with appropriately established milestones subsequent to the effective date of a Form S-1 registration statement ("Post-registration Approval"). Mr. Kopfli also agrees, as of Post-registration Approval, to resign as Chief Executive Officer of Chromocell Corporation although he may continue to service on the Board of Directors of Chromocell Corporation, including as its Board Chair. The employment agreement provides that Mr. Kopfli receive an option to acquire 200,000 shares of our Common Stock, vesting quarterly over 10 quarters and beginning October 1, 2022. This option shall have an exercise price equal to the fair market value of our Common Stock on the date of grant and shall expire on the 10th anniversary of the date of grant. The option was awarded as of January 10, 2023. The employment agreement contemplates an annual bonus, as determined by the Board. The target bonus is 50% of Mr. Kopfli's annualized salary and will be based on achievement of performance goals and objectives agreed to by Mr. Kopfli and the Board in January of each year. The Board may increase the bonus in recognition of performance in excess of the performance objectives. Any bonus shall only be paid if Mr. Kopfli remains employed on the date of payment, which will be no later than March 15 of the year following the year to which the bonus relates. Any bonus for 2022 is payable solely in the Board's discretion.

Pursuant to Mr. Kopfli's employment agreement, in the event he is involuntarily terminated by the Company other than for "Cause" or if he resigns for "Good Reason," he is entitled to receive (i) six months of salary at the same rate existing immediately prior to his termination, (ii) his target bonus, if performance goals and objectives have been established for the year and prorated for the period of service, and (iii) six months of additional vesting credit with respect to any outstanding time-based equity awards. "Cause" and "Good Reason" are each defined in the employment agreement.

Finally, Mr. Kopfli agrees to certain non-solicitation and non-competition provisions for a period of 12 months following termination and to certain confidentiality obligations. Additional terms and conditions are set forth in the employment agreement.

Consulting Agreement

The Company entered into a Consultant Agreement with Camden Capital LLC, dated January 10, 2023. This consulting agreement replaces an agreement with Mr. Francis Knuettel II dated June 2, 2022, and pursuant to the agreement, Camden Capital LLC agrees to provide the services of Mr. Knuettel, who shall serve as our Chief Financial and Strategy Officer, Treasurer and Secretary.

Under the consulting agreement, Camden Capital LLC accrued a consulting fee for the period June 6, 2022 through August 31, 2022 of $10,000 per month and effective September 1, 2022, began to accrue a consulting fee of $20,000 per month, payable in cash at the rate of $5,000 per month (a minimum of $1,125 per week), with the remainder accrued. All accrued consulting fees are payable as of the earliest of a sale or liquidation of the Company, the Company's bankruptcy or three days after Post-registration Approval. The consulting agreement provides for the following equity awards to Camden Capital LLC: (i) an option, awarded as of January 10, 2023, to acquire 200,000 shares of our Common Stock, vesting quarterly over 10 quarters and beginning October 1, 2022, with the option having an exercise price equal to the fair market value of our Common Stock on the date of grant and expiring on the 10th anniversary of the date of grant; (ii) an option, awarded as of January 10, 2023, to acquire 25,000 shares of our Common Stock, vesting 100% upon the sooner of the sale of the Company or Post-registration Approval, with the option having an exercise price equal to the fair market value of our Common Stock on the date of grant and expiring on the 10th anniversary of the date of grant; and (iii) a restricted stock unit ("RSU"), awarded as of January 10, 2023, of 150,000 shares of our Common Stock, vesting 100% on the day after the first trading window that opens after Post-registration Approval.

The consulting agreement contemplates an additional consulting fee, as determined by the Board. The potential additional consulting fee is 50% of the annualized consulting fee and will be based on achievement of performance goals and objectives established by the Board in concert with Mr. Knuettel in January of each year. The Board may increase the potential additional consulting fee in recognition of performance in excess of the performance objectives. Any amount shall only be paid if Camden Capital LLC continues to provide consulting services to the Company as of the date of payment, which will be no later than March 15 of the year following the year to which the additional consulting fee relates. Any additional consulting fee for 2022 is payable solely in the Board's discretion.

Pursuant to the consulting agreement, in the event the relationship with Camden Capital LLC is involuntarily terminated by the Company other than for "Cause" or if Camden Capital LLC terminates the relationship for "Good Reason," Camden Capital LLC is entitled to receive (i) six months of consulting fees at the same rate existing immediately prior to termination, (ii) a potential additional consulting fee, if performance goals and objectives have been established for the year and prorated for the period of service, and (iii) six months of additional vesting credit with respect to any outstanding time-based equity awards. "Cause" and "Good Reason" are each defined in the consulting agreement.

Finally, Camden Capital LLC and Mr. Knuettel agree to certain non-solicitation and non-competition provisions for a period of 12 months following termination of the relationship and to certain confidentiality obligations. Additional terms and conditions are set forth in the consulting agreement.

Bridge Financing

On April 17, 2023, the Company and entered into a bridge loan (referred to herein as the Bridge Financing) with various accredited investors, including Boswell Prayer Ltd., Motif Pharmaceuticals Ltd, Aperture Healthcare Ventures Ltd., MDB Merchants Park LLC, Balmoral Financial Group LLC and AME EQUITIES LLC (each a related party). The Bridge Financing consists of senior secured convertible notes that have a maturity date of October 17, 2023. Such notes accrue interest on the unpaid principal amount at a rate of eight percent (8%) per annum and will automatically convert into shares of Common Stock at the initial public offering at a twenty percent (20%) discount to the price per IPO Share.

Option Issuances

On January 10, 2023, the Company issued a total of 800,000 options to purchase shares of the Company's common stock to directors and officers, pursuant to their serving as a director or their consulting or employment agreements, respectively. These options have an exercise price of $2.52, a term of 10 years, and 600,000 of these options will vest over 2.5 years and 200,000 of the options will vest upon the Company's establishment of a second clinical program, which shall include an acquisition or entrance into a joint venture.

CHROMOCELL THERAPEUTICS CORPORATION
CONDENSED BALANCE SHEETS

	September 30, 2023 (Unaudited)	December 31, 2022
ASSETS		
CURRENT ASSETS		
Cash	$ 22,786	$ 55,074
TOTAL CURRENT ASSETS	$ 22,786	$ 55,074
LIABILITIES AND STOCKHOLDERS' DEFICIT		
CURRENT LIABILITIES		
Accounts payable and accrued expenses	$ 4,160,800	$ 2,993,920
Accrued compensation	562,036	221,875
Bridge loan, net of debt discount	450,000	435,630
Loan payable	181,008	-
Loan payable - related party	568,144	104,800
Due to parent	5,386	5,386
TOTAL CURRENT LIABILITIES	5,927,374	3,761,611
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' DEFICIT		
Preferred stock, $0.0001 par value, 700,000 shares authorized, 600,000 and 600,000 shares issued and outstanding	60	60
Common stock, $0.0001 par value, 100,000,000 shares authorized, 8,876,296 and 10,000,000 shares issued and outstanding, respectively	888	1,000
Additional paid in capital	3,574,960	2,431,259
Accumulated deficit	(9,480,496)	(6,138,856)
TOTAL STOCKHOLDERS' DEFICIT	(5,904,588)	(3,706,537)
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	$ 22,786	$ 55,074

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

CHROMOCELL THERAPEUTICS CORPORATION
CONDENSED STATEMENTS OF OPERATIONS

	For the Three Months Ended September 30, 2023 (Unaudited)	For the Three Months Ended September 30, 2022 (Unaudited)	For the Nine Months Ended September 30, 2023 (Unaudited)	For the Nine Months Ended September 30, 2022 (Unaudited)
OPERATING EXPENSES				
General and administrative expenses	$ 661,572	$ 143,229	$ 1,677,078	$ 371,283
Research and development	49,132	27,981	285,204	97,147
Professional fees	581,022	347,633	1,021,187	634,913
Total Operating Expenses	1,291,726	518,843	2,983,469	1,103,343
NET LOSS FROM OPERATIONS	(1,291,726)	(518,843)	(2,983,469)	(1,103,343)
OTHER INCOME (LOSS)				
Interest expense	(130,006)	(37,812)	(358,171)	(97,818)
Total Other Loss	(130,006)	(37,812)	(358,171)	(97,818)
Net loss before provision for income taxes	(1,421,732)	(556,655)	(3,341,640)	(1,201,161)
Provision for income taxes	-	-	-	-
NET LOSS	$ (1,421,732)	$ (556,655)	$ (3,341,640)	$ (1,201,161)
Net loss per common share - basic and diluted	$ (0.16)	$ (0.10)	$ (0.36)	$ (0.64)
Weighted average number of common shares outstanding during the period - basic and diluted	8,860,970	5,543,478	9,286,928	1,868,132

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

CHROMOCELL THERAPEUTICS CORPORATION
CONDENSED STATEMENT OF CHANGES IN STOCKHOLDERS' DEFICIT
FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2023 AND 2022
(Unaudited)

	Common Shares	Par	Preferred Shares	Preferred Shares Par	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
Balance December 31, 2021	—	$ —	—	$ —	$ —	$ (3,680,267)	$ (3,680,267)
Net distribution from Chromocell Corporation						(23,668)	(23,668)
Net loss						(310,450)	(310,450)
Balance March 31, 2022	—	—	—	—	—	(4,014,385)	(4,014,385)
Net distribution from Chromocell Corporation						(18,541)	(18,541)
Net loss						(334,056)	(334,056)
Balance June 30, 2022	—	—	—	—	—	(4,366,982)	(4,366,982)
Contribution agreement	10,000,000	10,000	600,000	600	1,889,400		1,900,000
Net contribution from Chromocell Corporation						15,930	15,930
Net loss						(556,655)	(556,655)
Balance September 30, 2022	10,000,000	$ 1,000	600,000	$ 60	$ 1,889,400	$ (4,907,707)	$ (3,007,707)

	Common Shares	Par	Preferred Shares	Preferred Shares Par	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
Balance December 31, 2022	10,000,000	$ 1,000	600,000	$ 60	$ 2,431,259	$ (6,138,856)	$ (3,706,537)
Stock-based compensation					272,221		272,221
Net loss						(966,561)	(966,561)
Balance March 31, 2023	10,000,000	1,000	600,000	60	2,703,480	(7,105,417)	(4,400,877)
Stock-based compensation					327,338		327,338
Common stock issued for extension of bridge loan	50,000	5			125,995		126,000
Shares forfeited	(1,203,704)	(120)			120		—
Net loss						(953,347)	(953,347)
Balance June 30, 2023	8,846,296	885	600,000	60	3,156,933	(8,058,764)	(4,900,886)
Stock option compensation					342,430		342,430
Common stock issued for extension of bridge loan	30,000	3			75,597		75,600
Net loss						(1,421,732)	(1,421,732)
Balance September 30, 2023	8,876,296	$ 888	600,000	$ 60	$ 3,574,960	$ (9,480,496)	$ (5,904,588)

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

CHROMOCELL THERAPEUTICS CORPORATION
CONDENSED STATEMENTS OF CASH FLOWS

	For the Nine Months Ended September 30, 2023 (Unaudited)	For the Nine Months Ended September 30, 2022 (Unaudited)
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (3,341,640)	$ (1,201,161)
Adjustments to reconcile net loss to net cash used in operating activities		
Amortization of debt discount	66,786	97,818
Common stock issued for extension of bridge loan	201,600	—
Stock-based compensation	941,989	—
Changes in operating assets and liabilities:		
Accounts payable and accrued expenses	1,166,880	82,331
Accrued compensation	340,161	120,481
Net Cash Used In Operating Activities	(624,224)	(900,531)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from loan net of debt discount	181,008	—
Proceeds from loan net of debt discount - related party	410,928	—
Proceeds from bridge loan net of debt discount	—	300,000
Net contribution from Chromocell Corporation	—	(26,279)
Advance from Chromocell Corporation	—	800,050
Net Cash Provided By Financing Activities	591,936	1,073,771
NET (DECREASE) INCREASE IN CASH	(32,288)	173,240
CASH AT BEGINNING OF PERIOD	55,074	—
CASH AT END OF PERIOD	$ 22,786	$ 173,240
Supplemental cash flow information:		
Cash paid for income taxes	$ —	$ —
Cash paid for interest expense	$ —	$ —
NONCASH INVESTING AND FINANCING ACTIVITIES:		
Original issuance discount on notes payable	$ —	$ 150,000
Shares forfeited	$ 120	$ —

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

CHROMOCELL THERAPEUTICS CORPORATION
NOTES TO CONDENSED FINANCIAL STATEMENTS
(Unaudited)

NOTE 1 – ORGANIZATION AND NATURE OF BUSINESS

Company Background

Chromocell Therapeutics Corporation ("Chromocell" or the "Company") was incorporated in the State of Delaware on March 19, 2021. On August 10, 2022, the Company entered into that certain Contribution Agreement (the "Contribution Agreement") with Chromocell Corporation, a Delaware corporation ("Chromocell Holdings"), pursuant to which, effective July 12, 2022 (the "Contribution Date"), Chromocell Holdings contributed all assets and liabilities related to Chromocell Holdings' historical therapeutic business, including all patents, pre-clinical and Phase I study results and data, and trade secrets related to the CC8464 compound to the Company. (See Note 4)

The Company is a development stage life sciences company which improves consumer products and patient lives through breakthrough science and technologies. The Company is focused on the discovery and development of therapeutics through the use of pioneering Chromovert® technology. Chromovert technology enables the Company to use rare cells ideally suited for effective high-throughput screening. The Company's therapeutics pipeline is currently focused on analgesics and rare diseases, where Chromovert technology has proven highly effective in the rapid identification of potential new drug candidates.

The Company has a limited operating history and has not generated revenue from intended operations. The Company's business and operations are sensitive to general business and economic conditions in the U.S. and worldwide along with local, state, and federal governmental policy decisions. A host of factors beyond the Company's control could cause fluctuations in these conditions. Adverse conditions may include changes in the biotechnology regulatory environment, technological advances that render our technologies obsolete, availability of resources for clinical trials, acceptance of technologies into the medical community, and competition from larger, more well-funded companies.

On January 30, 2020, the World Health Organization declared the COVID-19 novel coronavirus outbreak a "Public Health Emergency of International Concern" and on March 10, 2020, declared it to be a pandemic. Actions taken around the world to help mitigate the spread of the coronavirus include restrictions on travel, and quarantines in certain areas, and forced closures for certain types of public places and businesses. The COVID-19 coronavirus and actions taken to mitigate it have had and are expected to continue to have an adverse impact on the economies and financial markets of many countries, including the geographical area in which the Company operates. On May 11, 2023, the United States government declared an end to the COVID-19 pandemic, but it is reasonably possible that future capital raising efforts and additional development of our technologies may still be negatively affected.

NOTE 2 – GOING CONCERN ANALYSIS

Management Plans

During the nine months ended September 30, 2023, the Company had a net loss of $3,341,640 and cash of $22,786 at September 30, 2023. These factors indicate substantial doubt about the Company's ability to continue as a going concern for the twelve months following the issuance of these condensed financial statements. The accompanying condensed financial statements have been prepared assuming that the Company will continue as a going concern.

The condensed financial statements included in this report do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the matters discussed herein. While the Company believes in the viability of our strategy to generate sufficient revenue, control costs, and raise additional funds, when necessary, there can be no assurances to that effect. The Company's ability to continue as a going concern is dependent upon the ability to implement the business plan, generate sufficient revenues and to control operating expenses.

Liquidity and Capital Resources

At September 30, 2023, the Company had $0.0 million in cash and cash equivalents and a working capital deficit of approximately $5.9 million, compared to approximately $0.1 million in cash and cash equivalents and a working capital deficit of approximately $3.7 million at December 31, 2022.

Based on the Company's current projections, management believes that due to the lack of cash, revenue and accounts receivables there is substantial doubt about its ability to continue to operate as a going concern and fund its operations through at least the next twelve months following the issuance of these condensed financial statements, unless the Company can raise additional funds through an initial public offering. While the Company will continue to invest in its business and the development of CC8464, and potentially other molecules, and it is unlikely that the Company will generate product or licensing revenue during the next twelve months, so the Company will need to raise funds though the initial public offering or via private investors or both; However, there is no assurance that the Company will be able to raise such additional funds on acceptable terms, if at all. If the Company raises additional funds by issuing securities, existing stockholders may be diluted.

If adequate funds are not available, the Company may be required to curtail its operations or other business activities or obtain funds through arrangements with strategic partners or others that may require the Company to relinquish rights to certain technologies or potential markets.

NOTE 3 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

Prior to the execution of the Contribution Agreement between Chromocell and Chromocell Holdings (see Note 4), Chromocell did not constitute a separate legal entity or group and as such, stand-alone financial statements were not previously prepared for the Company. As a result, carve-out financial statements for Chromocell were prepared for the nine months ended September 30, 2022, which include all of Chromocell's operations which have been conducted within Chromocell Holdings, which also has other activities. These condensed financial statements have been prepared on a stand-alone basis derived from the condensed financial statements and related accounting records of Chromocell Holdings. The accompanying carve-out condensed financial statements present the historical financial position, results of operations, changes in net assets and cash flows of the Company as it was historically conducted, as more fully described below in Note 4. The financial information in these condensed financial statements does not necessarily include all the expenses that would have been incurred had the Company operated as a separate stand-alone entity and may not reflect results of operations, financial position and cash flows had the Company been a stand-alone company during the nine months ended September 30, 2022.

With the execution of the Contribution Agreement on August 12, 2022, effective for the reporting period ended December 31, 2022 and all future reporting periods, the condensed financial statements reflect Chromocell as a stand-alone entity.

For all periods, the Company's condensed financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") and the rules and regulations of the Securities and Exchange Commission ("SEC").

Use of Estimates

The preparation of condensed financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the condensed financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. Significant estimates made by management include, but are not limited to, estimating the useful lives of patent assets, realization of long-lived assets, valuation of deferred income taxes, unrealized tax positions and business combination accounting.

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of three months or less when purchased to be cash equivalents. As of September 30, 2023 and December 31, 2022, the Company did not have any cash equivalents. As of September 30, 2023 and December 31, 2022, the Company did not have any deposits in excess of Federally insured limits.

Research and Development

We incur research and development costs during the process of researching and developing our technologies and future offerings. We expense these costs as incurred unless such costs qualify for capitalization under applicable guidance.

Below is a disaggregation of R&D expenses:

	For the Nine Months Ended September 30, 2023	For the Nine Months Ended September 30, 2022
Consultant	$ 36,200	$ 42,850
Lab Gas	—	5,731
Lab Cell Storage	33,000	31,904
IP Services	216,004	16,662
Total	$ 285,204	$ 97,147

Fair Value Measurements and Fair Value of Financial Instruments

The Company adopted FASB ASC Topic 820, Fair Value Measurements ("ASC Topic 820"). ASC Topic 820 clarifies the definition of fair value, prescribes methods for measuring fair value, and establishes a fair value hierarchy to classify the inputs used in measuring fair value as follows:

- Level 1 Inputs are unadjusted quoted prices in active markets for identical assets or liabilities available at the measurement date.
- Level 2 Inputs are unadjusted quoted prices for similar assets and liabilities in active markets, quoted prices for identical or similar assets and liabilities in markets that are not active, inputs other than quoted prices that are observable, and inputs derived from or corroborated by observable market data.
- Level 3 Inputs are unobservable inputs which reflect the reporting entity's own assumptions on what assumptions the market participants would use in pricing the asset or liability based on the best available information.

The Company did not identify any assets or liabilities that are required to be presented on the balance sheets at fair value in accordance with ASC Topic 820.

Due to the short-term nature of all financial assets and liabilities, their carrying value approximates their fair value as of the balance sheet dates.

Stock-Based Compensation

The Company accounts for stock-based compensation costs under the provisions of ASC 718, Compensation—Stock Compensation, which requires the measurement and recognition of compensation expense related to the fair value of stock-based compensation awards that are ultimately expected to vest. Stock-based compensation expense recognized includes the compensation cost for all stock-based payments granted to employees, officers, and directors based on the grant date fair value estimated in accordance with the provisions of ASC 718. ASC 718 is also applied to awards modified, repurchased, or cancelled during the periods reported. Stock-based compensation is recognized as expense over the employee's requisite vesting period and over the nonemployee's period of providing goods or services. Pursuant to ASC 718, the Company can elect to either recognize the expenses on a straight-line or graded basis and has elected to do so under the straight-line basis.

Basic and Diluted Net Loss per Common Share

Basic loss per common share is computed by dividing the net loss by the weighted average number of shares of common stock outstanding for each period. Diluted loss per share is computed by dividing the net loss by the weighted average number of shares of common stock outstanding plus the dilutive effect of shares issuable through the common stock equivalents. The weighted-average number of common shares outstanding excludes common stock equivalents because their inclusion would be anti-dilutive. As of September 30, 2023, 1,878,000 stock options were excluded from dilutive earnings per share as their effects were anti-dilutive.

Income Taxes

The Company accounts for income taxes pursuant to the provision of ASC 740 "Accounting for Income Taxes," which requires, among other things, an asset and liability approach to calculating deferred income taxes. The asset and liability approach requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of temporary differences between the carrying amounts and the tax bases of assets and liabilities. A valuation allowance is provided to offset any net deferred tax assets for which management believes it is more likely than not that the net deferred asset will not be realized.

The Company follows the provision of the ASC 740 related to Accounting for Uncertain Income Tax Position. When tax returns are filed, it is more likely than not that some positions taken would be sustained upon examination by the taxing authorities, while others are subject to uncertainty about the merits of the position taken or the amount of the position that would be ultimately sustained. In accordance with the guidance of ASC 740-10, the benefit of a tax position is recognized in the condensed financial statements in the period during which, based on all available evidence, management believes it is most likely that not that the position will be sustained upon examination, including the resolution of appeals or litigation processes, if any. Tax positions taken are not offset or aggregated with other positions.

Tax positions that meet the more-likely-than-not recognition threshold are measured as the largest amount of tax benefit that is more than 50% likely of being realized upon settlement with the applicable taxing authority. The portion of the benefits associated with tax positions taken that exceeds the amount measured as described above should be reflected as a liability for uncertain tax benefits in the accompanying balance sheet along with any associated interest and penalties that would be payable to the taxing authorities upon examination. The Company believes its tax positions will more likely than not be upheld upon examination. As such, the Company has not recorded a liability for uncertain tax benefits.

The federal and state income tax returns of the Company are subject to examination by the Internal Revenue Service and state taxing authorities, generally for three years after they were filed. The Company is in the process of filing the tax returns for the 2022 year. After review of the prior year financial statements and the results of operations through December 31, 2022, the Company has recorded a full valuation allowance on its deferred tax asset.

Recent Accounting Pronouncements

There are no recently issued accounting pronouncements the Company has not yet adopted that will materially impact the Company's consolidated financial statements.

Subsequent Events

The Company has evaluated all transactions through the date the condensed financial statements were issued for subsequent event disclosure consideration.

NOTE 4 – CARVE-OUT CRITERIA AND ASSUMPTIONS

The carve-out statements of comprehensive income, as set forth above and which was the subject of the statement contained herein, reflect direct revenues and expenses and allocations of indirect expenses related to certain support functions that are provided on a centralized basis by Chromocell Holdings. These expenses, assets, and liabilities have been allocated to the Company on the basis of direct usage when identifiable, with others allocated based on relevant data criteria.

- Employment related expenses – allocated all Chromocell direct salaries and an allocation of headquarters salaries based on headcounts.
- General and administrative expenses and Professional fees – allocated all direct Chromocell related expenses and corporate expense have been allocated to reflect the utilization of those corporate services by the Company.
- Research and development expenses – all Research and development expenses are direct Chromocell expenses.
- Rent and related expenses and security deposits – applied a ratio based on floor space used by Chromocell.
- Long lived assets – long lived assets are owned by Chromocell Holdings Inc and under shared use by its components including the Company. Operating expenses are allocated that reflect the usage of the long-lived asset by the Company.
- Accounts payable and accrued expenses – allocated all direct Chromocell liabilities and an allocation corporate expense reflecting the utilization of those corporate services by the Company.
- PPP loan and PPP loan forgiveness – allocated to reflect the utilization of the proceeds by the Company.
- Bridge loan – the bridge loan was fully allocated to the Company. (See Note 6)

Chromocell Holdings uses a centralized approach to cash management of its operations. Any cash excess over comprehensive income earned by the Company were transferred to Chromocell Holdings through "net parent investment." Accordingly, none of the Chromocell Holdings cash and cash equivalents, have been assigned to the Company in the carve-out combined financial statements.

As these carve-out financial statements present a portion of the business of Chromocell Holdings, which does not constitute a separate legal entity for the purposes of carve-out financial statements, the net assets of the Chromocell Holdings have been presented as parent's net deficit. Except for the PPP loan, Chromocell Holdings third-party bank loans, related party loans and the related interest expense have not been included in the carve-out financial statements for any of the periods presented. Chromocell is not the legal obligor on those loans, and they were not directly attributable to the Chromocell operations.

As the lease is held by Chromocell Holdings, the Company does not have the right to control the use of the space being leased and only shares the space. As such, there is no lease liability or right of use asset recorded for Chromocell.

Management believes the assumptions underlying the carve-out combined financial statements, including the assumptions regarding allocation of expenses, are reasonable.

For the nine months ended September 30, 2023, the condensed financial statements reflect Chromocell as a stand-alone entity.

NOTE 5 – RELATED PARTY TRANSACTIONS

Employment Agreement

The Company entered into an employment agreement with Christian Kopfli, dated January 10, 2023. Pursuant to such agreement, Mr. Kopfli agreed to serve as the Company's Chief Executive Officer and Vice-Chairman of its Board of Directors (the "Board") in consideration for an annualized salary of $275,000, payable in cash at the rate of $5,000 per month (a minimum of $1,125 per week), with the remainder accrued and paid as of the earliest of a sale or liquidation of the Company, the Company's bankruptcy or three days after the approval by the Board of a funded budget with appropriately established milestones subsequent to the effective date of a Form S-1 registration statement ("Post-registration Approval"). Mr. Kopfli also agreed, as of Post-registration Approval, to resign as Chief Executive Officer of Chromocell Corporation although he may continue to service on the Board of Directors of Chromocell Corporation, including as its Board Chair. The employment agreement provides that Mr. Kopfli receive an option to acquire 200,000 shares of the Company's common stock, vesting quarterly over 10 quarters and beginning October 1, 2022. This option shall have an exercise price equal to the fair market value of the Company's common stock on the date of grant and shall expire on the 10th anniversary of the date of grant. The option was awarded as of January 10, 2023. The employment agreement contemplates an annual bonus, as determined by the Board. The target bonus is 50% of Mr. Kopfli's annualized salary and will be based on achievement of performance goals and objectives agreed to by Mr. Kopfli and the Board in January of each year. The Board may increase the bonus in recognition of performance in excess of the performance objectives. Any bonus shall only be paid if Mr. Kopfli remains employed on the date of payment, which will be no later than March 15 of the year following the year to which the bonus relates. Any bonus for 2022 is payable solely at the Board's discretion.

Pursuant to Mr. Kopfli's employment agreement, in the event he is involuntarily terminated by the Company other than for "Cause" or if he resigns for "Good Reason," he is entitled to receive (i) six months of salary at the same rate existing immediately prior to his termination, (ii) his target bonus, if performance goals and objectives have been established for the year and prorated for the period of service, and (iii) six months of additional vesting credit with respect to any outstanding time-based equity awards. "Cause" and "Good Reason" are each defined in the employment agreement.

Finally, Mr. Kopfli agrees to certain non-solicitation and non-competition provisions for a period of 12 months following termination and to certain confidentiality obligations. Additional terms and conditions are set forth in the employment agreement.

On July 28, 2023, the Company amended and restated Mr. Kopfli's employment agreement whereby Mr. Kopfli's title changed to Vice Chairman and Chief Strategy Officer. Other terms and conditions of the amended and restated employment agreement remain the same.

On November 27, 2023, Mr. Kopfli was removed from the Company's Board by the stockholders having a majority of the number of votes necessary to take such action. Mr. Kopfli was then terminated from his position as Vice Chairman and Chief Strategy Officer by the Company for "Cause", as defined in Mr. Kopfli's employment agreement, effective December 1, 2023.

Consulting Agreement

The Company entered into a Consultant Agreement with Camden Capital LLC, dated January 10, 2023. This consulting agreement replaces an agreement with Mr. Francis Knuettel II dated June 2, 2022, and pursuant to the agreement, Camden Capital LLC agreed to provide the services of Mr. Knuettel, who shall serve as our Chief Financial and Strategy Officer, Treasurer and Secretary.

Under the consulting agreement, Camden Capital LLC accrued a consulting fee for the period June 6, 2022 through August 31, 2022 of $10,000 per month and effective September 1, 2022, began to accrue a consulting fee of $20,000 per month, payable in cash at the rate of $5,000 per month (a minimum of $1,125 per week), with the remainder accrued. All accrued consulting fees are payable as of the earliest of a sale or liquidation of the Company, the Company's bankruptcy or three days after Post-registration Approval. The consulting agreement provides for the following equity awards to Camden Capital LLC: (i) an option, awarded as of January 10, 2023, to acquire 200,000 shares of the Company's common stock, vesting quarterly over 10 quarters and beginning October 1, 2022, with the option having an exercise price equal to the fair market value of the Company's common stock on the date of grant and expiring on the 10th anniversary of the date of grant; (ii) an option, awarded as of January 10, 2023, to acquire 25,000 shares of the Company's common stock, vesting 100% upon the sooner of the sale of the Company or Post-registration Approval, with the option having an exercise price equal to the fair market value of the Company's common stock on the date of grant and expiring on the 10th anniversary of the date of grant; and (iii) an RSU, awarded as of January 10, 2023, of 150,000 shares of the Company's common stock, vesting 100% on the day after the first trading window that opens after Post-registration Approval.

The consulting agreement contemplates an additional consulting fee, as determined by the Board. The potential additional consulting fee is 50% of the annualized consulting fee and will be based on achievement of performance goals and objectives established by the Board in concert with Mr. Knuettel in January of each year. The Board may increase the potential additional consulting fee in recognition of performance in excess of the performance objectives. Any amount shall only be paid if Camden Capital LLC continues to provide consulting services to the Company as of the date of payment, which will be no later than March 15 of the year following the year to which the additional consulting fee relates. Any additional consulting fee for 2022 is payable solely at the Board's discretion.

Pursuant to the consulting agreement, in the event the relationship with Camden Capital LLC is involuntarily terminated by the Company other than for "Cause" or if Camden Capital LLC terminates the relationship for "Good Reason," Camden Capital LLC is entitled to receive (i) six months of consulting fees at the same rate existing immediately prior to termination, (ii) a potential additional consulting fee, if performance goals and objectives have been established for the year and prorated for the period of service, and (iii) six months of additional vesting credit with respect to any outstanding time-based equity awards. "Cause" and "Good Reason" are each defined in the consulting agreement.

Finally, Camden Capital LLC and Mr. Knuettel agree to certain non-solicitation and non-competition provisions for a period of 12 months following termination of the relationship and to certain confidentiality obligations. Additional terms and conditions are set forth in the consulting agreement.

Director Note

On December 6, 2022, the Company and Mr. Todd Davis, one of the Company's directors, entered into the Director Note for $175,000. The Director Note has an original issuance discount of $75,000, and matures on December 31, 2023, or, if earlier to occur, upon the closing of an underwritten offering of securities resulting in at least $15 million in gross proceeds.

April and September Bridge Financings

On April 17, 2023 and September 1, 2023, the Company entered into bridge notes, the investors in which were almost entirely existing investors. Related party investors in the April Bridge Financing include Chromocell Holdings, Boswell Prayer Ltd., Motif Pharmaceuticals Ltd, Aperture Healthcare Ventures Ltd., MDB Merchants Park LLC, Balmoral Financial Group LLC and AME EQUITIES LLC (each a related party based on share ownership in excess of 5% or resulting from a principal at one of the entities being on the Company's board of directors). All of these investors, except Chromocell Holdings, also participated in the September Bridge Financing.

Due to Parent

As of September 30, 2023 and December 31, 2022, the Company had a $5,386 liability due to its parent company. This amount is comprised of expenses paid by the parent to be reimbursed by the Company. No interest is incurred on these amounts.

Side Letter to the Contribution Agreement and Issuance of Series C Convertible Redeemable Preferred Stock

On August 2, 2023, the Company entered into a side letter to the Contribution Agreement (the "Holdings Side Letter") with Chromocell Corporation, a Delaware corporation ("Chromocell Holdings"). Pursuant to the side letter, upon closing of the Company's initial public offering ("IPO"): (a) Chromocell Holdings will re-assume all $1.6 million in direct liabilities previously assumed by the Company in accordance with the Contribution Agreement, (b) Chromocell Holdings will waive the Company's obligations to make a cash payment in the amount of $0.6 million to Chromocell Holdings, and (c) in consideration thereof, the Company will issue to Chromocell Holdings 2,600 shares of Series C Convertible Redeemable Preferred Stock of the Company, par value of $0.0001 per share (the "Series C Preferred Stock").

The Series C Preferred Stock will have a liquidation preference of $1,000 per share. Holders of the Series C Preferred Stock will not be entitled to dividends, will have no voting rights other than as required by law, will be convertible into shares of Common Stock following the IPO at the holder's option, will convert into shares of Common Stock automatically if, following the IPO, the trading price of the Common Stock exceeds certain thresholds, and will be redeemable by the Company for cash.

NOTE 6 – NOTE PAYABLE

On February 4, 2022, the Company entered into a note for $450,000 with a third party. This note has an original issuance discount of $150,000, representing an implicit interest rate of 50%, a maturity date of February 3, 2023, and accrues no interest beyond the original issuance discount. As of September 30, 2023, the debt discount was fully amortized. There was $14,370 and $97,818, respectively, in amortization of debt discount included in interest expense on the statement of operations for the nine months ended September 30, 2023 and 2022.

On February 27, 2023, the note agreement was amended. The maturity date was extended from its original due date of February 3, 2023 to May 15, 2023, in return for the Company agreeing to pay 2% per month in accrued interest and the third party agreeing to settle its outstanding debt, including accrued interests in shares of common stock at the IPO. Accrued interest and related interest expense totaled $71,036 for the nine months ended September 30, 2023, compared to $0 for nine months ended September 30, 2022.

On June 23, 2023, the Company entered into a side letter with the holder of the note pursuant to which the Company (i) amended and restated the note to extend the maturity date to August 15, 2023 and (ii) in consideration therefor, issued to such holder 50,000 shares of common stock. The Company determined that this extension qualified as a modification of the note rather than an extinguishment. The Company recorded an expense of $126,000 from the issuance of the 50,000 shares of common stock based on a share price of $2.52. The $2.52 share price was based on a third-party valuation of the company's common stock, with certain adjustments as set forth below in detail in Note 7 – Stockholders' Equity. This expense was recorded to interest expense on the Company statement of operations for the nine months ended September 30, 2023.

On August 17, 2023, the Company entered into a second side letter with the holder of the Investor Note (the "August Investor Note Side Letter" and, together with the June Investor Note Side Letter, the "Investor Note Side Letters") pursuant to which the Company (i) amended and restated the Investor Note to extend the maturity date to September 30, 2023 and (ii) in consideration therefor, issued to such holder 30,000 shares of Common Stock. On September 24, 2023, the Company entered into an amendment to the Investor Note, which further extended the maturity date to October 10, 2023. The Investor Note provides for the accrual of interest equal to 2% of the face amount of $450,000 per month ($9,000 per month) and obligates the holder to subscribe for securities in the IPO in full satisfaction of our repayment obligations. In addition, pursuant to the Investor Note Side Letters, the Company agreed to register the 80,000 shares of Common Stock (50,000 issued for the June 23, 2023 side letter, and 30,000 issued for the August 17, 2023 side letter) for resale. The Company recorded an expense of $75,600 from the issuance of the 30,000 shares of common stock based on a share price of $2.52. The $2.52 share price was based on a third-party valuation of the company's common stock, with certain adjustments as set forth below in detail in Note 7 – Stockholders' Equity. This expense was recorded to interest expense on the Company statement of operations for the nine months ended September 30, 2023.

On December 6, 2022, the Company and Mr. Todd Davis, one of the Company's directors, entered into a note payable agreement (the "Director Note") for $175,000. The Director Note has an original issuance discount of $75,000, no other interest and matures on December 31, 2023, or, if earlier to occur, upon the closing of an underwritten offering of securities resulting in at least $15 million in gross proceeds. Mr. Davis, as lender, has the right but not the obligation to subscribe to the underwritten offering by presenting the Director Note in whole or in part to purchase such securities as legal tender therefor, on a dollar-for-dollar basis based upon the offering price of such securities to the public. The Director Note bears no interest except in the case of certain events of default. As of September 30, 2023, there was an unamortized debt discount of $17,784. There was $52,416 in amortization of debt discount included in interest expense on the statement of operations for the nine months ended September 30, 2023.

On April 17, 2023, the Company entered into a bridge loan for working capital purposes, with various accredited investors, all of whom are pre-existing stockholders, in the aggregate principal amount of $393,808 (the "April Bridge Financing"). During the three months ended March 31, 2023, the Company received $166,903 in Advances from certain participating investors. Such Advances accrued interest at a rate of 8% per annum until close of the April Bridge Financing on April 17, 2023, for a total of $1,870 in aggregate interest on all Advances. The April Bridge Financing consists of senior secured convertible notes that have a maturity date of October 17, 2023. Such notes accrue interest on the unpaid principal amount at a rate of 8% per annum and will automatically convert into shares of common stock at the initial public offering of shares of Common Stock at a 20% discount to the price per IPO Share. The senior secured convertible notes issued in the April Bridge Financing are secured by a security interest in all of our assets (including our patents and intellectual property licenses). In connection with the April Bridge Financing, on April 17, 2023, the Company also entered into a securities purchase agreement with holders of the notes, pursuant to which the Company is required to file a registration statement within 180 calendar days after consummation of the IPO, providing for the resale of Common Stock received by holders of the notes upon conversion of such notes.

On September 1, 2023, the Company entered into a bridge loan for working capital purposes, with various accredited investors, certain of which are pre-existing stockholders, in the aggregate principal amount of $198,128 (the "September Bridge Financing"). The September Bridge Financing consists of senior secured convertible notes that have a maturity date of March 1, 2024. Such notes accrue interest on the unpaid principal amount at a rate of eight percent (8%) per annum and will automatically convert into shares of Common Stock in connection with the IPO at a twenty percent (20%) discount to the price per IPO Share plus an additional 551 shares of Common Stock issuable as further consideration for the September Bridge Financing. The senior secured convertible notes issued in the September Bridge Financing are secured by a security interest in all of our assets (including our patents and intellectual property licenses). In connection with the September Bridge Financing, on September 1, 2023, the Company also entered into a securities purchase agreement with holders of the notes, pursuant to which the Company is required to file a registration statement within 180 calendar days after consummation of the IPO, providing for the resale of Common Stock received by holders of the notes upon conversion of such notes. Additionally, we entered into a subordination and intercreditor agreement, effective September 1, 2023, with the holders of the senior secured convertible notes issued in the April Bridge Financing, pursuant to which those notes and certain liens of the Company would be subordinated to the rights of the holders of the notes issued in the September Bridge Financing.

NOTE 7 – STOCKHOLDERS' EQUITY

Share Forfeiture

Pursuant to the terms of the April Bridge Financing, Chromocell Holdings forfeited 1,203,704 of the shares of common stock of the Company on April 17, 2023. All shareholders with ownership stakes greater than 5% of the Company agreed that the failure to invest its pro rata allocation in the April Bridge Financing would result in the forfeiture of a pro rata percentage of their shares. Chromocell Holdings did not invest its full pro rata allocation, leading to the forfeiture of a portion of their shares of common stock of the Company.

Stock-Based Compensation

Options

On January 10, 2023, the Company granted options to acquire 450,000 shares of the Company's common stock to employees and consultants of the Company pursuant to their employment or consulting agreements. These options had a grant date fair value of $1,122,244. These options have an exercise price of $2.52, a term of 10 years, and vest quarterly over ten quarters, with such vesting commencing on October 1, 2022. Since the options began vesting on October 1, 2022, despite being approved by the board of directors on January 10, 2023, the Company applied guidance found in ASC 718-10-55-82 which indicate that the grant date for an award will be the date that a grantee begins to benefit from, or be adversely affected by, subsequent changes in the price of the grantor's equity shares. Since the options began vesting on October 1, 2022, the Company began recording the related expense for the options at the same time and recognized the issuance of the options as a 2022 event.

On January 10, 2023, the Company granted an option to acquire 25,000 shares of the Company's common stock to a consultant of the Company pursuant to their consulting agreements. This option had a grant date fair value of $62,336. This option has an exercise price of $2.52, a term of 10 years, and vests upon the IPO or sale of the Company.

On January 10, 2023, the Company issued a total of 800,000 options to purchase shares of the Company's common stock to several of its directors, pursuant to their serving as a director. These options had a grant date fair value of $1,994,768. These options have an exercise price of $2.52, a term of 10 years, and 600,000 of these options will vest over 2.5 years commencing on January 10, 2023, and 200,000 of the options will vest upon the Company's establishment of a second clinical program, which shall include an acquisition or entrance into a joint venture.

On March 9, 2023, the Company issued an option to acquire 135,000 shares of the Company's common stock to a director, pursuant to their serving as a director. This option had a grant date fair value of $336,606. This option has an exercise price of $2.52, a term of 10 years, and will vest over 2.25 years commencing on March 9, 2023.

On May 15, 2023, the Company issued an option to acquire 250,000 shares of the Company's common stock to a director, pursuant to their serving as a director. This option had a grant date fair value of $623,057. This option has an exercise price of $2.52, a term of 10 years, and vests upon the IPO or sale of the Company.

On May 15, 2023, the Company issued an option to acquire 218,000 shares of the Company's common stock to a director, pursuant to their serving as a director. This option had a grant date fair value of $543,306. This option has an exercise price of $2.52, a term of 10 years, and will vest over 3 years.

During the nine months ended September 30, 2023, the fair value of each stock option granted was estimated using the Black-Scholes Option Pricing Model using the following inputs:

Exercise price	$ 2.52
Expected dividend yield	0%
Risk free interest rate	3.50-3.93%
Expected life in years	10

Expected volatility	157-158%

The risk-free interest rate assumption for options granted is based upon observed interest rates on the United States Government Bond Equivalent Yield appropriate for the expected term of the options.

With certain adjustments outlined below, the Company based its determination of the underlying fair value of the Company's common stock on the findings of an independent third party engaged by the Company to determine the fair value of the Company's intellectual property. The Company had the analysis conducted in conjunction with the Contribution Agreement, which was executed on August 10, 2022. The analysis determined that the fair value of the Company's intellectual property was $44.8 million. At the time of the Contribution Agreement and the option grants, there was 10,685,714 shares (on an as converted basis reflecting the conversion of the 600,000 Series A Convertible Preferred Stock held by Chromocell Holdings). The resulting value per common share was $4.19. The Company then adjusted this value in accordance with the following:

Value of intellectual property	$44.8 million
Common shares outstanding (as converted)	10,685,714
Value per common share	$4.19
Illiquidity discount	20%
Minority discount	20%
Fair value of the common stock	$2.52

The Company determined the expected volatility assumption for options granted using the historical volatility of comparable public companies' common stock. The Company will continue to monitor peer companies and other relevant factors used to measure expected volatility for future option grants, until such time that the Company's common stock has enough market history to use historical volatility.

The dividend yield assumption for options granted is based on the Company's history and expectation of dividend payouts. The Company has never declared nor paid any cash dividends on its common stock, and the Company does not anticipate paying any cash dividends in the foreseeable future.

The Company recognizes option forfeitures as they occur as there is insufficient historical data to accurately determine future forfeitures rates.

The following is an analysis of the stock option grant activity:

	Number	Weighted Average Exercise Price	Weighted Average Remaining Life
Stock Options			
Outstanding December 31, 2022	450,000	$ 2.52	9.76
Granted	1,428,000	$ 2.52	9.67
Expired	—	$ —	—
Exercised	—	$ —	—
Outstanding September 30, 2023	1,878,000	$ 2.52	9.32
Exercisable September 30, 2023	419,833	2.52	9.20

A summary of the status of the Company's nonvested options as of September 30, 2023, and changes during the nine months ended September 30, 2023, is presented below:

Non-vested Options	Options	Weighted-Average Exercise Price
Non-vested at December 31, 2022	410,000	$ 2.52
Granted	1,428,000	$ 2.52
Vested	(379,833)	$ 2.52
Forfeited	—	$ —
Non-vested at September 30, 2023	1,458,167	$ 2.52

The total number of options granted during the nine months ended September 30, 2023 and 2022 was 1,428,000 and 0, respectively. The exercise price for these options was $2.52 per share and there was an intrinsic value of $0.

The Company recognized stock-based compensation expense related to option vesting amortization of $941,989 and $0 for the nine months ended September 30, 2023 and 2022, respectively, which is included in general and administrative expenses in the statement of operations.

As of September 30, 2023, the unamortized stock option expense was $2,184,284. As of September 30, 2023, the weighted average period for the unamortized stock compensation to be recognized is 3.85 years.

On June 22, 2023, the Company and Camden Capital LLC amended and restated the Consultant Agreement by entering into an Amended and Restated Consultant Agreement, whereby the RSU for 150,000 shares of common stock was cancelled, and the Company agreed to grant Camden Capital LLC an option to acquire 250,000 shares of common stock within 30 days of the closing of the IPO. As of June 22, 2023, such RSU for 150,000 shares of common stock had not vested, and no expense was recorded on the Company's financial statements.

NOTE 8 – SUBSEQUENT EVENTS

Standby Investor Side letter

On October 11, 2023, the Company entered into a securities purchase agreement with an institutional investor (the "Standby Investor"), pursuant to which (i) the Standby Investor agreed to purchase, upon close of the IPO and at the Company's election, an aggregate of up to 750 shares of Series B Convertible Preferred Stock, par value of $0.0001 per share (the "Series B Preferred Stock") for a purchase price of $1,000 per share, and (ii) in consideration therefor, the Company would issue upon close of the IPO, and regardless of whether the Company would have issued any shares of Series B Preferred Stock, an aggregate of 37,500 shares (such shares, the "Standby Shares") of Common Stock to the Standby Investor (such agreement, the "Series B Securities Purchase Agreement"). In addition, pursuant to the Series B Securities Purchase Agreement, the Company was required to file a registration statement within 180 calendar days after consummation of the IPO, providing for the resale of the Standby Shares and shares of Common Stock issuable upon conversion of the Series B Preferred Stock, if issued.

Effective November 13, 2023, the Company entered into a side letter with the Standby Investor (the "Standby Investor Side Letter"), pursuant to which it (i) waived in full the Standby Investor's obligation to fund the aggregate amount to be paid for the Series B Preferred Stock to be purchased under the Series B Securities Purchase Agreement and (ii) agreed to continue to have the obligation to issue the full amount of the Standby Shares upon the closing of the IPO. The Company and the Standby Investor also agreed to terminate each of their obligations solely with respect to the Series B Preferred Stock under the Series B Securities Purchase Agreement and that certain Registration Rights Agreement between the Company and the Standby Investor, which was required to be delivered pursuant to the Series B Securities Purchase Agreement.

Amendment to Investor Note

Effective October 10, 2023, the Company entered into a side letter with the Holder of the Investor Note, which extended the maturity date of the Investor Note to November 14, 2023 and the Company issued to the Holder of the Investor Note 30,000 shares of Common Stock.

Effective November 13, 2023, the Company entered into another side letter with the holder of the Investor Note pursuant to which the Company (i) amended and restated the Investor Note to extend the maturity date to January 31, 2024, and (ii) in consideration therefor, agreed to issue to such Holder of the Investor Note 30,000 shares of Common Stock on each of November 29, 2023, December 29, 2023 and January 29, 2024, provided the Investor Note remained outstanding as of such date.

Effective January 30, 2024, the Company entered into another side letter with the holder of the Investor Note (the "January Investor Note Side Letter") pursuant to which the Company (i) amended and restated the Investor Note to extend the maturity date to February 29, 2024, and (ii) in consideration therefor, agreed to issue to such Holder of the Investor Note 700,000 shares of Common Stock on the earlier to occur of the IPO or February 29, 2024.

October Promissory Notes

On October 12, 2023, the Company and four existing investors entered into promissory notes (the "October Promissory Notes") with an aggregate face amount of $210,000 and an aggregate purchase price of $175,000. The October Promissory Notes mature on November 12, 2023 or, if earlier to occur, upon the closing of the IPO. The October Promissory Notes bear no interest except in the case of certain events of default. On November 7, 2023, the Company amended and restated the October Promissory Notes to extend the maturity dates of the October Promissory Notes to November 17, 2023. On November 13, 2023, the Company amended and restated the October Promissory Notes to further extend the maturity dates of the October Promissory Notes to February 29, 2024.

Amendments to April Bridge Financing Notes

On October 12, 2023, the Company entered into a first amendment to the senior secured convertible notes in the April Bridge Financing, which extended the maturity of the notes to November 1, 2023. On October 24, 2023, the Company entered into a second amendment to the senior secured convertible notes in the April Bridge Financing, which extended the maturity of the notes to November 14, 2023. On November 13, 2023, the Company entered into a third amendment to the senior secured convertible notes in the April Bridge Financing, which further extended the maturity of the notes to February 29, 2024.

Rights Offering

On November 22, 2023, the Company commenced a rights offering (the "Rights Offering") pursuant to which the Company distributed non-transferable subscription rights ("Subscription Rights") to each holder of its Common Stock held as of 5:00 p.m. Eastern Standard Time on November 22, 2023, the record date for the Rights Offering (the "Rights Offering Record Date"). The Subscription Rights could be exercised at any time during the subscription period, which commenced on November 22, 2023 and expired at 5:00 p.m., Eastern Standard Time, on December 1, 2023. Each Subscription Right entitled the eligible holder to purchase up to three shares of the Company's Common Stock at a price per whole share of Common Stock of $0.0112 (the "Subscription Price"). Holders who fully exercised their rights could also subscribe for additional shares of Common Stock not subscribed for by other holders on a pro rata basis. In addition, the Company could distribute to one or more additional persons, at no charge to such person, additional non-transferable subscription rights to purchase shares of its Common Stock in the Rights Offering at the same Subscription Price, without notice to the holders of its Common Stock. Upon the closing of the Rights Offering, the Company issued an aggregate of 21,982,216 shares of Common Stock and received aggregate net proceeds of $246,201, after giving effect to the Representative Affiliate Transactions (as defined below), which it intends to use primarily for general corporate purposes and expenses associated with the IPO.

Benuvia License Agreement

On December 23, 2023, the Company entered into an exclusive licensing agreement (the "Benuvia License Agreement") with Benuvia Operations, LLC ("Benuvia") for a sublingual formulation of a Diclofenac spray for the treatment of acute pain, a Rizatriptan sublingual spray formulation and an Ondansetron sublingual spray formulation (collectively, the "Spray Formulations"), diversifying its pipeline of non-opioid pain treatment therapies, while adding therapeutic options for related conditions. The Diclofenac Spray Formulation is patented and has started clinical development in human volunteers. Preliminary pharmacokinetics suggest that this formulation may have a faster onset of action than oral Diclofenac tablets. Diclofenac is a non-steroidal anti-inflammatory drug that is also marketed under additional brand names including Voltaren and Cataflam in its pill form. Rizatriptan, whose brand name is Maxalt, is used for the acute treatment of Migraines as a pill. By a number of clinical measures it is thought to be superior to Sumatriptan. A sublingual formulation of Rizatriptan may potentially have a faster onset of action than an oral form and may be easier to tolerate than swallowing a pill when patients are experiencing nausea as a result of the migraine headache. Ondansetron is an anti-emetic that is available in oral and intravenous form. An Ondansetron sublingual spray formulation may potentially have a faster onset of action than an oral form and may be easier to tolerate than swallowing a pill when patients are experiencing nausea. Under the terms of the Benuvia License Agreement, Benuvia will be responsible for the manufacturing and supply of the Spray Formulations, but the Company will have exclusive, worldwide rights to develop, commercialize and distribute the Spray Formulations.

In connection with the Benuvia License Agreement, the Company agreed to pay Benuvia a 6.5% royalty on net sales of the Spray Formulations for a period of up to 15 years from the date of the first commercial sale of any of the Spray Formulations. In addition, on December 23, 2023, the Company entered into a stock issuance agreement with Benuvia pursuant to which the Company agreed to issue Benuvia 3,458,033 shares of the Company's Common Stock, which may be offered and sold pursuant to a resale prospectus.

The issuance of 3,458,033 shares of our Common Stock to Benuvia was negotiated between the parties based on an agreed upon determination of the reasonable value of the Spray Formulations and an unofficial pre-IPO valuation for the Company. The Company is in the process of determining the appropriate purchase price accounting related to the Benuvia License Agreement, but at a high level, the Company expects to allocate the purchase price to patent assets, book the issuance of equity at par value and book the amount in excess of par value as additional paid in capital. Since the Benuvia License Agreement was entered into subsequent to the date of the financial statements contained

herein, this accounting is not included in these financial statements.

Amendment to Director Note

On December 28, 2023, the Company entered into an amendment to the Director Note, which extended the maturity date to February 29, 2024.

Bridge Financing Note Amendments and Recission Agreement

On February 8, 2024, the Company and certain affiliates of A.G.P./Alliance Global Partners ("A.G.P.") entered into amendments to the senior secured convertible notes issued to such affiliates of the AG.P. in the April Bridge Financing and September Bridge Financing to remove the automatic conversion features from such notes (the "Bridge Financing Note Amendments"). Under the Bridge Financing Note Amendments, both notes issued in the April Bridge Financing and the September Bridge Financing have a maturity date of March 1, 2024, and the full principal amount of both notes and any accrued interest thereon shall be payable solely in cash upon the consummation of this IPO. Both notes have an annual interest rate of eight percent (8%), which accrues daily, and is calculated on the basis of a 360-day year (consisting of twelve 30 calendar day periods).

On February 10, 2024, the Company entered into a Stock Rescission Agreement with certain affiliates of A.G.P. (the "Stock Rescission Agreement" and, together with the Bridge Financing Note Amendments, the "Representative Affiliate Transactions"), pursuant to which the Company rescinded 1,000,160 shares of Common Stock held by such affiliates of A.G.P. and agreed to refund an aggregate of $91,512.53 paid by such affiliates of A.G.P. in consideration therefor within 30 days of the effective date of the Stock Rescission Agreement.

CHROMOCELL THERAPEUTICS CORPORATION

2,969,823 SHARES OF COMMON STOCK

The date of this prospectus is February 15, 2024