

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2024

or

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

For the transition period from _____ to _____

Commission file number: 333-269188

Channel Therapeutics Corporation

(Exact name of registrant as specified in its charter)

Nevada

(State or other jurisdiction of
incorporation or organization)

86-3335449

(I.R.S. Employer
Identification No.)

**4400 Route 9 South, Suite 1000
Freehold, NJ 07728**

(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: **(877) 265-8266**

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

Title of each class:	Trading Symbol	Name of each exchange on which registered:
Common Stock, \$0.0001 par value	CHRO	The NYSE American LLC

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

None

(Title of class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes No

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

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

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

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report.

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements.

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b).

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes No

The aggregate market value of the Common Stock held by non-affiliates of the registrant, as of June 28, 2024, the last business day of the second fiscal quarter, was approximately \$6.8 million based on a closing price of \$1.32 per share on such date. Shares of Common Stock held by each director, each officer and each person who owns 10% or more of the outstanding Common Stock have been excluded from this calculation in that such persons may be deemed to be affiliates. The determination of affiliate status is not necessarily conclusive.

The registrant had 6,103,813 shares of its common stock outstanding as of March 26, 2025.

References in this Annual Report on Form 10-K to the “Company,” “Channel,” “we,” “us,” or “our” mean Channel Therapeutics Corporation unless otherwise expressly stated or the context indicates otherwise.

Documents Incorporated By Reference: None.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (this “Report”) contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act of 1933, as amended (the “Securities Act”), and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). 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 Report include, but are not limited to, statements about the following:

- the initiation, timing, progress and results of preclinical and clinical trials for CC8464, CT2000, CT3000 and any other 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 U.S. Food and Drug Administration (“FDA”) marketing and other regulatory approval of CC8464, CT2000 and CT3000;
 - our ability to achieve certain accelerated or orphan drug designations from the FDA;
 - our estimates regarding the potential market opportunity for CC8464, CT2000 and CT3000;
 - our research and development programs for our lead compounds, CC8464, CT2000 and CT3000;
 - our plans and ability to successfully develop and commercialize future compounds, including CC8464, CT2000 and CT3000;
 - our ability to identify and develop new 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 our lead and any other future 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;
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- 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 Jumpstart Our Business Startups Act of 2012 (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 Report. 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 Report 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 Report. You should read this Report and the documents that we have filed as exhibits hereto 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.

For discussion of factors that we believe could cause our actual results to differ materially from expected and historical results, see “*Item 1A - Risk Factors*” below. These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties and by us.

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PART I

Item 1. 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”, which has been genetically validated as a pain receptor in human physiology. 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.

We have formally launched three programs developing pain treatment therapeutics, all of which are based on the same proprietary molecule, as follows:

Eye Pain: Based on a novel formulation of CC8464, our Eye Pain program, titled CT2000, is for the potential treatment of both acute and chronic eye pain. NaV1.7 channels are present on the cornea, making it 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 CT2000 as a topical agent for the relief of eye pain. A potential advantage of this approach is that topical administration of CT2000 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 developed topical ophthalmic formulations and are pursuing trial plans as set forth below.

Current options for the treatment of ocular pain center on the use of corticosteroids and non-steroidal anti-inflammatory drug (“NSAID”) based therapeutics. These options suffer from sight-threatening complications such as Glaucoma and corneal melting, thus there is a large unmet need for other approaches. As an example of the potential patient population, we estimate that there are approximately 5 million cases of corneal abrasions per year in the United States. In addition, other potential indications associated with eye pain include:

- severe dry eye,
- side effects from photorefractive keratectomy (PRK) and pterygium surgery,
- second eye cataract surgery,
- neuropathic corneal pain, and
- severe uveitis and severe iritis/scleritis.

As NaV1.7 channels are present on the cornea and is a viable biological target for treating eye pain, we believe that we have a sound scientific basis for our ability to treat a multitude of eye pain indications. We have successfully developed an eye drop formulation and have determined that the eye drops are well tolerated by animals. We have completed animal efficacy studies and are in the process of running toxicology studies on animals. We expect to announce the efficacy and toxicology results by April 2025.

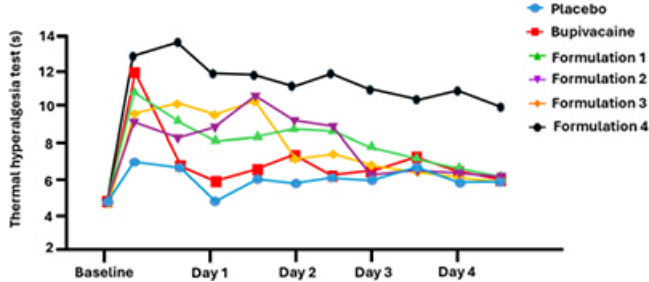
Following the animal studies, if successful, we intend to move into proof-of-concept (“POC”) studies in humans. We plan to conduct the POC study in Australia to avail ourselves of a 43.5% tax credit for clinical expenses incurred in Australia and, on January 9, 2023, established an Australian subsidiary through which the work will be conducted. We are planning to conduct the POC in a clinic in Brisbane, Australia and are in the process of contracting the services to perform such trial.

Depot Program: Based on several novel formulations of CC8464, the Company’s most recently launched program, titled CT3000, is for the potential treatment of post operative pain with the use of nerve blocks. Examples would include knee surgery or shoulder surgery. Existing therapies for nerve blocks lead to neuromuscular blockade which prevents movement following surgery. Doctors often want patients to move soon after surgery to avoid complications such as blood clots. A NaV1.7 inhibitor used for nerve blocks may provide good analgesia but will not lead to neuromuscular blockade that prevents movement like other local anesthetics.

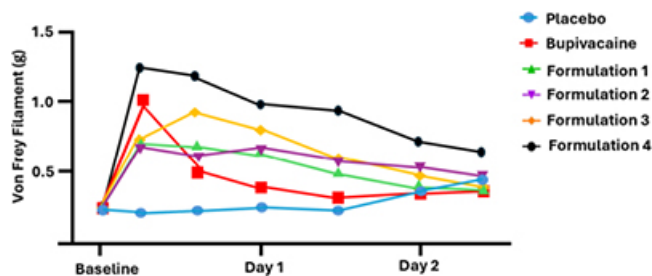
The Company has successfully developed a number of formulations and in December 2024, announced that it achieved its endpoints in two pre-clinical in vivo models of the Company's nerve block formulations for acute pain, showing material improvement over the existing standard of care, bupivacaine, in both efficacy and duration.

The Company performed a thermal hyperalgesia test in rodents with a placebo arm, bupivacaine arm and four arms of the main formulations of the Company's molecule. The Company also performed a mechanical allodynia test in rodents with the same arms as above. For both models, the drugs were administered as a sciatic nerve block. All four Company formulations showed a depot effect in excess of four days, an improvement over bupivacaine, the current standard of care.

The results of the thermal hyperalgesia results are shown in the chart below. After thirty minutes, three of the four formulations showed materially better efficacy than bupivacaine, with each of the three being statistically superior to placebo for more than two days longer than bupivacaine. One of the formulations remained statistically superior to placebo for more than four days. Further, as NaV1.7 does not have an impact on mobility, this approach may offer a better option for post-surgical physical therapy as current nerve block therapies cause temporary paralysis in the affected area.



Similarly for the mechanical allodynia test results, three of the four formulations showed statistically better efficacy for a longer duration of time than bupivacaine. The mechanical allodynia test is shorter in duration, reflecting the subject's innate swift recovery rate to surgical incisions. Nonetheless, the results mirrored the successful results set forth with the thermal hyperalgesia test.



The Company will commence toxicology and CMC work in 2025 and expects to commence human POC trial in early 2026.

Neuropathic Pain: CC8464 is being developed to address certain types of neuropathic pain. The chemical characteristics of CC8464 restrict its entry into the CNS and limit its effect to the NaV1.7 channels in the peripheral nervous system, which consists of the nerves outside the brain and spinal cord. Activation of other channels in the CNS can result in side effects, including addiction and other centrally mediated adverse effects. Since CC8464 is designed to not penetrate the CNS it is highly unlikely to produce CNS mediated side effects including euphoria or addiction. Based on its characteristics, preclinical studies (described below) and the Phase 1 studies we have completed to date, we believe that CC8464, if approved, could become an attractive option for both patients and physicians as a treatment for moderate-to-severe pain in Erythromelalgia (“EM”) and idiopathic small fiber neuropathy (“iSFN”).

We conducted four Phase 1 trials with 207 patients. The results showed that CC8464 has a good overall tolerability and demonstrated no liver or renal toxicity, no central nervous system changes and no cardiovascular findings but may cause skin rashes in certain patients. The occurrence of skin rashes is not uncommon with the class of molecules to which CC8464 belongs and the rashes were successfully treated in all cases with topical steroids and/or topical antihistamines (with the exception of one patient requiring systemic steroids).

As a result of the potential for skin rashes, following discussions with the FDA, we will conduct a slow dose escalation study to further evaluate the incidence of rashes. By titrating the dose over several weeks, we anticipate that we will reduce or eliminate this side effect. We expect that the slow dose escalation study will also help determine the need for dose escalation in the final treatment regime. 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).

When the dose escalation trial is funded, we will enroll approximately 20 healthy volunteers who will receive CC8464 over a period of several weeks, with the dose escalation study expected to take approximately 9-12 months in total. We anticipate that the slower dose escalation will decrease the likelihood of drug-related skin reactions. The primary endpoint of the dose escalation trial 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. Even if it is ultimately determined that we will need an escalation period for chronic pain treatment therapy, which patients could well take for the remainder of their lives, we do not believe the dose escalation approach will be consequential.

We plan to conduct the dose escalation trial in Australia to avail ourselves of the tax credit set forth above, utilizing our Australian subsidiary through which the work will be conducted. The location of the POC has not been determined at this time, with availability of facilities and patient population, costs, tax credits, centers of excellence in the respective fields (EM or iSFN) are all factors in the ultimate determination of the location.

In parallel with the dose escalation study, we expect to run a pilot efficacy study on approximately ten EM patients. In this study, we will induce EM flares, determine baseline pain, and then dose escalate CC8464, after which, we will attempt to induce flares. The primary endpoint will be the amount of pain experienced, and the secondary endpoint is a determination if CC8464 reduces the frequency of EM flares.

We are currently working on the development of the Phase 2a POC plan and expect to launch the Phase 2a POC study following the dose escalation study and EM pilot study, to assess the potential efficacy of CC8464 in iSFN patients. Both of iSFN and EM are orphan indications for which we plan to apply for orphan drug designations. The orphan indication may decrease the scope of the ultimate development program that is necessary for approval and is associated with a marketing exclusivity period from the FDA along with some tax advantages.

Though the Phase 2a POC study design has not yet been completed, the study will take approximately twelve months after it is initiated. The primary endpoint will be the amount of pain experienced from iSFN with secondary endpoints including other measurements like pain relief and neuropathy scores. The final design may change based on feedback from regulatory authorities or information learned during the dose escalation trial.

The potential population for EM in the United States is estimated to be between 5,000 and 50,000 patients and the potential population for iSFN in the United States is estimated to be between 20,000 and 80,000 patients. In both instances, we expect patients would potentially take our drug for the remainder of their lives, and given the lack of good therapeutic alternatives, we expect to have a robust, ongoing, and durable market.

The Phase 2a results will have significance beyond EM and iSFN 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. We believe that positive results from the Phase 2a study could not only act as support for CC8464's potential in EM and iSFN but may also provide guidance of its potential for other indications of peripheral neuropathic pain.

We may further expand our pipeline with other internal or external compounds in the future, but all other internally discovered compounds are pre-clinical.

Benuvia Spray Formulations: In addition to our NaV1.7 programs set forth above, on December 23, 2023, we entered into an exclusive licensing agreement (the "Benuvia License Agreement") with Benuvia for a sublingual formulation of a Diclofenac spray for the treatment of acute pain, a Rizatriptan intranasal spray formulation and an Ondansetron sublingual spray formulation (collectively, the "Spray Formulations"). The Spray Formulations diversify our pipeline of non-opioid pain treatment therapies, while adding therapeutic options for related conditions. The sublingual formulation of a Diclofenac spray for the treatment of acute pain (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 Diclofenac Spray Formulation. 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 Diclofenac Spray Formulation 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-HT_{1A}-receptor) agonists and are indicated for the treatment of migraine. An intranasal spray formulation of Rizatriptan (the "Rizatriptan 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 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. 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 (the “Ondansetron 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.

We currently do not have strategy and development plans for the Spray Formulations licensed from Benuvia.

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 pain associated with neuropathic pain and eye pain. The key elements of our strategy to achieve our mission are:

- **Develop CT2000 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, NaV1.7 receptor is present on the cornea and as such, is a viable biological target for treating eye pain. We have developed a number of topical ophthalmic formulation of CT2000 that are being evaluated for ophthalmic efficacy and toxicology in two in vivo models, which will be followed by a POC trial in patients. We expect the human POC trials for this ophthalmic formulation of CT2000 to start in the second quarter 2025.
- **Develop CT3000 for the treatment of post-surgical pain.** Based on its pre-clinical profile, and the target validation, if approved by the FDA, we believe that CT3000 has the potential to become a drug for treatment of acute post operative surgical pain for knee and shoulder surgery where nerve blocks are appropriate, potentially delivering meaningful clinical benefits over the currently available standard of care.
- **Advance the development of CC8464 towards FDA approval for treating EM and iSFN.** 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 and iSFN patients, potentially delivering meaningful clinical benefits over the currently available standard of care.
- **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 NaV1.9, 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, CT2000 and CT3000 as our primary pain blocking candidates.
- **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 our lead compounds; however, we may opportunistically enter into strategic collaborations in certain geographic or clinical settings to maximize the value of our pipeline.

While CT2000 and CT3000 are the focus of our efforts, we may also allocate future resources towards the discovery and development of other compounds that could potentially treat pain.

CC8464’s FDA Orphan Drug Designation

We are considering submitting a request to the FDA for Orphan Drug Designation for EM and iSFN, 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 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 Report, we have not submitted an application for orphan drug designation for CC8464.

CC8464, CT2000 and CT3000 Manufacturing

We plan to manufacture the clinical and eventual commercial supply through Clinical Manufacturing Organizations (“CMOs”) in the U.S. and potentially other jurisdictions. We do not produce drug substances in house. External CMOs have produced enough CC8464 drug substance to conduct the dose escalation trial, prepare the eye pain formulation, conduct the eye pain toxicology trial and potentially, to conduct the Phase 2 proof of concept for neuropathic pain and acute and chronic eye pain.

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.

The Company has developed the formulation for the eye drops associated with the eye pain treatment therapy and depot injections associated with the nerve block therapy and are in the early stages of determining our manufacturing strategy. We expect to pursue a similar strategy to have CT2000 and CT3000 manufactured by CMOs.

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. We have been granted a patent in the United States directed to the composition of matter and use of our lead compound, CC8464. We have also obtained patents in France, Japan, India in Mexico, Israel and South Korea. Our U.S. patent for CC8464 will expire in 2035. In addition, we have an additional pending patent application in India.

We have pending patent applications for each of CT2000 ophthalmic formulation and CT3000 injectable formulations, and for the treatment of pain.

Granted U.S. Patent 9,855,234 is directed to the diclofenac spray formulation and will expire in April of 2036. 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 in May 2034 and August 2036, respectively. 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 molecules that modulate NaV (including NaV1.7 and NaV1.8) activities or address pain through other methods of action and therefore have the potential to mitigate eye, post-surgical and EM and iSFN pain. These companies and new entrants may potentially compete with our products in the future with novel delivery technologies. Competition in this space will remain strong and we do not know if we will be successful in obtaining orphan designation from the FDA for CC8464, encounter challenges to our issued patents and continue to advance CC8464, C2000 and CT3000 through clinical development towards approval.

In connection with the Company's initial public offering (the "IPO"), we 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 that certain Contribution Agreement (the "Contribution Agreement") with Chromocell Holdings. Pursuant to the Contribution Agreement, effective July 12, 2022 (the "Contribution Date"), (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 March 26, 2025, we had four full-time employees and seven individual 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 two person Scientific Advisory Board 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.

Demand Letter from Mr. Kopfli's Attorney

On February 14, 2024, our Board 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 Report. Mr. Kopfli alleged an improper termination for "cause" and claimed to seek monetary damages in the amount of \$479,169. Of the \$479,169 asserted by Mr. Kopfli, as of September 30, 2024, the Company had accrued \$363,091 in compensation expenses associated with Mr. Kopfli's prior employment with the Company. However, the Company believed the assertions made by Mr. Kopfli were without merit and commenced a lawsuit against Mr. Kopfli and Chromocell Holdings in the Supreme Court for the State of New York, County of New York on June 7, 2024 (Index No. 652917/2024, the "New York Action"), asserting causes of action against Mr. Kopfli for breach of the Employment Agreement entered into on January 10, 2023 between the Company and Mr. Kopfli, breach of fiduciary duty by Mr. Kopfli, as well as breach of contract against Chromocell Holdings. The Company also asserted a "faithless servant" claim against Mr. Kopfli, seeking a ruling that Mr. Kopfli was not entitled to compensation from the Company. The Company sought monetary damages against Mr. Kopfli and Chromocell Holdings in the New York Action, plus disgorgement of all compensation previously paid or accrued to Mr. Kopfli by the Company.

By Order dated October 3, 2024, the court in the New York Action awarded the Company a default judgment against Mr. Kopfli and Chromocell Holdings on all claims, and ordered an assessment of damages against Mr. Kopfli and Chromocell Holdings (to be held at a date to be determined). As of December 31, 2024, the Company has removed the accrual of \$363,091 in compensation expenses and recorded a gain on default judgement in the same amount.

Parexel Claim

On July 31, 2024, the Company received a demand letter from an attorney representing Parexel International (IRL) Limited (“Parexel”). The letter, which was addressed to both the Company and Chromocell Holdings, purports to be a notice of default of the Promissory Note between Chromocell Holdings and Parexel (the “Promissory Note”) and seeks the payment of allegedly unpaid principal in the amount of \$682,551 plus interest exceeding \$177,000. The Company denies that it is liable for any of the amounts sought by Parexel; the Company is not a party to the Promissory Note and does not believe it is liable for any amounts allegedly due thereunder. The Company intends to defend itself vigorously in the matter.

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, Clinical Research Organizations (“CRO”), clinical investigators, clinical trial sites and contract manufacturing organizations, 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, a sponsor must submit a U.S. New Drug Application (“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 Good Laboratory Practice (“GLP”) requirements;

- completion of the manufacture, under current Good Manufacturing Practices (“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 Investigational New Drug Application (“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, Good Clinical Practice (“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 several 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 policies 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 2025, the application fee for each application containing clinical data is \$4,310,002. PDUFA also imposes an annual program fee for each approved prescription drug, which has been set at \$403,889 for fiscal year 2025. 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 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 I 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 federal False Claims Act (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 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 Abbreviated New Drug Application (“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 Centers for Medicare & Medicaid Services (“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.
- The federal Health Insurance Portability and Accountability Act of 1996 (“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 the Health Information Technology for Economic and Clinical Health Act (“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 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 European Union 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 European Medicines Agency (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 for one of our compounds 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 “reference 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 European Union. 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 European Union 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 European Union 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 European Union member states’ legislation implementing the Clinical Trials Directive. Under the current regime (the European Union 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 European Union 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 “European Union 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 European Union 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 European Union 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 European Union, 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 European Union, 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.

Recent Developments of the Company

Bridge Note

On February 25, 2025, the Company issued an unsecured promissory note in the aggregate principal amount of \$325,000 (the “Bridge Note”) to 3i, L.P., a Delaware limited partnership (the “Holder”), for a purchase price of \$250,000, pursuant to which the Company promises to pay the Holder or its registered assigns the principal sum of \$325,000 or such amount equal to the outstanding principal amount of the Note together with interest. The Note will bear interest on the outstanding principal amount at an annual rate equal to 6.0%. The Note may be prepaid by the Company without penalty, in whole or in part, upon two days’ prior written notice to the Holder. All unpaid principal, together with any then unpaid and accrued interest and other amounts payable under the Note, will otherwise be due and payable on the earliest of: (i) May 25, 2025, (ii) the consummation of a Corporate Event (as defined in the Note), or (iii) when, upon or after the occurrence of an Event of Default (as defined in the Note), such amounts are declared due and payable by the Holder or made automatically due and payable in accordance with the terms of the Note.

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 Holdings.

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.

Channel Therapeutics Corporation was incorporated in Delaware on March 19, 2021. On November 18, 2024 (“Reincorporation Merger Effective Date”), Chromocell Therapeutics Corporation, a Delaware corporation (the “Predecessor”), merged with and into its wholly-owned subsidiary, Channel Therapeutics Corporation, a Nevada corporation (the “Reincorporation Merger”), pursuant to an agreement and plan of merger, dated as of November 18, 2024 (the “Reincorporation Merger Agreement”). All information disclosed in this Form 10-K for periods prior to the Reincorporation Merger Effective Date relates to the Predecessor, and all information disclosed in this Form 10-K for periods after the Reincorporation Merger Effective Date relates to Channel Therapeutics Corporation, a Nevada corporation.

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.channeltherapeutics.com. Information contained on, or that can be accessed through, our website is not incorporated by reference into this Report, and you should not consider information on our website to be part of this Report.

We make available free of charge under the “Investors” section of our website all of our filings with the Securities and Exchange Commission (the “SEC”), including our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, proxy statements and amendments to such documents, each of which is provided on our website as soon as reasonably practicable after we electronically file or furnish, as applicable, the information with the SEC.

Implications of Being an Emerging Growth and Smaller Reporting Company

We qualify as an “emerging growth company” as defined in 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;
- 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 our IPO.

We may choose to take advantage of some but not all of these reduced reporting burdens.

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 U.S. Securities and Exchange Commission (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.

Item 1A. Risk Factors

Our business, financial condition and operating results are subject to a number of risk factors, both those that are known to us and identified below and others that may arise from time to time. These risk factors could cause our actual results to differ materially from those suggested by forward-looking statements in this Report and elsewhere, and may adversely affect our business, financial condition or operating results. If any of these risk factors should occur, moreover, the trading price of our securities could decline, and investors in our securities could lose all or part of their investment in our securities. These risk factors should be carefully considered in evaluating our prospects.

Summary of Risk Factors

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 Report 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:

- The report of the independent registered public accounting firm on our 2024 and 2023 financial statements contains a going concern qualification;
- We are a clinical stage biopharmaceutical company with a limited operating history;
- We have incurred net losses since inception. We 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;
- We will need to raise additional funding to receive approval for CC8464, CT2000, CT3000 or any other future 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;
- 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 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 efforts to develop both of CT2000 and CT3000 and have not moved into pre-clinical or clinical trials. If we are unable to advance CT2000 and CT3000 through pre-clinical and clinical trials, obtain regulatory approval and ultimately commercialize CT2000 and CT3000, or if we experience significant delays in doing so, our business will be materially harmed;
- 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;
- Even if we obtain and maintain approval for CC8464, CT2000 and CT3000 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;
- 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 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;
- 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;
- 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;

- If the market opportunities for CC8464, CT2000, CT3000 or our future compounds are smaller than we believe they are, our revenues may be adversely impacted, and our business may suffer;
- Government price controls or other changes in pricing regulation could restrict the amount that we are able to charge for CC8464, CT2000 and CT3000, if approved, or any of our other future compounds that may be approved in the future, which would adversely affect our revenue and results of operations;
- If we are unable to obtain and maintain adequate U.S. and foreign patent protection for our compounds, including CC8464, CT2000 and CT3000, 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, CT2000, CT3000 and any of our other current or future compounds may be adversely affected;
- We could issue “blank check” preferred stock without stockholder approval with the effect of diluting then current stockholder interests and impairing their voting rights; and provisions in our charter documents could discourage a takeover that stockholders may consider favorable;
- Our articles of incorporation (which, as may be amended and/or restated, we refer to as our “articles of incorporation”) designate the Second Judicial District Court, in and for the State of Nevada, located in Washoe County, Nevada, as the exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit stockholders’ ability to obtain a favorable judicial forum for disputes with us or our directors, officers, employees or agents;
- The other factors set forth under “Risk Factors.”

These and other risks are more fully described in the section entitled “Risk Factors” in this Report. 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.

Risks Related to Our Business

The report of the independent registered public accounting firm on our 2024 and 2023 financial statements contains a going concern qualification.

The report of the independent registered public accounting firm covering our consolidated financial statements for the years ended December 31, 2024 and 2023 stated that certain factors, including that we have suffered recurring losses from operations and have an accumulated deficit at December 31, 2024, 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 iSFN, CT2000 for eye pain, CT3000 for post-surgical pain 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 compounds and establish commercial supply;
- successfully complete the clinical trials necessary to obtain regulatory approval for the marketing of CC8464, CT2000 and CT3000;
- secure market exclusivity and/or adequate intellectual property rights for our compounds in each jurisdiction in which we do or plan to commercialize our compounds 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 compounds 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 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 \$21.5 million and \$13.5 million as of December 31, 2024 and December 31, 2023, respectively, which includes a net loss of approximately \$8.0 million for year ended December 31, 2024, and approximately \$7.4 million the year ended December 31, 2023, 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 consolidated 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, government grants and the IPO (from which we raised net proceeds of approximately \$5.7 million, after deducting underwriting discounts, commissions and other offering expenses). 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, CT2000, CT3000 and/or additional compounds. We expect that it will take several years, if ever, before we have a commercialized compound. The net losses we incur may fluctuate significantly from quarter to quarter.

If we are required by the FDA, the 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, CT2000, CT3000 and/or other future 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, CT2000 and CT3000;
- launch human proof of concept of CT2000 for the treatment of eye pain;
- conduct CMC and develop GMP formulations and human proof of concept of CT3000 for the treatment of post-surgical pain;
- initiate additional clinical trials and preclinical studies for any additional compounds that we may pursue in the future;
- prepare an 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 portfolio of compounds;
- establish a business development operation to in- our out-license certain assets;
- establish a sales, marketing and distribution infrastructure to commercialize any 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 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 our compounds, manufacturing, and marketing. Licensing and selling any future compounds for which we may obtain marketing approval and satisfying any post-marketing requirements. If we were required to discontinue development of CC8464, CT2000 or CT3000, if CC8464, CT2000 or CT3000 does not receive regulatory approval, if we do not obtain our targeted indication(s) for CC8464, CT2000 or CT3000, or if CC8464, CT2000 or CT3000 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.

Our business could be adversely impacted if there are deficiencies in our disclosure controls and procedures or our internal control over financial reporting.

The design and effectiveness of our disclosure controls and procedures and our internal control over financial reporting may not prevent all errors, misstatements or misrepresentations. There can be no guarantee that our disclosure controls and procedures and internal control over financial reporting will be effective in accomplishing all control objectives all of the time. Deficiencies, including any material weaknesses, in our disclosure controls and procedures or internal control over financial reporting could result in misstatements of our results of operations or our consolidated financial statements or could otherwise materially and adversely affect our business, reputation, results of operations, financial condition or liquidity.

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

Prior to our IPO, 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 consolidated financial statements for the years ended December 31, 2024 and 2023, 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 consolidated 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 consolidated 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, CT2000, CT3000 or any other future 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, CT2000 and CT3000 and to build the sales, marketing, licensing and distribution infrastructure that we believe will be necessary to commercialize CC8464, CT2000 and CT3000, if approved, we will require substantial additional funding. In addition, if we obtain marketing approval for CC8464, CT2000 and CT3000, 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 dose escalation and phase 2 clinical trial for CC8464;
- the progress, timing, results and costs of our human POC trials for CT2000;
- the progress, timing, results and costs of our GMP manufacturing and human POC for CT3000;
- 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 future compounds;
- the initiation, scope, progress, timing, costs and results of drug discovery, laboratory testing, manufacturing, preclinical studies and clinical trials for any other future 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, CT2000, CT3000 or any other future compounds we may develop;
- the extent to which the costs of future 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, CT2000, CT3000 and other future compounds if we receive marketing approval for CC8464, CT2000, CT3000 or any other future 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, CT2000, CT3000 or any of our other future 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 iSFN 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 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 compound's revenues, if any, will be derived from or based on sales of 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 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 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.

We are early in our efforts to develop CT2000 and have not moved into clinical trials. If we are unable to advance CT2000 through clinical trials, obtain regulatory approval and ultimately commercialize CT2000, or if we experience significant delays in doing so, our business will be materially harmed.

We are early in our development of CT2000. The development and commercialization of CT2000 (or any other compound that we may advance towards clinical development in the future) is subject to many uncertainties, including the following:

- successful final completion of the formula for eye drops;
- positive results from our planned future pre-clinical and 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 CT2000, if and when approved, whether alone or in collaboration with others; and
- acceptance of CT2000, 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 CT2000, which would materially harm our business. If we do not receive regulatory approvals for CT2000, our business, financial condition, results of operations and prospects could be materially and adversely affected. Advancing a different compound than CT2000 towards clinical development would take substantial time and resources and be subject to the same risks as described here for CT2000.

We are early in our efforts to develop CT3000 and have not moved into clinical trials. If we are unable to advance CT3000 through clinical trials, obtain regulatory approval and ultimately commercialize CT3000, or if we experience significant delays in doing so, our business will be materially harmed.

We are early in our development of CT3000. The development and commercialization of CT3000 (or any other compound that we may advance towards clinical development in the future) is subject to many uncertainties, including the following:

- successful final completion of the formula for the nerve block;
- positive results from our planned future pre-clinical and 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 CT3000, if and when approved, whether alone or in collaboration with others; and
- acceptance of CT3000, 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 CT3000, which would materially harm our business. If we do not receive regulatory approvals for CT3000, our business, financial condition, results of operations and prospects could be materially and adversely affected. Advancing a different compound than CT3000 towards clinical development would take substantial time and resources and be subject to the same risks as described here for CT3000.

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 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 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 pre-clinical and 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, CT2000 and CT3000 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. 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 have to make manufacturing or formulation changes to CC8464, CT2000 and CT3000, we would need to conduct additional studies to bridge our modified compound to earlier versions. Clinical trial delays could also shorten any periods during which we may have the exclusive right to commercialize CC8464, CT2000, and CT3000, 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 CC8464, CT2000 and CT3000 and 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 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, CT2000 and CT3000 and the approval may be for a narrower indication than we seek.

We cannot commercialize a compound until the appropriate regulatory authorities have reviewed and approved the compound. Even if CC8464, CT2000 and CT3000 meet their respective 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 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, CT2000 and CT3000. Any of the foregoing scenarios could materially harm the commercial prospects for CC8464, CT2000 and CT3000 and materially and adversely affect our business, financial condition, results of operations and prospects as CC8464 is our only compound in clinical development and CT2000 and CT3000 have not yet entered pre-clinical trials.

CC8464, CT2000 and CT3000 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 I clinical trials have shown that CC8464 can lead to rashes. In addition to this side effect and possibly others caused by CC8464, 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 compound may be harmed and our ability to generate revenues from this 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 compound;
- regulatory authorities may require additional warnings on the label;
- we may be required to change the way a 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, India and Japan, where we are initially targeting our products, may impose similar conditions or post-monitoring requirements as a result of such findings.

We have yet to begin evaluating CT2000 and CT3000 in humans to determine if it has any side effects, but could face similar or other issues, including but not limited to the disclosures set forth above for CC8464 with respect to FDA approval, ongoing monitoring programs and label requirements.

CC8464, CT2000 and CT3000 are based on specific modes of administration (dose escalation regime, eye drops and injection, respectively), 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, CT2000 and CT3000 or future compounds or lead to significant post-approval limitations or restrictions. As we advance CC8464, CT2000 and CT3000, 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, CT2000 and CT3000. 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, CT2000 and CT3000, our compounds will remain subject to regulatory oversight.

Even if we obtain any regulatory approval for CC8464, CT2000 and CT3000, our lead compounds, they 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, CT2000 and CT3000 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, CT2000, CT3000 or any future 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, CT2000 and CT3000 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, CT2000 and CT3000. 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 CC8464, CT2000 and CT3000 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, CT2000 and CT3000 or other future 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, CT2000 and CT3000 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, CT2000, CT3000 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 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 one of our two lead compounds, CC8464, for the treatment of EM and iSFN, we also plan to seek orphan drug designation from the FDA. As of the date of this Report, we have not submitted an application for orphan drug designation for CC8464. Under the Orphan Drug Act of 1983, the FDA may designate a 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 European Union, 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 compounds, may not lead to a faster development, regulatory review or approval process and do not increase the likelihood that any of our 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 for our compounds. 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 our 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 of our 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 our 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 compound, we may relinquish valuable rights to that 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 compound.

If we are not successful in discovering, developing and commercializing additional 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, CT2000 and CT3000 towards approval in the U.S. and other countries, an additional component of our strategy is to discover, develop and potentially commercialize a portfolio of compounds to treat orphan diseases and potentially, non-orphan diseases. Identifying new compounds requires substantial technical, financial and human resources, whether any other 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 new compounds that initially show promise, we may fail to successfully develop and commercialize such new compounds for many reasons, including the following:

- the research methodology used may not be successful in identifying potential new compounds;

- competitors may develop alternatives that render our compounds obsolete;
- new compounds we develop may nevertheless be covered by third parties' patents or other exclusive rights;
- a new 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 new compound may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- a new 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 new 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 CC8464, CT2000 and CT3000.

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, CT2000 and CT3000 uneconomical or obsolete, and we may not be successful in marketing CC8464, CT2000 and CT3000 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.

Rizatriptan 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, CT2000, CT3000 or any of our other 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, CT2000, CT3000 or any of our other 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 existing compounds is complex, novel and has not been validated for commercial use. To produce enough quantities of our existing compounds for future clinical trials and initial U.S. 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, CT2000 and CT3000 are 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, CT2000 and CT3000 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, CT2000 and CT3000 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 Compounds

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

We currently do not have a market development organization. To successfully commercialize CC8464, CT2000 and CT3000, 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 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 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 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 compounds are 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, CT2000, CT3000 or our future 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 iSFN, CT2000 for acute and chronic eye pain, CT3000 for post-surgical pain and, potentially, other fields of neuropathic pain. Our understanding of both the number of people who have EM or iSFN, as well as the subset of people with either disease who have the potential to benefit from treatment with CC8464, are based on estimates in published literature. Similarly, our understanding of the number of people who could benefit from treatment with CT2000 and CT3000, 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 European Union and elsewhere may turn out to be lower than expected or these patients may not be otherwise amenable to treatment with CC8464, CT2000 and CT3000 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, CT2000 and CT3000 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 and iSFN, the discovery of novel medications for EM and iSFN 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, CT2000 and CT3000, if approved, or any of our other future 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 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 compounds will depend substantially, both domestically and abroad, on the extent to which the costs of our 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 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 countries 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 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 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, CT2000 and CT3000, the future success of our business depends upon our ability to identify, develop and commercialize compounds based on the platform technology. CC8464, along with CT2000 and CT3000, which were derived from 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 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 our 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 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 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 European Union 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 approvals for CC8464, CT2000 and CT3000 and begin commercializing them 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 ACA 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 ACA provides that a claim for items or services resulting from an Anti-Kickback Statute violation is a false claim under the FCA. Cases against pharmaceutical manufacturers support the view that certain marketing practices, including off-label promotion, may implicate the FCA;
- 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 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 enrollment 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, as well as the recent inflation in the United States, foreign and domestic government sanctions imposed on Russia as a result of its invasion of Ukraine, war or other military conflict, terrorist activities, 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 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. For example, 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.

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 compounds, including CC8464, CT2000 and CT3000, 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, CT2000, CT3000 and any of our other current or future 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, CT2000 and CT3000, additional new 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 have pending patent applications for both of CT2000 and CT3000 and there is no guarantee that any of these applications become patents in the United States or any other jurisdiction.

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, CT2000, CT3000 and future new 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 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, CT2000, CT3000 and future new 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 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, CT2000, CT3000 and future 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, CT2000, CT3000 or any future compounds, or related technologies, including, for example, interference proceedings, post grant review challenges, and *inter partes* review before the 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, CT2000 and CT3000, 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, CT2000 and CT3000. 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 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, CT2000, CT3000 and future new 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 new 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 our Common Stock

The market price 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, 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 Report; and
- general market and economic conditions.

Our Common Stock is currently listed on The NYSE American LLC (“NYSE American”). 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.

We could issue “blank check” preferred stock without stockholder approval with the effect of diluting then current stockholder interests and impairing their voting rights; and provisions in our charter documents could discourage a takeover that stockholders may consider favorable.

Our articles of incorporation authorizes the issuance of up to 20,000,000 shares of “blank check” preferred stock with designations, rights and preferences as may be determined from time to time by our Board. Our Board is empowered, without stockholder approval, to issue a series of preferred stock with dividend, liquidation, conversion, voting or other rights which could dilute the interest of, or impair the voting power of, our common stockholders. The issuance of a series of preferred stock could be used as a method of discouraging, delaying, or preventing a change in control of the Company. For example, it would be possible for our Board to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change control of the Company.

Our Series C Convertible Redeemable Preferred Stock, par value of \$0.0001 per share (“Series C Preferred Stock”) currently ranks (i) senior to the Common Stock and any class or series of capital stock of the Company created specifically ranking by its terms junior to the Series C Preferred Stock; and (ii) junior to any class or series of capital stock of the Company created after the creation of the Series C Preferred Stock specifically ranking by its terms senior to any Series C Preferred Stock, in each case, with respect to payment of dividends and distributions of assets upon liquidation, dissolution or winding up of the Corporation, whether voluntarily or involuntarily. For further information regarding our shares of Series C Preferred Stock, please refer to the Certificate of Designations of Series C Convertible Redeemable Preferred Stock, filed with the Secretary of State of the State of Nevada on November 8, 2024 filed as an exhibit to, and the disclosure contained in, our Post-Effective Amendment No. 1 on Form S-1 filed with the SEC on November 22, 2024.

Our articles of incorporation designate the Second Judicial District Court, in and for the State of Nevada, located in Washoe County, Nevada, as the exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit stockholders’ ability to obtain a favorable judicial forum for disputes with us or our directors, officers, employees or agents.

Our articles of incorporation require that, to the fullest extent permitted by law, and unless we otherwise consent in writing to the selection of an alternative forum, the Second Judicial District Court, in and for the State of Nevada, located in Washoe County, Nevada, (or if the Second Judicial District Court does not have jurisdiction, any other state district court located in the State of Nevada, and if no state district court in the State of Nevada has jurisdiction, any federal court located in the State of Nevada), will be the exclusive forum for each of the following:

- any derivative action, suit or proceeding brought on behalf of the Company,
- any action, suit or proceeding asserting a claim of breach of a fiduciary duty owed by any director, officer, employee or stockholder of the Company to the Company or to the Company’s stockholders, or
- any action, suit or proceeding arising pursuant to any provision of the Nevada Revised Statutes (“NRS”) Chapter 78 of the State of Nevada, as amended or our bylaws or our articles of incorporation (as either may be amended and/or restated from time to time)

The exclusive forum provision provides federal courts located in the State of Nevada as the forum for suits brought to enforce any duty or liability for which Section 27 of the Exchange Act establishes exclusive jurisdiction with the federal courts, or any other claim for which the federal courts have exclusive jurisdiction. In addition, Section 22 of the Securities Act provides that federal and state courts have concurrent jurisdiction over lawsuits brought under the Securities Act or the rules and regulations thereunder. To the extent the exclusive forum provision restricts the courts in which claims arising under the Securities Act may be brought, there is uncertainty as to whether a court would enforce such a provision. We note that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. Although we believe this provision will benefit the Company by providing increased consistency in the application of Nevada law in the types of lawsuits to which it applies, the provision may have the effect of discouraging lawsuits against our directors and officers.

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.

All of the shares of Common Stock in the IPO are immediately tradable without restriction under 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 of the Company outstanding, other than the 2,969,823 shares (the “Selling Stockholder Shares”) of Common Stock that we have registered on behalf of certain selling stockholders (the “Selling Stockholders”) identified in a separate prospectus (the “Resale Prospectus”) and which may be resold by such Selling Stockholders from time to time, are 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.

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.

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 Channel Therapeutics Corporation 2023 Equity Incentive Plan, as amended (the “2023 Plan”) 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 any lock-up agreements, unless purchased by our affiliates. In addition, 1,944,444 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 (defined below), we were 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 (as defined below), received by holders of the senior secured convertible notes upon conversion of such notes. As of March 26, 2025, the Company has not filed a registration statement in connection with the Bridge Financings, and the investors that participated in the Bridge Financings have not objected to the fact that the Company has not filed such registration statement nor have they requested the payment of partial liquidated damages pursuant to the terms of the Bridge Documents.

In connection with the CEF Purchase Agreement, we filed a registration statement, providing for the resale of the shares of Common Stock issuable pursuant to the CEF Purchase Agreement. 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 the CEF Purchase Agreement, 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 has a liquidation preference over our Common Stock.

The Series C Preferred Stock has 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 relies, 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.

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 pre-clinical and clinical trials of our existing lead or new future compounds 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 compounds or clinical development programs;
- the results of our efforts to discover, develop, acquire or in-license additional new 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.

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.

We have broad discretion in the use of our cash and may not use them effectively.

Our management will have broad discretion in the application of our cash and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our Common Stock. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the price of our Common Stock to decline and delay the development of CC8464, CT2000 and any other new compounds that we may develop. Pending their use, we may invest our cash in a manner that does not produce income or that loses value.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies, CC8464, CT2000 and CT3000.

We may seek additional capital through a combination of draw-downs under the CEF Purchase Agreement, 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, CC8464, CT2000 and CT3000 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 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 Report. 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.

The requirements of being a public company may strain our resources and divert management's attention.

As a public company, we are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act and other applicable securities rules and regulations. The Exchange Act requires, among other things, that we file annual and current reports with the SEC with respect to our business and operating results. Compliance with these rules and regulations increases our legal and financial compliance costs, makes some activities more difficult, time-consuming, or costly, and increases demand on our systems and resources.

As a result of disclosure of information in this Annual Report on Form 10-K and in filings required of a public company, our business and financial condition is more visible, which we believe may result in threatened or actual litigation, including by competitors and other third parties. If such claims are successful, our business and operating results could be harmed, and even if the claims do not result in litigation or are resolved in our favor, these claims, and the time and resources necessary to resolve them, could divert resources of our management and harm our business and operating results.

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 CEF Purchase Agreement

It is not possible to predict the actual number of Purchase Shares we will sell under the CEF Purchase Agreement, or the actual gross proceeds resulting from those sales. We may not have access to the full amount available under the CEF Purchase Agreement with Tikkun.

On July 26, 2024, we entered into the CEF Purchase Agreement (the "CEF Purchase Agreement") with Tikkun Capital LLC ("Tikkun"), pursuant to which Tikkun committed to purchase up to \$30.0 million in shares of our Common Stock, subject to certain limitations and conditions set forth in the CEF Purchase Agreement.

The shares of Common Stock that may be issued under the CEF Purchase Agreement (the "Purchase Shares") may be sold by us to Tikkun at our discretion from time to time until July 26, 2026, commencing after the satisfaction of certain conditions set forth in the CEF Purchase Agreement, including a registration statement covering the resale of shares of Common Stock that may be issued under the CEF Purchase Agreement is declared effective by the SEC, a final prospectus in connection therewith is filed, and the other conditions set forth in the CEF Purchase Agreement are satisfied. We generally have the right to control the timing and amount of any sales of Purchase Shares to Tikkun under the CEF Purchase Agreement. Sales of Purchase Shares to Tikkun under the CEF Purchase Agreement will depend upon market conditions and other factors to be determined by us. We may ultimately decide to sell to Tikkun all or a portion of the Purchase Shares that may be available pursuant to the CEF Purchase Agreement.

Because the purchase price per share to be paid by Tikkun for the Purchase Shares that we may elect to sell to Tikkun under the CEF Purchase Agreement will fluctuate based on the market prices of our Common Stock during the applicable volume weighted average price purchase valuation period for each purchase, it is not possible for us to predict the total number of Purchase Shares that we will sell to Tikkun under the CEF Purchase Agreement, the purchase price per share that Tikkun will pay for shares purchased from us under the CEF Purchase Agreement, or the aggregate gross proceeds that we will receive from those purchases by Tikkun under the CEF Purchase Agreement.

Although the CEF Purchase Agreement provides that we may sell up to an aggregate of \$30.0 million of Purchase Shares to Tikkun, only 2,000,000 Purchase Shares are being registered for resale by Tikkun under the registration statement on Form S-1 filed with the SEC on July 29, 2024, which we may elect to sell to Tikkun, in our sole discretion, from time to time from and after the Commencement Date under the CEF Purchase Agreement.

If after the Commencement Date, we elect to sell to Tikkun all of the 2,000,000 Purchase Shares being registered for resale under the prospectus in the registration statement on Form S-1 filed with the SEC on July 29, 2024, that are available for sale by us to Tikkun in purchases under the CEF Purchase Agreement, depending on the market prices of our Common Stock during the applicable volume weighted average price purchase valuation period for each purchase made pursuant to the CEF Purchase Agreement, the actual gross proceeds from the sale of all such shares may be substantially less than the \$30.0 million (the “Total Commitment”) available to us under the CEF Purchase Agreement, which could materially adversely affect our liquidity.

If it becomes necessary for us to issue and sell to Tikkun under the CEF Purchase Agreement more than 2,000,000 Purchase Shares being registered for resale under the registration statement on Form S-1 filed with the SEC on July 29, 2024 in order to receive aggregate gross proceeds equal to the Total Commitment of an aggregate of \$30.0 million under the CEF Purchase Agreement, we must file with the SEC one or more additional registration statements to register under the Securities Act the resale by Tikkun of any such additional Purchase Shares we wish to sell from time to time under the CEF Purchase Agreement, which the SEC must declare effective. Tikkun will not be required to purchase any Purchase Shares if such sale would result in Tikkun and its affiliates’ beneficial ownership exceeding than 4.99% of the outstanding shares of the Common Stock (the “Beneficial Ownership Limit”).

Any issuance and sale by us under the CEF Purchase Agreement of a substantial amount of Purchase Shares could cause additional substantial dilution to our stockholders. The number of Purchase Shares ultimately offered for resale by Tikkun is dependent upon the number of Purchase Shares we ultimately sell to Tikkun under the CEF Purchase Agreement.

Our inability to access a portion or the full amount available under the CEF Purchase Agreement, in the absence of any other financing sources, could have a material adverse effect on our business.

Sales of a substantial number of our Common Stock in the public market by our existing stockholders could cause the price of our shares of our Common Stock to fall.

Tikkun may resell up to 2,000,000 Purchase Shares, from time to time during the term of the CEF Purchase Agreement. If all of the 2,000,000 Purchase Shares were issued and outstanding as of the date hereof (without taking into account the Exchange Cap limitation), such shares would represent approximately 24.7% of the total number of outstanding shares of our Common Stock and approximately 26.9% of the total number of outstanding shares of our Common Stock held by non-affiliates of our Company, in each case as of March 7, 2025.

Sales of a substantial number of our shares of our Common Stock in the public market by Tikkun and/or by our other existing stockholders, or the perception that those sales might occur, could depress the market price of shares of our Common Stock and could impair our ability to raise capital through the sale of additional equity securities.

Investors who buy shares of our Common Stock at different times will likely pay different prices.

Pursuant to the CEF Purchase Agreement, we will have discretion, subject to market demand, to vary the timing, prices, and numbers of Purchase Shares sold to Tikkun. If and when we do elect to sell Purchase Shares to Tikkun under the CEF Purchase Agreement, after Tikkun has acquired such shares, Tikkun may resell all or a portion of such shares at any time or from time to time in its discretion and at different prices. As a result, investors who purchase shares of our Common Stock from Tikkun at different times will likely pay different prices for those shares, and so may experience different levels of dilution and in some cases substantial dilution and different outcomes in their investment results. Investors may experience a decline in the value of the shares they purchase from Tikkun as a result of future sales made by us to Tikkun at prices lower than the prices such investors paid for their shares.

We may require additional financing to sustain our operations and, without it, we will not be able to continue operations.

The extent to which we rely on Tikkun 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. If obtaining sufficient funding from Tikkun were to prove unavailable or prohibitively dilutive, we may need to secure another source of funding in order to satisfy our working capital needs. Even if we were to sell to Tikkun all of the shares of our Common Stock available for sale to Tikkun under the CEF Purchase Agreement, we will still need additional capital to fully implement our business plan. Should the financing we require to sustain our working capital needs be unavailable or prohibitively expensive when we require it, the consequences would be a material adverse effect on our business, operating results, financial condition and prospects.

On July 24, 2024, we entered into a securities purchase agreement with an accredited investor (the “July Holder”), pursuant to which the Company issued to the July Holder a senior unsecured convertible note (the “July Note”) in the aggregate principal amount of \$750,000, which is convertible into shares of the Company’s common stock. If we were to default on the July Note and such default is not waived, the July Note shall bear interest at a rate of 12% per annum, and the Holder may require us to redeem all or any portion of the July Note. The July Note also imposes certain restrictions on us and our subsidiaries. These restrictions limit us and our subsidiaries’ ability, among other things, to incur or guarantee certain additional indebtedness, engage in transactions with affiliates, sell certain assets, and create liens, and they place restrictions on the ability of us to make dividends and our subsidiaries to pay dividends. If we fail to maintain compliance with the restrictions and covenants under the Securities Purchase Agreement and the July Note, we would be subject to events of default which in turn would materially and adversely affect our business, financial condition, and results of operations and our liquidity.

The terms of the CEF Purchase Agreement limit the amount of shares of Common Stock we may issue to Tikkun, which may have an adverse effect on our liquidity.

The CEF Purchase Agreement includes restrictions on our ability to sell shares of our Common Stock to Tikkun, including, subject to specified limitations, if a sale would cause Tikkun and its affiliates to beneficially own more than the Beneficial Ownership Limit. Accordingly, we cannot guarantee that we will be able to sell all \$30.0 million of shares of Common Stock under the CEF Purchase Agreement. If we cannot sell the full amount of the shares that Tikkun has committed to purchase because of these limitations, we may be required to utilize more costly and time-consuming means of accessing the capital markets, which could materially adversely affect our liquidity and cash position.

Future sales of substantial amounts of our Common Stock, or the possibility that such sales could occur, could adversely affect the market price of our Common Stock.

In order to raise additional capital, we may in the future offer additional shares of our Common Stock or other securities convertible into or exchangeable for our Common Stock. Investors purchasing shares or other securities in the future could have rights superior to existing shareholders. The price per share at which we sell additional shares of our Common Stock, or securities convertible or exchangeable into common stock, in future transactions may be higher or lower than the price per share paid by investors in previous offerings by us.

Management will have broad discretion as to the use of the proceeds from our sale of Purchase Shares to Tikkun under the CEF Purchase Agreement, and such uses may not improve our financial condition or market value.

Because we have not designated the amount of net proceeds from our sale to Tikkun of Purchase Shares to be used for any particular purpose, our management will have broad discretion as to the application of such net proceeds. Our management may use the net proceeds for corporate purposes that may not improve our financial condition or advance our business objectives.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity

Risk management and strategy

We are an R&D stage pharmaceutical company, with no commercial operations or revenue streams. Since our IPO, our sole business activity has been ongoing research into our drug therapies. Therefore, we do not consider that we face significant cybersecurity risk and have not adopted a formal cybersecurity risk management program or process for assessing cybersecurity risk currently. We assess material risks from cybersecurity threats on an ongoing basis, including any potential unauthorized occurrence on or conducted through our information systems that may result in adverse effects on the confidentiality, integrity, or availability of our information systems or any information residing therein. As our Company grows, we plan to develop a more robust and detailed strategy for cybersecurity in alignment with nationally accepted standards. We have not encountered cybersecurity challenges that have materially impaired our operations or financial standing. For additional information regarding risks from cybersecurity threats, please refer to Item 1A, "Risk Factors," in this Annual Report on Form 10-K.

Governance

Our management and board of directors recognize the critical importance of maintaining the trust and confidence of our business partners and employees, including the importance of managing cybersecurity risks as part of our larger risk management program. While all of our personnel play a part in managing cybersecurity risks, one of the key functions of our board of directors is informed oversight of our risk management process, including risks from cybersecurity threats. Our board of directors is responsible for monitoring and assessing strategic risk exposure, and our executive officers are responsible for the day-to-day management of the material risks that we face. In general, we seek to address cybersecurity risks through a cross-functional approach that is focused on preserving the confidentiality, integrity, and availability of the information that we collect and store by identifying, preventing, and mitigating cybersecurity threats and effectively responding to cybersecurity incidents when they occur.

Item 2. Properties.

Our principal executive offices are located at 4400 Route 9 South, Suite 1000, Freehold, NJ 07728. The lease for our principal executive offices is on a month-to-month basis. We believe our executive offices are adequate to meet our current needs, although we may seek to negotiate new leases or evaluate additional or alternate space to support our operations and regulatory needs. We believe appropriate alternative space will be readily available on commercially reasonable terms.

Item 3. 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 our 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.

Demand Letter from Mr. Kopfli's Attorney

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 Report. Mr. Kopfli alleged an improper termination for “cause” and claimed to seek monetary damages in the amount of \$479,169. Of the \$479,169 asserted by Mr. Kopfli, as of December 31, 2024, the Company had accrued \$363,091 in compensation expenses associated with Mr. Kopfli’s prior employment with the Company. However, the Company believed the assertions made by Mr. Kopfli were without merit and commenced the New York Action against Mr. Kopfli and Chromocell Holdings, asserting causes of action against Mr. Kopfli for breach of the Employment Agreement entered into on January 10, 2023 between the Company and Mr. Kopfli, breach of fiduciary duty by Mr. Kopfli, as well as breach of contract against Chromocell Holdings. The Company also asserted a “faithless servant” claim against Mr. Kopfli, seeking a ruling that Mr. Kopfli was not entitled to compensation from the Company. The Company sought monetary damages against Mr. Kopfli and Chromocell Holdings in the New York Action, plus disgorgement of all compensation previously paid or accrued to Mr. Kopfli by the Company.

By Order dated October 3, 2024, the court in the New York Action awarded the Company a default judgment against Mr. Kopfli and Chromocell Holdings on all claims and ordered an assessment of damages against Mr. Kopfli and Chromocell Holdings (to be held at a date to be determined). As of December 31, 2024, the Company has removed the accrual of \$363,091 in compensation expenses and recorded a gain on default judgement in the same amount.

Parexel Claim

On July 31, 2024, the Company received a demand letter from an attorney representing Parexel. The letter, which was addressed to both the Company and Chromocell Holdings, purports to be a notice of default of the Promissory Note and seeks the payment of allegedly unpaid principal in the amount of \$682,551.49 plus interest exceeding \$177,000. The Company denies that it is liable for any of the amounts sought by Parexel; the Company is not a party to the Promissory Note and does not believe it is liable for any amounts allegedly due thereunder. The Company intends to defend itself vigorously in the matter.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

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

Market Information

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

Holders of our Common Stock

As of March 7, 2025, there were approximately 16 holders of record of our Common Stock. This number does not include shares of Common Stock held by brokerage clearing houses, depositories or others in unregistered form.

Dividends

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.

Securities Authorized for Issuance under Equity Compensation Plans

Reference is made to "Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters—Securities Authorized for Issuance under Equity Compensation Plans" for the information required by this item.

Recent Sales of Unregistered Securities

On June 12, 2024, the Company agreed to issue up to an aggregate of 140,000 shares of Common Stock to a vendor in considerations for the services provided by the vendor to the Company, with 51,187 shares issued between June 1, 2024 and December 31, 2024

On August 12, 2024, the Company agreed to issue 10,000 shares of Common Stock to a vendor in exchange for outstanding invoices related to services provided by the vendor to the Company.

On October 22, 2024, the Company agreed to issue up to an aggregate of 76,667 shares of Common Stock to three vendors in considerations for the services provided by the vendor to the Company.

Also on October 22, 2024, the Company granted a different vendor options to purchase up to an aggregate of 50,000 shares of Common Stock at a grant price of \$0.73 per share.

On November 18, 2024, the Company agreed to issue up to 25,000 shares of Common Stock to a vendor in considerations for the services provided by the vendor to the Company.

Between September 1, 2024 and December 31, 2024, we issued and sold an aggregate of 155,953 shares of Common Stock to Tikkun pursuant to the CEF Purchase Agreement at an average price per share of \$0.70, resulting in aggregate gross proceeds to the Company of \$108,552.

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.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

Stock Repurchase Plan

On August 5, 2024, the board of directors authorized a stock repurchase plan (the “Repurchase Plan”) pursuant to which up to \$250,000 of the Company’s Common Stock may be repurchased prior to December 31, 2024, unless completed sooner or otherwise extended. During the year ended December 31, 2024, the Company repurchased 86,196 shares of Common Stock. Open market purchases are intended to be conducted in accordance with applicable Securities and Exchange Commission regulations, including the guidelines and conditions of Rule 10b-18 and Rule 10b5-1 of the Exchange Act. We established the Repurchase Plan on the premise that the value of the Company’s programs and prospects were not reflected in the trading price of the Company’s Common Stock on the NYSE American and in an effort to maintain a minimum price relative to NYSE American’s listing standards. Further, the Company endeavored to balance the repurchase of what the Company felt was undervalued stock and the Company’s available cash, as a result of which, the timing and actual number of shares repurchased have depended and will continue to depend on a variety of factors including trading price of the Company’s Common Stock on the NYSE American, the Company’s financial performance, corporate and regulatory requirements and other market conditions.

Repurchase Plan Amendment

On October 22, 2024, the board of directors authorized an amendment (the “Plan Amendment”) to the Repurchase Plan to increase the total value of shares of Common Stock available for repurchase by the Company under the Repurchase Plan by an additional \$500,000, to \$750,000. In addition, the Plan Amendment extended the termination date of the Repurchase Plan from December 31, 2024 to June 30, 2025, prior to which Common Stock may be repurchased, unless completed sooner or otherwise extended.

We did not repurchase any shares during the fourth quarter of the fiscal year covered by this Annual Report on Form 10-K.

Item 6. Reserved

Item 7. 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 our consolidated financial statements and related notes appearing in this Report. Some of the information contained in this discussion and analysis or set forth elsewhere in this Report, 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 Report, 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”, which has been genetically validated as a pain receptor in human physiology. 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.

We have formally launched three programs developing pain treatment therapeutics, all of which are based on the same proprietary molecule, as follows:

Eye Pain: Based on a novel formulation of CC8464, our Eye Pain program, titled CT2000, is for the potential treatment of both acute and chronic eye pain. NaV1.7 channels are present on the cornea, making it 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 CT2000 as a topical agent for the relief of eye pain. A potential advantage of this approach is that topical administration of CT2000 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 developed topical ophthalmic formulations and are pursuing trial plans as set forth below.

Current options for the treatment of ocular pain center on the use of corticosteroids and non-steroidal anti-inflammatory drug (“NSAID”) based therapeutics. These options suffer from sight-threatening complications such as Glaucoma and corneal melting, thus there is a large unmet need for other approaches. As an example of the potential patient population, we estimate that there are approximately 5 million cases of corneal abrasions per year in the United States. In addition, other potential indications associated with eye pain include:

- severe dry eye,
- side effects from photorefractive keratectomy (PRK) and pterygium surgery,
- second eye cataract surgery,
- neuropathic corneal pain, and
- severe uveitis and severe iritis/scleritis.

As NaV1.7 channels are present on the cornea and is a viable biological target for treating eye pain, we believe that we have a sound scientific basis for our ability to treat a multitude of eye pain indications. We have successfully developed an eye drop formulation and have determined that the eye drops are well tolerated by animals. We have completed animal efficacy studies and are in the process of running toxicology studies on animals. We expect to announce the efficacy and toxicology results by April 2025.

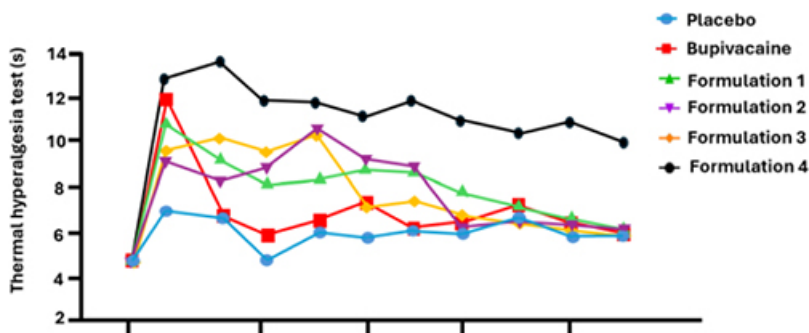
Following the animal studies, if successful, we intend to move into POC studies in humans. We plan to conduct the POC study in Australia to avail ourselves of a 43.5% tax credit for clinical expenses incurred in Australia and, on January 9, 2023, established an Australian subsidiary through which the work will be conducted. We are planning to conduct the POC in a clinic in Brisbane, Australia and are in the process of contracting the services to perform such trial.

Depot Program: Based on several novel formulations of CC8464, the Company’s most recently launched program, titled CT3000, is for the potential treatment of post operative pain with the use of nerve blocks. Examples would include knee surgery or shoulder surgery. Existing therapies for nerve blocks lead to neuromuscular blockade which prevents movement following surgery. Doctors often want patients to move soon after surgery to avoid complications such as blood clots. A NaV1.7 inhibitor used for nerve blocks may provide good analgesia but will not lead to neuromuscular blockade that prevents movement like other local anesthetics.

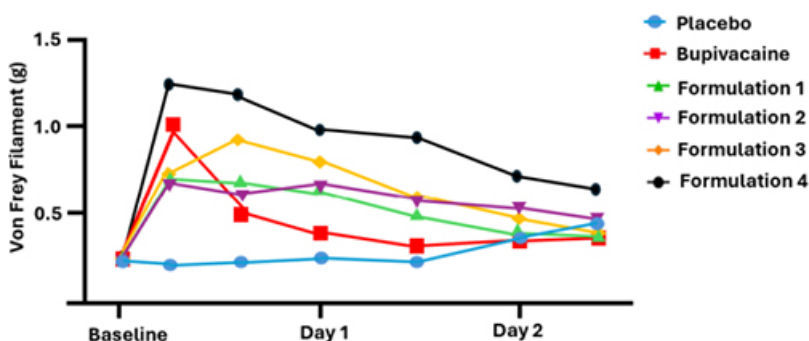
The Company has successfully developed a number of formulations and in December 2024, announced that it achieved its endpoints in two pre-clinical in vivo models of the Company’s nerve block formulations for acute pain, showing material improvement over the existing standard of care, bupivacaine, in both efficacy and duration.

The Company performed a thermal hyperalgesia test in rodents with a placebo arm, bupivacaine arm and four arms of the main formulations of the Company’s molecule. The Company also performed a mechanical allodynia test in rodents with the same arms as above. For both models, the drugs were administered as a sciatic nerve block. All four Company formulations showed a depot effect in excess of four days, an improvement over bupivacaine, the current standard of care.

The results of the thermal hyperalgesia results are shown in the chart below. After thirty minutes, three of the four formulations showed materially better efficacy than bupivacaine, with each of the three being statistically superior to placebo for more than two days longer than bupivacaine. One of the formulations remained statistically superior to placebo for more than four days. Further, as NaV1.7 does not have an impact on mobility, this approach may offer a better option for post-surgical physical therapy as current nerve block therapies cause temporary paralysis in the affected area.



Similarly for the mechanical allodynia test results, three of the four formulations showed statistically better efficacy for a longer duration of time than bupivacaine. The mechanical allodynia test is shorter in duration, reflecting the subject's innate swift recovery rate to surgical incisions. Nonetheless, the results mirrored the successful results set forth with the thermal hyperalgesia test.



The Company will commence toxicology and CMC work in 2025 and expects to commence human POC trial in early 2026.

Neuropathic Pain: CC8464 is being developed to address certain types of neuropathic pain. The chemical characteristics of CC8464 restrict its entry into the CNS and limit its effect to the NaV1.7 channels in the peripheral nervous system, which consists of the nerves outside the brain and spinal cord. Activation of other channels in the CNS can result in side effects, including addiction and other centrally mediated adverse effects. Since CC8464 is designed to not penetrate the CNS it is highly unlikely to produce CNS mediated side effects including euphoria or addiction. Based on its characteristics, preclinical studies (described below) and the Phase 1 studies we have completed to date, we believe that CC8464, if approved, could become an attractive option for both patients and physicians as a treatment for moderate-to-severe pain in Erythromelalgia (“EM”) and idiopathic small fiber neuropathy (“iSFN”).

We conducted four Phase 1 trials with 207 patients. The results showed that CC8464 has a good overall tolerability and demonstrated no liver or renal toxicity, no central nervous system changes and no cardiovascular findings but may cause skin rashes in certain patients. The occurrence of skin rashes is not uncommon with the class of molecules to which CC8464 belongs and the rashes were successfully treated in all cases with topical steroids and/or topical antihistamines (with the exception of one patient requiring systemic steroids).

As a result of the potential for skin rashes, following discussions with the FDA, we will conduct a slow dose escalation study to further evaluate the incidence of rashes. By titrating the dose over several weeks, we anticipate that we will reduce or eliminate this side effect. We expect that the slow dose escalation study will also help determine the need for dose escalation in the final treatment regime. 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).

When the dose escalation trial is funded, we will enroll approximately 20 healthy volunteers who will receive CC8464 over a period of several weeks, with the dose escalation study expected to take approximately 9-12 months in total. We anticipate that the slower dose escalation will decrease the likelihood of drug-related skin reactions. The primary endpoint of the dose escalation trial 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. Even if it is ultimately determined that we will need an escalation period for chronic pain treatment therapy, which patients could well take for the remainder of their lives, we do not believe the dose escalation approach will be consequential.

We plan to conduct the dose escalation trial in Australia to avail ourselves of the tax credit set forth above, utilizing our Australian subsidiary through which the work will be conducted. The location of the POC has not been determined at this time, with availability of facilities and patient population, costs, tax credits, centers of excellence in the respective fields (EM or iSFN) are all factors in the ultimate determination of the location.

In parallel with the dose escalation study, we expect to run a pilot efficacy study on approximately ten EM patients. In this study, we will induce EM flares, determine baseline pain, and then dose escalate CC8464, after which, we will attempt to induce flares. The primary endpoint will be the amount of pain experienced, and the secondary endpoint is a determination if CC8464 reduces the frequency of EM flares.

We are currently working on the development of the Phase 2a POC plan and expect to launch the Phase 2a POC study following the dose escalation study and EM pilot study, to assess the potential efficacy of CC8464 in iSFN patients. Both of iSFN and EM are orphan indications for which we plan to apply for orphan drug designations. The orphan indication may decrease the scope of the ultimate development program that is necessary for approval and is associated with a marketing exclusivity period from the FDA along with some tax advantages.

Though the Phase 2a POC study design has not yet been completed, the study will take approximately twelve months after it is initiated. The primary endpoint will be the amount of pain experienced from iSFN with secondary endpoints including other measurements like pain relief and neuropathy scores. The final design may change based on feedback from regulatory authorities or information learned during the dose escalation trial.

The potential population for EM in the United States is estimated to be between 5,000 and 50,000 patients and the potential population for iSFN in the United States is estimated to be between 20,000 and 80,000 patients. In both instances, we expect patients would potentially take our drug for the remainder of their lives, and given the lack of good therapeutic alternatives, we expect to have a robust, ongoing, and durable market.

The Phase 2a results will have significance beyond EM and iSFN 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. We believe that positive results from the Phase 2a study could not only act as support for CC8464's potential in EM and iSFN but may also provide guidance of its potential for other indications of peripheral neuropathic pain.

We may further expand our pipeline with other internal or external compounds in the future, but all other internally discovered compounds are pre-clinical.

Benuvia Spray Formulations: In addition to our NaV1.7 programs set forth above, on December 23, 2023, we entered into an exclusive licensing agreement (the “Benuvia License Agreement”) with Benuvia for a sublingual formulation of a Diclofenac spray for the treatment of acute pain, a Rizatriptan intranasal spray formulation and an Ondansetron sublingual spray formulation (collectively, the “Spray Formulations”). The Spray Formulations diversify our pipeline of non-opioid pain treatment therapies, while adding therapeutic options for related conditions. The sublingual formulation of a Diclofenac spray for the treatment of acute pain (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 Diclofenac Spray Formulation. 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 Diclofenac Spray Formulation 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-HT_{1A}-receptor) agonists and are indicated for the treatment of migraine. An intranasal spray formulation of Rizatriptan (the “Rizatriptan 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 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. 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 (the “Ondansetron 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.

We currently do not have strategy and development plans for the Spray Formulations licensed from Benuvia.

Background

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 1,111,112 shares of our common stock, par value \$0.0001 per share (“Common Stock”) and (ii) 600,000 shares of Series A Convertible Preferred Stock (“Series A Preferred Stock”).

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 our initial public offering (“IPO”): (a) Chromocell Holdings re-assumed all \$1.6 million in direct liabilities previously assumed by the Company in accordance with the Contribution Agreement, (b) Chromocell Holdings waived 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 issued to Chromocell Holdings 2,600 shares of Series C Preferred Stock.

On February 21, 2024, we completed the IPO and issued and sold 1,100,000 shares of Common Stock at a price to the public of \$6.00 per share. The aggregate net proceeds from the IPO were approximately \$5.7 million after deducting underwriting discounts and commissions of approximately \$0.5 million and offering expenses of approximately \$0.4 million.

In connection with the completion of the IPO: (A) we effected the 9-for-1 reverse stock split effective February 15, 2024 (the “Reverse Stock Split”) of our shares of Common Stock, (B) all 600,000 issued and outstanding shares of our Series A Preferred Stock automatically converted 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 a bridge financing in April 2023 for an aggregate principal amount of \$393,808 (the “April Bridge Financing”) after giving effect to the Representative Affiliate Transactions (as defined below), automatically converted 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 a bridge financing in September 2023 for an aggregate principal amount of \$198,128 (the “September Bridge Financing” and together with the April Bridge Financing, the “Bridge Financings”) after giving effect to the Representative Affiliate Transactions, automatically converted 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 issued 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 effected the Representative Affiliate Transactions, (G) we effected the transactions contemplated by the Holdings Side Letter, and issued an aggregate of 2,600 shares of Series C Preferred Stock to Chromocell Holdings pursuant thereto, and (H) we issued (i) 93,823 shares to a lender holding a note payable for \$450,000 (the “Investor Note”) and (ii) 29,167 shares to one of our directors holding the 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 IPO price of \$6.00 per share of Common Stock). We refer to these actions as the “IPO Transactions.”

In addition, certain stockholders of the Company (“Selling Stockholders”), as identified in the Registration Statement, have agreed to offer for resale of up to an aggregate of 2,969,823 shares of Common Stock (the “Selling Stockholder Shares”) to the public. After conversion of the convertible notes or shares of preferred stock, as applicable, the Selling Stockholders, or their respective transferees, pledgees, donees or other successors-in-interest, may sell the Selling Stockholders Shares through public or private transactions at prevailing market prices, at prices related to prevailing market prices or at privately negotiated prices. We will not receive any proceeds from the sale of the Selling Stockholder Shares by the Selling Stockholders.

The affirmative vote of a majority of the outstanding shares of Common Stock present in person, by remote communication, if applicable, or represented by proxy at the annual meeting of stockholders held on October 22, 2024 approved a reincorporation merger of the Company in the State of Nevada with and into Channel Therapeutics Corporation, a wholly-owned subsidiary of the Company, with Channel Therapeutics Corporation remaining as the surviving corporation immediately following the reincorporation merger (the “Reincorporation Merger”). The Reincorporation Merger occurred on November 18, 2024.

On December 18, 2024, 747,187 shares of Common Stock and 2,600 shares of Series C Preferred Stock held by Chromocell Holdings were transferred by the Company to Alexandra Wood (Canada) Inc. (“AWI”) in satisfaction of a default judgement against Chromocell Holdings regarding the default by Chromocell Holdings of a secured promissory note by order of the Supreme Court of the State of New York, County of New York on November 25, 2024 in the matter *Alexandra Wood (Canada) Inc v. Chromocell Corp.*, Index No. 651735/2024. AWI subsequently transferred 173,000 shares of Chromocell Holding’s shares of Common Stock that it received such that AWI now owns 574,187 shares of the Common Stock originally issued to Chromocell Holdings in connection with the Contribution Agreement.

Trends and Other Factors Affecting Our Business

On December 23, 2023, we entered into an exclusive licensing agreement (the “Benuvia License Agreement”) with Benuvia Operations LLC (“Benuvia”) for the Diclofenac Spray Formulation (as defined below), an intranasal spray formulation of Rizatriptan and an Ondansetron sublingual spray formulation (collectively, the “Spray Formulations”), diversifying our pipeline of non-opioid pain treatment therapies, while adding therapeutic options for related conditions. The sublingual formulation of a Diclofenac spray for the treatment of acute pain (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 a stock issuance agreement with Benuvia pursuant to which we issued to Benuvia 384,226 shares of our Common Stock, which may be offered and sold pursuant to the resale prospectus which forms a part of the Registration Statement.

While we currently do not have strategy and development plans for the Spray Formulations licensed from Benuvia, beginning in the first quarter of 2025, 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.

Going Concern

For the years ended December 31, 2024 and 2023, we had a net loss of approximately \$8.0 million and approximately \$7.4 million, respectively, and will require additional capital in order to operate in the normal course of business and fund clinical studies. The IPO closed on February 21, 2024, from which, the Company received net proceeds from the IPO of approximately \$5.7 million after deducting the underwriting discounts and commissions and offering expenses payable by the Company (excluding any exercise of the warrants issued to A.G.P./Alliance Global Partners (the "Representative") or its designees, in connection with the IPO).

Based on the Company's current projections, management believes 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 consolidated financial statements. While the Company will continue to invest in its business and the development of CC8464, CT2000 and CT 3000, and potentially other molecules, it is unlikely that the Company will generate product or licensing revenue during the next twelve months. During the period, the Company completed its initial public offering, raising \$5.7 million, after deducting the underwriting discounts and commissions and offering expenses, and the Company may need to raise additional funds through either strategic partnerships or the capital markets. 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.

Results of Operations

Comparison of the Years Ended December 31, 2024 and 2023

The following table summarizes our results of operations for the years ended December 31, 2024 and 2023:

	Years Ended December 31, 2024 and 2023			
	2024	2023	\$ Change	% Change
OPERATING EXPENSES				
General and administrative expenses	\$ 4,110,045	\$ 2,738,948	\$ 1,371,097	50%
Research and development	1,179,436	2,579,418	(1,399,982)	(54)%
Professional fees	2,281,968	1,543,918	738,050	48%
Total operating expenses	7,571,449	6,862,284	709,165	10%
Loss from operations	(7,571,449)	(6,862,284)	(709,165)	10%
Other expense	(383,889)	(518,509)	134,620	(26)%
Net loss before provision for income taxes	(7,955,338)	(7,380,793)	(574,545)	8%
Provision for income taxes	—	—	—	NA
Net loss	\$ (7,955,338)	(7,380,793)	(574,545)	8%

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 years ended December 31, 2024 and 2023 of \$4,110,045 and \$2,738,948, respectively. For the year ended December 31, 2024, compared to the same period in 2023, this represented an increase of \$1,371,097, or 50%, primarily as a result of increases of \$495,688 in compensation expenses, an increase of \$212,956 marketing expenses, an increase of \$367,723 in D&O insurance, an increase of \$259,535 in IPO fees, and an increase of \$137,582 in board expenses.

Research and Development Expenses

We incurred research and development expenses for the years ended December 31, 2024 and 2023 of \$1,179,436, and \$2,579,418, respectively. For the year ended December 31, 2024, compared to the same period in 2023, this represented a decrease of \$1,399,982, or 54%, with the details set forth in the table below:

	Years Ended December 31, 2024 and 2023			
	2024	2023	\$ Change	% Change
Consultant	\$ 286,680	\$ 68,900	\$ 217,780	316%
Lab Gas	1,818	—	1,818	NA
Lab Cell Storage	88,662	48,572	40,090	83%
Chemistry Manufacturing and Controls (“CMC”)	642,304	—	642,304	NA
IP Services	159,972	2,461,946	(2,301,974)	(94)%
Total	\$ 1,179,436	\$ 2,579,418	\$ (1,399,982)	(54)%

The Company incurred less research and development expenses for the year ended December 31, 2024, as compared to the corresponding period in 2023 primarily as a result of a decrease in IP services of \$2,301,974.

Professional Fees

We incurred professional expenses for the years ended December 31, 2024 and 2023 of \$2,281,968 and \$1,543,918, respectively. For the year ended December 31, 2024, compared to the same period in 2023, this represented an increase of \$738,050, or 48%, as a result of higher auditing and legal expenses associated with the Company operating as a public company since February 2024.

Other (Expense) Income

We incurred other expense for the year ended December 31, 2024 of \$383,889 as compared to other expense for the year ended December 31, 2023 of \$518,509. For the year ended December 31, 2024, compared to the same period in 2023, this represented a decrease of \$134,620 or 26%. The other expense for the years ended December 31, 2024 and 2023 was primarily the result of increased interest expense, net of a gain on default judgement of \$363,091. The increase in the interest expense was due to the remaining amortization of the debt discount on the Company’s notes being accelerated upon the conversion of the notes to equity upon consummation of the IPO.

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 product sales of any of our compounds for several years.

Cash totaled \$0.5 million and \$0.1 million as of December 31, 2024 and December 31, 2023, respectively. As of December 31, 2024 and December 31, 2023, we had an accumulated deficit of approximately \$21.5 million and \$13.5 million, respectively, and had a working capital deficit of approximately \$2.7 million and \$6.4 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.

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 had a maturity date of March 1, 2024, and the full principal amount of both notes and any accrued interest thereon was payable solely in cash upon the consummation of the IPO. Both notes had an annual interest rate of eight percent (8%), which accrued daily, and was 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 held by such affiliates of the Representative and agreed to refund an aggregate of \$91,513 paid by such affiliates of the Representative in consideration therefor within 30 days of the effective date of the Stock Rescission Agreement. At September 30, 2024, all such amounts have been paid pursuant to the Representative Affiliate Transactions and there are no remaining obligations thereto.

On February 21, 2024, we completed the IPO and issued 1,100,000 shares of Common Stock at a price of \$6.00 per share. The aggregate net proceeds from the IPO were approximately \$5.7 million after deducting approximately \$0.9 million in underwriting discounts and commissions and offering expenses.

In connection with the completion of the IPO: (A) we effected the Reverse Stock Split, effective as of February 15, 2024 (B) all 600,000 issued and outstanding shares of our Series A Preferred Stock automatically converted into 499,429 shares of Common Stock, (C) principal in the amount of \$389,757, along with accrued interest of approximately \$28,336 as of February 21, 2024, outstanding under our senior secured convertible notes issued in the April Bridge Financing (after giving effect to the Representative Affiliate Transactions), automatically converted into approximately 87,109 shares of Common Stock, (D) principal in the amount of \$197,421, along with accrued interest of \$8,169 as of February 21, 2024, outstanding under our senior secured convertible notes issued in the September Bridge Financing (after giving effect to the Representative Affiliate Transactions), automatically converted into approximately 43,385 shares of Common Stock, which includes an additional 549 Bonus Shares issuable as consideration for the September Bridge Financing, (E) we issued 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 effected the Representative Affiliate Transactions, (G) we effected the transactions contemplated by the Holdings Side Letter, and issued an aggregate of 2,600 shares of Series C Preferred Stock to Chromocell Holdings pursuant thereto, and (H) we issued (i) 93,823 shares to a lender holding the Investor Note and (ii) 29,167 shares to one of our directors holding the Director Note in full satisfaction of our obligations thereunder (in the case of (A) through (D) and (H) above, based on the IPO price of \$6.00 per IPO Share).

In addition, certain Selling Stockholders, as identified in the Registration Statement, have agreed to offer for resale of up to an aggregate of 2,969,823 Selling Stockholder Shares to the public. After conversion of the convertible notes or shares of preferred stock, as applicable, the Selling Stockholders, or their respective transferees, pledgees, donees or other successors-in-interest, may sell the Selling Stockholders Shares through public or private transactions at prevailing market prices, at prices related to prevailing market prices or at privately negotiated prices. We will not receive any proceeds from the sale of the Stockholder Shares by the Selling Stockholders.

On July 26, 2024, the Company entered into a Common Stock Purchase Agreement, dated as of July 26, 2024 (the “CEF Purchase Agreement”), with Tikkun Capital LLC (“Tikkun”), providing for a committed equity financing facility, pursuant to which, upon the terms and subject to the satisfaction of the conditions contained in the CEF Purchase Agreement, Tikkun has committed to purchase, at the Company’s direction in its sole discretion, up to an aggregate of \$30,000,000 (the “Total Commitment”) of the shares of Common Stock (the “Purchase Shares”), subject to certain limitations set forth in the CEF Purchase Agreement, from time to time during the term of the CEF Purchase Agreement. Concurrently with the execution of the CEF Purchase Agreement, the Company and Tikkun also entered into a Registration Rights Agreement, dated as of July 26, 2024, pursuant to which the Company agreed to file with the SEC one or more registration statements, to register under the Securities Act, the offer and resale by Tikkun of all of the Purchase Shares that may be issued and sold by the Company to Tikkun from time to time under the CEF Purchase Agreement.

On August 5, 2024, our board of directors authorized the Repurchase Plan, pursuant to which up to \$250,000 of our Common Stock may be repurchased prior to December 31, 2024, unless completed sooner or otherwise extended. Open market purchases are intended to be conducted in accordance with applicable Securities and Exchange Commission regulations, including the guidelines and conditions of Rule 10b-18 and Rule 10b5-1 of the Securities Exchange Act of 1934, as amended. The timing and actual number of shares repurchased will depend on a variety of factors including trading price, the Company's financial performance, corporate and regulatory requirements and other market conditions. On October 22, 2024, the board of directors authorized an amendment (the "Amendment") to the Repurchase Plan to increase the total value of shares of Common Stock available for repurchase by the Company under the Repurchase Plan by an additional \$500,000, to \$750,000.

Future Funding Requirements

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

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, research and development is a significant expense which has been utilized for the furtherance of the Company's CC8464, CT2000 and CT3000 programs. We have based the research and development costs on current clinical and pre-clinical trial parameters and expectations on certain existing tax credits, and there is no certainty that the clinical and pre-clinical 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. As a result, we expect to continue to incur operating losses and negative operating cash flows for the foreseeable future.

As a result, we will need to raise additional funding through strategic relationships, public or private equity or debt financings, credit facilities, grants or other arrangements or some combination thereof. 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 years ended December 31, 2024 and 2023:

	Years Ended December 31, 2024 and 2023			
	2024	2023	\$ Change	% Change
Net cash used in operating activities	\$ (5,792,483)	\$ (981,031)	\$ (4,811,452)	490%
Net cash provided by financing activities	6,209,535	1,022,348	5,187,187	507%
Net increase in cash	\$ 417,052	\$ 41,317	\$ 375,735	909%

Net Cash Used in Operating Activities

For the year ended December 31, 2024, we incurred a net loss of \$7,955,338, and net cash flows used in operating activities was \$5,792,483. The cash flow used in operating activities was primarily due to a net loss of \$7,955,338, offset by stock-based compensation expense of \$1,799,295, amortization of debt discount of \$692,020, a change in account payable and accrued expense of \$1,178,573, offset by a change in prepaid expenses of \$65,300, a change of \$45,786 in due from Chromocell Corporation, and a change in accrued compensation in the amount of \$282,856, and deferred offering costs of \$750,000.

For the year ended December 31, 2023, we incurred a net loss of \$7,380,793, and net cash flows used in operating activities was \$981,031. The cash flow used in operating activities was primarily due to a net loss of \$7,380,793, offset by stock-based compensation expense of \$1,733,233, shares issued for license of \$2,225,733, amortization of debt discount of \$188,119, a change in account payable and accrued expense of \$1,627,005, 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 \$424,072.

Net Cash (Used in) Provided by Investing Activities

The Company neither received nor used cash in investing activities during the years ended December 31, 2024 and 2023.

Net Cash Provided by Financing Activities

For the year ended December 31, 2024, net cash flows provided by financing activities were \$6,209,535 resulting from net proceeds from common stock issued for cash of \$5,972,000, net proceeds from common stock issued for cash under the equity line of credit of \$82,620, proceeds from loans of \$536,184, partially offset by payment of recession on stock of \$91,512, payment of repurchase of common stock under Stock Repurchase Plan of \$75,000 and payments on loans of \$214,757.

For the year ended December 31, 2023, net cash flows provided by financing activities were \$1,022,348 resulting from proceeds from loans of \$766,936, with \$565,928 of that amount derived from related parties and \$255,412 from common stock issued for cash.

Off-Balance Sheet Arrangements

During the year ended December 31, 2024 and 2023, 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 consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States.

The preparation of these consolidated 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 consolidated 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 consolidated 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.

Recently Issued and Adopted Accounting Pronouncements

The FASB issues ASUs to amend the authoritative literature in the Accounting Standards Codification (“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 consolidated 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. Other than below, 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 consolidated financial statements.

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures, which requires disaggregated information about a reporting entity’s effective tax rate reconciliation, as well as information related to income taxes paid to enhance the transparency and decision usefulness of income tax disclosures. This ASU will be effective for the annual periods beginning after December 15, 2024. The Company is currently evaluating the timing and impacts of adoption of this ASU.

Segment Reporting

The clinical-stage biotech segment 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”, which has been genetically validated as a pain receptor in human physiology. 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. This segment is currently pre-revenue.

The accounting policies of the clinical-stage biotech segment are the same as those described in the summary of significant accounting policies.

The chief operating decision maker assesses performance for the clinical-stage biotech segment and decides how to allocate resources based on net loss that also is reported on the statement of operations as consolidated net loss.

The measure of segment assets is reported on the balance sheet as total assets.

The chief operating decision maker uses net loss to evaluate spending in deciding how funds should be allocated in performing the Company’s research and development. Net loss is used to monitor budget versus actual results.

The Company has one reportable segment: clinical-stage biotech. This segment performs research and development for biotech products. Since the Company only has one segment, the segment information is the same as the consolidated financials.

The Company’s chief operating decision maker includes the chief executive officer, with such individual also holding the position of chief financial officer.

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

As a smaller reporting company, as defined in Rule 12b-2 of the Exchange Act, we are not required to provide the information required by this Item.

Item 8. Financial Statements and Supplementary Data.

The Company's consolidated financial statements, notes to the consolidated financial statements, and the reports of the Company's independent registered accountants required to be filed in response to this Item 8 begin on page F-1 of this Report.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.**Evaluation of Disclosure Controls and Procedures**

As required by Rule 13a-15 under the Exchange Act, we have carried out an evaluation of the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Report. This evaluation was carried out under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer.

Disclosure controls and procedures are controls and other procedures that are designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include controls and procedures designed to ensure that information required to be disclosed in our company's reports filed under the Exchange Act is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the controls system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected. Based on the evaluation of our disclosure controls and procedures as of December 31, 2024, our Chief Executive Officer and our Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were not effective.

Management identified the following material weaknesses:

1. We lack the necessary corporate accounting resources to maintain adequate segregation of duties. Such a lack of segregation of duties is typical in a company with limited resources.
2. We lack the ability to provide multiple levels of review in connection with the financial reporting process, which means that we cannot ensure that we are meeting certain financial reporting and transaction processing controls standards.
3. We lack the necessary internal IT infrastructure to ensure proper IT general controls. Additionally, we are reliant on third-party software for our financial systems and cannot ensure there are no vulnerabilities in these systems.

Management's Report on Internal Control over Financial Reporting

This Report does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of the Company's registered public accounting firm due to a transition period established by rules of the SEC for newly public companies. Additionally, our auditors will not be required to formally opine on the effectiveness of our internal control over financial reporting pursuant to Section 404 until we are no longer an "emerging growth company" as defined in the JOBS Act.

Changes in Internal Control over Financial Reporting

There were no changes in the Company's internal control over financial reporting during the year ended December 31, 2024, that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

Item 9B. Other Information

During the three months ended December 31, 2024, none of our directors and officers adopted or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement", as each term is defined in Item 408(a) of Regulation S-K.

Item 9C. Disclosure Regarding Foreign Jurisdictions That Prevent Inspections

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

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

Name	Age	Position
Executive Officers		
Francis Knuettel II	58	Chief Executive Officer and President, Chief Financial Officer, Treasurer and Secretary
Eric Lang	63	Chief Medical Officer
Directors		
Todd Davis	64	Director (Chairman of the Board)
Ezra Friedberg	55	Director
Richard Malamut	65	Director
Chia-Lin Simmons	51	Director
Francis Knuettel II	58	Director

Biographic Information

Francis Knuettel II has served as our Chief Executive Officer since July 2023, as our Chief Financial Officer, Treasurer and Secretary since June 2022, as our Chief Executive Officer since March 2024, and has served as a member of our board of directors since August 2024. 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 is also a board member at Ethers Pharmaceuticals Corp. 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 May 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. In addition, Dr. Lang serves on several boards including with Cytogel Pharmaceuticals and the NIH/NINDS EPPIC initiative. 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.

Todd Davis has served as a member of our board of directors since January 2023. He is the Chief Executive Officer of Ligand Pharmaceuticals Incorporated since December 2022 and is a member of the board of directors since 2007. 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 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., Virocell Biologics and Ligand Pharmaceuticals Incorporated. He is also a former 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 on our board of directors since May 2021, bringing over 30 years of investment experience across public and private markets. Since co-founding Multiplier Capital in 2011, a private credit fund specializing in sponsor-backed growth companies, he has acted as General Partner and a member of the fund's investment committee. A seasoned investor, Mr. Friedberg has a strong focus on the biotechnology sector, including his tenure on the board of Humanigen (Nasdaq: HGEN), a clinical-stage biopharmaceutical company developing monoclonal antibodies. His broader portfolio spans private equity, venture capital, and real estate investments. In addition to his work with Multiplier Capital, Mr. Friedberg manages diverse investments and businesses through Liberty Peak Capital, Key Recovery Group, and related entities. A graduate of Johns Hopkins University, he is also deeply committed to civic engagement, having founded and actively served on the boards of several community organizations, including a nonprofit mentoring agency. His extensive investment expertise and understanding of our industry were key factors in his selection to our board of directors.

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 served as a member of the governing 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 currently serves on its Investment Board. Ms. Simmons serves on the board of 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.

Family Relationships

There are no family relationships among any of our directors or executive officers.

Involvement in Certain Legal Proceedings

None.

Code of Ethics

We have a written code of conduct and ethics that applies to our directors, officers, employees and contractors, including our principal executive officer, principal financial officer, principal accounting officer or controller, and persons performing similar functions. The code of conduct and ethics is available on our website at www.channeltherapeutics.com. We intend to disclose future amendments to such code, or any waivers of its requirements, applicable to any principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions or our directors on our website identified above or in a Current Report on Form 8-K that we would file with the SEC.

Delinquent Section 16(a) Reports

Under the securities laws of the United States, our directors, executive (and certain other) officers, and any persons holding ten percent or more of our Common Stock must report on their ownership of the Common Stock and any changes in that ownership to the SEC. Specific due dates for these reports have been established. During the fiscal year ended December 31, 2024, all reports required to be filed by such persons pursuant to Section 16(a) were filed on a timely basis.

Corporate Governance

Board of Directors

Our board of directors consists 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.

Board Meetings and Attendance

During the 2024 fiscal year, the board of directors held five (5) board meetings, with all board members in attendance for each, and also conducted other matters by unanimous written consent.

Annual Meeting Attendance

On October 22, 2024, the Company held its 2024 Annual Meeting of Stockholders (the "Annual Meeting"). Set forth below are the five proposals that were voted on at the Annual Meeting and the stockholder votes on each such proposal, as certified by the inspector of elections for the Annual Meeting. These proposals are described in further detail in the Definitive Proxy Statement on Schedule 14A filed by the Company with the SEC on September 26, 2024 (the "Proxy Statement").

As of the close of business on September 20, 2024, the record date for the Annual Meeting, 5,766,704 shares of the Company's common stock, par value \$0.0001 per share ("Common Stock"), were issued, outstanding and entitled to vote. Holders of shares of Common Stock were entitled to one vote per share for each share of Common Stock. Stockholders holding an aggregate of 3,950,312 votes were present at the Annual Meeting, in person or represented by proxy, which number constituted a quorum.

Proposal 1 – The five (5) nominees named in the Proxy Statement were elected at the Annual Meeting to serve as the Company’s directors until the Company’s 2025 Annual Meeting of Stockholders and until each of their respective successors are elected and qualified or until each of their earlier resignation or removal. The final voting results with respect to the election of each such nominee were as follows:

Nominee	For	Withheld
Todd Davis	3,534,258	815
Ezra Friedberg	3,534,258	815
Francis Knuettel II	3,534,258	815
Dr. Richard Malamut	3,534,254	819
Chia-Lin Simmons	3,532,834	2,239

There were 415,239 broker non-votes with respect to each such nominee for the first proposal.

Proposal 2 – The amendment to the Company’s 2023 Equity Incentive Plan to increase the number of shares authorized for issuance thereunder was approved by the Company’s stockholders. The final voting results were as follows:

For	Against	Abstain
3,527,889	4,985	2,199

There were 415,239 broker non-votes with respect to the second proposal.

Proposal 3 – The proposal to waive the limit on the number of shares of Common Stock that may be issued to certain shareholders pursuant to that certain Securities Purchase Agreement, dated July 24, 2024, and that certain Common Stock Purchase Agreement, dated July 26, 2024, as required by NYSE American, was approved by the Company’s stockholders. The final voting results were as follows:

For	Against	Abstain
3,126,104	406,770	2,199

There were 415,239 broker non-votes with respect to the third proposal.

Proposal 4 – The reincorporation of the Company in Nevada and simultaneous name change to “Channel Therapeutics Corporation” was approved by the Company’s stockholders. The final voting results were as follows:

For	Against	Abstain
2,603,047	2,335	929,691

There were 415,239 broker non-votes with respect to the fourth proposal.

Proposal 5 – The appointment of Marcum LLP as the independent registered public accounting firm of the Company for the fiscal year ending December 31, 2024 was ratified by the Company’s stockholders. The final voting results were as follows:

For	Against	Abstain
3,941,195	6,918	2,199

Role of our Board of Directors in Risk Oversight

One of the key functions of the board of directors is informed oversight of our risk management process. The board of directors does not anticipate having a standing risk management committee but rather anticipates administering this oversight function directly through our board of directors as a whole, as well as through various standing committees of our board of directors that address risks inherent in their respective areas of oversight. In particular, our board of directors is responsible for monitoring and assessing strategic risk exposure and our audit committee has the responsibility to consider and discuss our major financial risk exposures and the steps our management has to take to monitor and control such exposures, including guidelines and policies to govern the process by which risk assessment and management is undertaken. The audit committee also monitors compliance with legal and regulatory requirements. Our compensation committee also assesses and monitors whether our compensation plans, policies and programs comply with applicable legal and regulatory requirements.

Committees of Our Board of Directors

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee, each of which has the composition and the 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 will be posted on the investor relations section of our website at www.channeltherapeutics.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 consolidated 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; 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.

Director Nomination Procedures

There have been no material changes to the procedures by which security holders may recommend nominees to our board of directors.

Insider Trading Arrangements and Policies

We have a written insider trading policy that applies to our directors, officers, employees and contractors, including our principal executive officer, principal financial officer, principal accounting officer or controller, and persons performing similar functions. We intend to disclose future amendments to such policy, or any waivers of its requirements, applicable to any principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions or our directors on our website identified above or in a Current Report on Form 8-K that we would file with the SEC.

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 non-public information subject to compliance with the terms of our insider trading policy. Prior to 180 days after the date of the pricing of our IPO, 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.

Item 11. Executive Compensation.

Our named executive officers for 2024 were Mr. Francis Knuettel II, our Chief Executive Officer and President, Chief Financial Officer, Treasurer and Secretary, and Dr. Eric Lang, our Chief Medical Officer. Mr. Knuettel was first appointed in June 2022, and Dr. Lang was first appointed in May 2023.

Summary Compensation Table

The following table provides information regarding the compensation of our named executive officers during the years ended December 31, 2024 and 2023.

Name and Principal Position	Year	Salary	Bonus	Option Awards	Non-Equity Incentive Plan Compensation	All Other Compensation	Total
Francis Knuettel II	2024	\$ 424,923	\$ 56,666	\$ 361,833	\$ —	\$ —	\$ 843,422
Chief Executive and Chief Financial Officer	2023	\$ 107,500	\$ —	\$ 199,510	\$ —	\$ —	\$ 307,010
Eric Lang ⁽¹⁾	2024	\$ 446,154	\$ —	\$ 230,318	\$ —	\$ —	\$ 676,472
Chief Medical Officer	2023	\$ 166,767	\$ —	\$ 120,735	\$ —	\$ —	\$ 287,502
Christian Kopfli	2024	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —
Former Chief Executive Officer, Former Chief Strategy Officer, and Former Vice Chairman ⁽²⁾	2023	\$ 11,280 ⁽³⁾	\$ —	\$ 149,633	\$ —	\$ —	\$ 160,913

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

(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. Kopfli's salary attributable to his services to the Company during the years ended December 31, 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 directors 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 of directors 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 of directors. 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 of directors in January of each year. The board of directors 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 of directors' 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 of directors 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 (“Camden”), 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 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 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: (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 of directors. 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 of directors in concert with Mr. Knuettel in January of each year. The board of directors 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 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 of directors’ discretion.

Pursuant to the Consultant Agreement, in the event the relationship with Camden is involuntarily terminated by the Company other than for “Cause” or if Camden terminates the relationship for “Good Reason,” Camden 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 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 whereby the RSU for 16,667 shares of Common Stock was cancelled, and we agreed to grant Camden an option to acquire 27,777 shares of Common Stock within 30 days of the closing of the IPO. As of June 23, 2023, such RSU for 16,667 shares of our Common Stock had not vested, and no expense was recorded on the Company’s consolidated 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.

Effective July 19, 2023, the board of directors appointed Francis Knuettel II as Interim Chief Executive Officer and as of March 13, 2024, the board of directors appointed Francis Knuettel II as Chief Executive Officer of the Company, at which time Mr. Knuettel became an employee of the Company. Mr. Knuettel will serve as the Company’s Chief Executive Officer until a successor is duly elected and qualified, unless sooner removed. In addition to his role as Chief Executive Officer of the Company, Mr. Knuettel will continue to serve in his capacity as Chief Financial Officer, Treasurer and Secretary of the Company.

Eric Lang

We are a party to an employment agreement with Eric Lang, effective May 15, 2023. Pursuant to such agreement, Dr. Lang agreed to serve as our Chief Medical Officer, in consideration for an annualized salary of \$400,000. The employment agreement provides that Dr. 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 of directors. The target bonus is 50% of Dr. 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 Dr. 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 of directors may, in its sole discretion, and for so long as Dr. 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 Dr. 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, Dr. 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, 2024.

Name and Principal Position	Option Awards					Stock Awards			
	Number of Securities Underlying Unexercised Options Exercisable	Number of Securities Underlying Unexercised Options Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised 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 Shares	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares
Francis Knuettel II, Chief Executive Officer and Chief Financial Officer	17,778	4,445	—	\$ 22.68	09/30/2032	—	\$ —	—	\$ —
Francis Knuettel II, Chief Executive Officer and Chief Financial Officer	2,778	—	—	22.68	1/10/2033	—	—	—	—
Francis Knuettel II, Chief Executive Officer and Chief Financial Officer	27,778	—	—	22.68	5/15/2033	—	—	—	—
Francis Knuettel II, Chief Executive Officer and Chief Financial Officer	81,000	243,000	—	1.30	6/14/2024	—	—	—	—
Eric Lang, Chief Medical Officer	10,093	14,130	—	\$ 22.68	5/15/2033	—	\$ —	—	\$ —
Eric Lang, Chief Medical Officer	32,500	97,500	—	1.30	6/14/2034	—	—	—	—

Equity Incentive Plans

The Channel Therapeutics Corporation 2023 Equity Incentive 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 and on October 22, 2024, we further amended the 2023 Plan to increase the number of shares available for issuance thereunder to 1,944,444. 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 this Report. 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 1,944,444 shares of our Common Stock for issuance under the 2023 Plan. 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 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, suspend 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 141,667 shares of Common Stock to employees and directors and (b) 16,667 RSUs to employees. On March 9, 2023, pursuant to the 2023 Plan, we granted an option to purchase up to 15,000 shares of Common Stock to a director. On June 23, 2023, we granted options to acquire 52,000 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 16,667 shares issued to an employee on January 10, 2023.

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.

Director Compensation for Fiscal Year 2024

We have not implemented a formal policy with respect to compensation payable 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. In 2024, independent directors received \$14,396 in cash compensation. In addition, in 2024 directors were granted options to purchase 90,000 shares of Common Stock at fair market value as of the date of issuance, expiring ten years from issuance and RSUs representing 356,664 shares of Common Stock. In addition, we reimburse our directors for expenses associated with attending meetings of our board of directors and its committees. Our board of directors is still in the process of considering the non-employee director compensation policy.

Name	Fees Earned or Paid in Cash (\$)	Stock Awards (\$)	Stock Option Awards (\$)(1)	Non-Equity Incentive Plan Compensation (\$)	Nonqualified Deferred Compensation Earnings (\$)	All Other Compensation (\$)	Total (\$)
Todd Davis	14,396	52,258	299,215	—	20,000	—	385,869
Ezra Friedberg	14,396	26,111	149,608	—	20,000	—	210,115
Richard Malamut	14,396	26,111	149,608	—	20,000	—	210,115
Chia-Lin Simmons	14,396		183,675	—	20,000	—	218,071

(1) Amounts reflect the aggregate grant date fair value of the stock options granted to each named executive officer during the fiscal year ended December 31, 2024 and 2023, as computed in accordance with Financial Accounting Standards Board ASC 718.

Policies and Practices Related to The Grant of Certain Equity Awards

We maintain the 2023 Plan through which we grant equity awards, including stock options and stock appreciation rights, to our named executive officers, other employees, and directors as part of our compensation program. In addition, certain employment agreements with our named executive officers provide for the grant of such equity awards. We do not currently have a formal policy governing the timing of grants of stock options, stock appreciation rights, or similar option-like instruments to named executive officers or directors in relation to the release of material nonpublic information. Equity awards under the 2023 Plan have been granted from time to time, including to directors to encourage their initial or continued service on our board of directors. Our board of directors is evaluating the adoption of a policy concerning the timing of such awards relative to material non-public information disclosures. We have not adopted any practice of timing, and do not time, the release of material non-public information to affect the value of equity awards granted to named executive officers or directors.

During the year ended December 31, 2024, there were no equity grants made to our executive officers during any period beginning four business days before the filing of a periodic report or current report disclosing material non-public information and ending one business day after the filing or furnishing of such report with the SEC.

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

The following table sets forth certain information regarding the beneficial ownership of our capital stock as of March 21, 2025 by (a) each person, or group of affiliated persons, who is known to us to own beneficially 5% or more of our outstanding equity securities; (b) each of our directors; (c) each of our named executive officers; and (d) all of our named executive officers and directors as a group. Except as otherwise indicated in the footnotes below, we believe, based on the information provided to us, that all persons listed below have sole voting power and investment power with respect to their shares of Common Stock or other equity securities that they beneficially own, subject to community property laws where applicable.

For purposes of this table, a person or group of persons is deemed to have “beneficial ownership” of any shares of Common Stock or other equity securities of the Company that such person has the right to acquire within sixty (60) days of March 26, 2025. For purposes of computing the percentage of outstanding shares of our Common Stock or other equity securities of the Company held by each person or group of persons named above, any shares that such person or persons has the right to acquire within sixty (60) days of March 21, 2025 is deemed to be outstanding, but is not deemed to be outstanding for the purpose of computing the percentage ownership of any other person. The percentage ownership information shown in the table is based upon 6,103,813 shares of Common Stock issued and outstanding as of March 26, 2025. The inclusion herein of any shares of Common Stock or other equity securities of the Company listed as beneficially owned does not constitute an admission of beneficial ownership. Unless otherwise identified, the address of our directors and executive officers is 4400 Route 9 South, Suite 1000, Freehold, NJ 07728.

Name of and Address of Beneficial Owner(1):	Shares of Common Stock Beneficially Owned	Percentage of Common Stock Beneficially Owned
Directors and executive officers		
Francis Knuettel II (2)	285,232	4.6%
Ezra Friedberg (3)	568,084	9.4%
Todd Davis (4)	136,300	2.2%
Richard Malamut (5)	47,365	*%
Chia-Lin Simmons (6)	47,083	*%
Eric Lang (7)	62,880	1.0%
All executive officers and directors as a group (6 persons)	1,145,212	17.9%
5% or greater stockholders:		
Alexandra Wood (Canada) Inc. (8)	574,187	9.5%
Boswell Prayer Ltd (9)	471,592	7.8%
Motif Pharmaceuticals Ltd. (10)	483,406	8.0%
Balmoral Financial Group LLC (11)	520,719	8.6%
AME Equities LLC (12)	369,178	6.1%
Aperture Healthcare Ventures Ltd. (13)	444,071	7.4%
Benuvia Operations, LLC (15)	384,226	6.4%

* Less than 1%

- (1) Except as otherwise indicated, the persons named in the table above have sole voting and investment power with respect to all shares of Common Stock shown as beneficially owned by them.
- (2) For Mr. Knuettel, includes 22,223 shares of Common Stock issuable upon the exercise of stock options which are exercisable for shares of Common Stock at a price of \$22.68 per share, 2,778 shares of Common Stock issuable upon the exercise of stock options which are exercisable for shares of Common Stock at a price of \$22.68 per share, 27,778 shares of Common Stock issuable upon the exercise of stock options which are exercisable for shares of Common Stock at a price of \$22.68 per share, 121,500 shares of Common Stock issuable upon the exercise of stock options which are exercisable for shares of Common Stock at a price of \$1.30 per share and 110,953 shares held by the Lara Knuettel Revocable Trust. The option for 121,500 shares is owned by Mr. Knuettel directly and all other stock options are held of record by Camden. Mr. Knuettel serves as Managing Member of Camden and co-trustee, with individual dispositive power of the Lara Knuettel Revocable Trust, and accordingly, may be deemed to beneficially own the shares of Common Stock owned directly by Camden and the Lara Knuettel Revocable Trust.
- (3) For Mr. Friedberg, includes 15,000 shares of Common Stock issuable upon the exercise stock options held by Mr. Friedberg, which are exercisable for shares of Common Stock at a price of \$22.68 per share, a RSU for 31,934 shares and 520,711 shares of Common Stock owned by Balmoral Financial Group LLC (“Balmoral”). In addition, Mr. Friedberg serves as a manager with individual dispositive power of Balmoral, and accordingly, may be deemed to beneficially own the shares of Common Stock owned directly by Balmoral.
- (4) For Mr. Davis, includes 20,001 shares of Common Stock issuable upon the exercise of stock options held by Mr. Davis, which are exercisable for shares of Common Stock at a price of \$22.68 per share, 22,223 shares of Common Stock issuable upon the exercise of stock options held by Mr. Davis, which are exercisable for shares of Common Stock at a price of \$22.68 per share, an RSU for 64,039 shares and 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.
- (5) For Mr. Malamut, includes 15,000 shares of Common Stock issuable upon the exercise of stock options held by Mr. Malamut, which are exercisable for shares of Common Stock at a price of \$22.68 per share and an RSU for 31,934 shares.
- (6) For Ms. Simmons, includes 13,333 shares of Common Stock issuable upon the exercise of stock options held by Ms. Simmons, which are exercisable for shares of Common Stock at a price of \$22.68 per share and 33,750 shares of Common Stock issuable upon the exercise of stock options held by Ms. Simmons, which are exercisable for shares of Common Stock at a price of \$1.30.
- (7) For Dr. Lang, includes 14,130 shares of Common Stock issuable upon the exercise of stock options held by Dr. Lang, which are exercisable for shares of Common Stock at a price of \$22.68 per share and 48,750 shares of Common Stock issuable upon the exercise of stock options held by Dr. Lang, which are exercisable for shares of Common Stock at a price of \$1.30.

- (8) Alexandra Wood (Canada) Inc. has sole voting power and dispositive power over the shares held by Alexandra Wood (Canada) Inc. The principal executive office of Alexandra Wood (Canada) Inc. is 45 Adelaide Street West, Toronto ON M5H 4E5, Canada.
- (9) 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.
- (10) None of the directors of that board of directors has sole voting or dispositive power with respect to the shares of Common Stock held by Motif Pharmaceuticals Ltd. The principal executive office of Motif Pharmaceuticals Ltd. is 25 and 28 North Wall Quay, Dublin 1, Ireland.
- (11) Ezra Friedberg has sole voting and dispositive power over the shares held by Balmoral. The principal executive office of Balmoral is 106 Court Road, Suite 202, Baltimore, MD 21208.
- (12) 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.
- (13) None of the directors of that board of directors has sole voting or dispositive power with respect to the shares of Common Stock 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.
- (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.

Securities Authorized for Issuance under Equity Compensation Plans

Plan Category	Number of Securities to Be Issued upon Exercise of Outstanding Options, Warrants and Rights (2)	Weighted Average Exercise Price of Outstanding Options, Warrants and Rights (2)	Number of Securities Remaining Available for Future Issuance under the Plan (excluding securities reflected in column (a) (2))
	(a)	(b)	(c)
Equity compensation plans approved by security holders (1)	925,449	\$ 5.95	1,018,995
Equity compensation plans not approved by security holders			
Total			1,018,995

(1) Represents the shares of Common Stock authorized for issuance under the 2023 Plan. In February 2024, the board of directors approved an amendment to the 2023 Plan, subject to stockholder approval which was subsequently obtained. An aggregate of 3,000,000 shares were originally authorized for issuance under the 2023 Plan, and after the amendment and our Reverse Stock Split in connection with the IPO, an aggregate of 444,444 shares have been authorized under the 2023 Plan. On June 12, 2024, the board of directors authorized an amendment to the 2023 Plan to increase the number of shares of Common Stock authorized for issuance thereunder by 1,500,000 from 444,444 shares to 1,944,444 shares. On October 22, 2024, the increase in the number of shares in the 2023 Plan was approved by the affirmative vote of a majority of the outstanding shares of Common Stock present in person, by remote communication, if applicable, or represented by proxy at the Annual Meeting. As of March 26, 2025, options to purchase an aggregate of 925,449 shares of our Common Stock with a weighted-average exercise price of \$5.95 per share, were outstanding under the 2023 Plan, with 1,108,995 shares of our Common Stock remaining available for future issuance. Unissued shares subject to awards that expire, are forfeited, or are cancelled will again become available for issuance under the 2023 Plan.

(2) As of December 31, 2024.

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

Transactions with Related Parties

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 consolidated 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 Holdings' therapeutics business, which we transferred to the Company (the "Therapeutics Business"), including all intellectual property secrets related to Chromocell Holdings' NaV1.7 program and its clinical-stage CC8464 lead compound, (2) assumption by the Company of direct liabilities related to Chromocell Holdings' 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 1,111,112 shares of its Common Stock and 600,000 shares of 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 re-assumed all \$1.6 million in direct liabilities previously assumed by the Company in accordance with the Contribution Agreement, (b) Chromocell Holdings waived 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 issued to Chromocell Holdings 2,600 shares of Series C Preferred Stock.

On April 17, 2023, Chromocell Holdings forfeited 133,745 shares of Common Stock 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 18, 2024, 747,187 shares of Common Stock and 2,600 shares of Series C Preferred Stock held by Chromocell Holdings were transferred by the Company to Alexandra Wood (Canada) Inc. ("AWI") in satisfaction of a default judgement against Chromocell Holdings regarding the default by Chromocell Holdings of a secured promissory note by order of the Supreme Court of the State of New York, County of New York on November 25, 2024 in the matter *Alexandra Wood (Canada) Inc v. Chromocell Corp.*, Index No. 651735/2024. AWI subsequently transferred 173,000 shares of Chromocell Holding's Common Stock that it received such that AWI now owns 574,187 shares of the Common Stock originally issued to Chromocell Holdings in connection with the Contribution Agreement.

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 December 31, 2023, there was an unamortized debt discount of \$0. 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, including Chromocell Holdings, Boswell Prayer Ltd., Motif Pharmaceuticals Ltd, Aperture Healthcare Ventures Ltd., MDB Merchants Park LLC, Balmoral 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 year ended December 31, 2023, the Company received an aggregate of \$303,651 in Advances 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 \$19,323 in aggregate interest on all Advances during the year ended December 31. 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 IPO 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 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 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 automatically converted 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 IPO 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, 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.

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 the 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. The October Promissory Notes were repaid on February 26, 27 and 28, 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. The Subscription Rights were offered to all of our pre-existing stockholders, including Aperture Healthcare Ventures Ltd., MDB Merchants Park LLC, Balmoral 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 1,211,238 shares of Common Stock at the Subscription Price. In addition, we distributed to Mr. Knuettel, our 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 158,731 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 27,778 of those shares to Temple Israel of the City of New York. On June 28, 2024, the Knuettel Trust made an additional charitable donation of 5,000 shares to Temple Israel of the City of New York and 15,000 shares to The Hewitt School. Also on December 27, 2023, AME Equities LLC made a charitable donation of 87,778 of its shares to Ballantyne Jewish Center, Inc. Upon the closing of the Rights Offering, we issued an aggregate of 2,442,468 shares of our Common Stock and received aggregate net proceeds of \$246,201, after giving effect to the Representative Affiliate Transactions, which we used primarily for general corporate purposes and expenses associated with our IPO.

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 384,226 shares 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 had a maturity date of March 1, 2024, and the full principal amount of both notes and any accrued interest thereon was payable solely in cash upon the consummation of the IPO. Both notes had an annual interest rate of eight percent (8%), which accrued daily, and was 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 held by such affiliates of the Representative and agreed to refund an aggregate of \$91,512 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

We have 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. Such 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 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.

Item 14. Principal Accountant Fees and Services.

Marcum LLP is our independent registered public accounting firm and performed the audits of our consolidated financial statements for the years ended December 31, 2024 and 2023. The following table sets forth all fees billed or to be billed for such periods:

	2024	2023
Audit fees (1)	\$ 211,817	\$ 164,229
Audit-related fees (2)	82,546	156,346
Tax fees (3)	—	—
All other fees (4)	77,092	43,490
Total	<u>\$ 371,455</u>	<u>\$ 364,065</u>

(1) "Audit fees" include fees for professional services rendered in connection with the audit of our annual consolidated financial statements, review of our quarterly condensed consolidated financial statements and advisory services on accounting matters that were addressed during the annual audit and quarterly review. This category also includes fees for services that were incurred in connection with statutory and regulatory filings or engagements, such as consents and review of documents filed with the SEC.

(2) “Audit-related fees” include fees billed for professional services rendered that are reasonably related to the performance of the audit or review of our consolidated financial statements including subscription for the online library of accounting research literature and are not reported under “Audit Fees”.

(3) “Tax fees” include fees for tax compliance. Tax compliance fees encompass a variety of permissible services, including technical tax advice related to federal and state income tax matters, and assistance with tax audits.

(4) “All other fees” include fees for the bring down and comfort letters associated with the IPO as well as work done in evaluating the Contribution Agreement.

Policy on Audit Committee Pre-Approval of Audit and Permissible Non-Audit Services of Independent Auditors

Our Audit Committee pre-approves all audit and non-audit services provided by the independent auditors prior to the engagement of the independent auditors with respect to such services. The chairman of our Audit Committee has been delegated the authority by such committee to pre-approve interim services by the independent auditors other than the annual audit. The chairman of our Audit Committee must report all such pre-approvals to the entire Audit Committee at the next committee meeting.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a) The following documents are filed as part of this Report:

(1) *Financial Statements:*

The audited balance sheets of the Company as of December 31, 2024 and December 31, 2023, the related statements of operations, changes in stockholders’ equity and cash flows for the years then ended, the footnotes thereto, and the report of Marcum LLP, an independent registered public accounting firm, are filed herewith.

(2) *Financial Schedules:*

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

(3) *Exhibits:*

The exhibits listed in the accompanying index to exhibits are filed with this Report or incorporated by reference into this Item 15(a)(3) as part of this Report.

(b) The following are exhibits to this Report and, if incorporated by reference, we have indicated the document previously filed with the SEC in which the exhibit was included.

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

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

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

Exhibit No.	Description of Exhibit
2.1	Contribution Agreement (filed as Exhibit 2.1 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on January 20, 2023 and incorporated by reference herein).
2.2	Side Letter to Contribution Agreement (filed as Exhibit 2.2 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on September 1, 2023 and incorporated by reference herein).
3.1	Amended and Restated Certificate of Incorporation (filed as Exhibit 3.1 to Registrant's Current Report on Form 8-K, filed with the SEC on February 22, 2024 and incorporated by reference herein).
3.2	Certificate of Designation of Series A Convertible Preferred Stock, as currently in effect (filed as Exhibit 3.2 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on January 20, 2023 and incorporated by reference herein).
3.3	Certificate of Designation of Series C Convertible Preferred Stock (filed as Exhibit 3.3 to Registrant's Annual Report on Form 10-K, filed with the SEC on April 16, 2024 and incorporated by reference herein).
3.4	Amended and Restated By-Laws (filed as Exhibit 3.2 to Registrant's Current Report on Form 8-K, filed with the SEC on February 22, 2024 and incorporated by reference herein).
3.5	Articles of Incorporation, filed with the Secretary of State of the State of Nevada on November 5, 2024 (filed as Exhibit 3.1(a) to Registrant's Current Report on Form 8-K, filed with the SEC on November 18, 2024 and incorporated by reference herein).
3.6	Certificate of Correction to Articles of Incorporation, filed with the Secretary of State of the State of Nevada on November 7, 2024 (filed as Exhibit 3.1(b) to Registrant's Current Report on Form 8-K, filed with the SEC on November 18, 2024 and incorporated by reference herein).
3.7	Certificate of Designations, Preferences and Rights of Series C Convertible Redeemable Preferred Stock, filed with the Secretary of State of the State of Nevada on November 8, 2024 (filed as Exhibit 3.1(c) to Registrant's Current Report on Form 8-K, filed with the SEC on November 18, 2024 and incorporated by reference herein).
3.8	Bylaws (filed as Exhibit 3.1(ii) to Registrant's Current Report on Form 8-K, filed with the SEC on November 18, 2024 and incorporated by reference herein).
4.1	Representative's Warrant (filed as Exhibit 4.1 to Registrant's Current Report on Form 8-K, filed with the SEC on February 22, 2024 and incorporated by reference herein).
4.2	Description of the Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934 (filed as Exhibit 4.2 to the Registrant's Annual Report on Form 10-K, filed with the SEC on April 16, 2024 and incorporated by reference herein).
4.4	Investor Promissory Note Issued by the Company (filed as Exhibit 4.6 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on January 20, 2023 and incorporated by reference herein).
4.5	Side Letter to Amended and Restated Investor Promissory Note issued by the Company (filed as Exhibit 4.7 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on June 30, 2023 and incorporated by reference herein).
4.6	Second Amended and Restated Investor Promissory Note Issued by the Company (filed as Exhibit 4.6 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on June 30, 2023 and incorporated by reference herein).
4.7	Third Amended and Restated Investor Promissory Note Issued by the Company (filed as Exhibit 4.4 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on September 1, 2023 and incorporated by reference herein).
4.8	Side Letter to Second Amended and Restated Investor Promissory Note Issued by the Company (filed as Exhibit 4.5 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on September 1, 2023 and incorporated by reference herein).
4.9	Director Promissory Note Issued by the Company (filed as Exhibit 4.7 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on January 20, 2023 and incorporated by reference herein).
4.10	Form of Senior Secured Convertible Promissory Note (April Bridge Financing; included in Exhibit 10.4) (filed as Exhibit 4.6 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on July 20, 2023 and incorporated by reference herein).

4.11	<u>Form of Senior Secured Convertible Promissory Note (September Bridge Financing; included in Exhibit 10.6) (filed as Exhibit 4.8 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on September 1, 2023 and incorporated by reference herein).</u>
4.12	<u>Amendment No. 1 to Third Amended and Restated Investor Promissory Note Issued by the Company (filed as Exhibit 4.8 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on October 16, 2023 and incorporated by reference herein).</u>
4.13	<u>Side Letter to Third Amended and Restated Investor Promissory Note Issued by the Company (filed as Exhibit 4.9 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on October 16, 2023 and incorporated by reference herein).</u>
4.14	<u>Fourth Amended and Restated Investor Promissory Note Issued by the Company (filed as Exhibit 4.10 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on October 16, 2023 and incorporated by reference herein).</u>
4.15	<u>First Amendment to Senior Secured Convertible Note (April Bridge Financing) (filed as Exhibit 4.11 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on October 25, 2023 and incorporated by reference herein).</u>
4.16	<u>October Promissory Note Issued by the Company (AME Equities LLC) (filed as Exhibit 4.12 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on October 16, 2023 and incorporated by reference herein).</u>
4.17	<u>October Promissory Note Issued by the Company (Balmoral Financial Group LLC) (filed as Exhibit 4.13 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on October 16, 2023 and incorporated by reference herein).</u>
4.18	<u>October Promissory Note Issued by the Company (Camden Capital LLC) (filed as Exhibit 4.14 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on October 16, 2023 and incorporated by reference herein).</u>
4.19	<u>October Promissory Note Issued by the Company (MDB Merchants Park LLC) (filed as Exhibit 4.15 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on October 16, 2023 and incorporated by reference herein).</u>
4.20	<u>Second Amendment to Senior Secured Convertible Note (April Bridge Financing) (filed as Exhibit 4.16 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on October 25, 2023 and incorporated by reference herein).</u>
4.21	<u>Amended and Restated October Promissory Note Issued by the Company (AME Equities LLC) (filed as Exhibit 4.17 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on November 8, 2023 and incorporated by reference herein).</u>
4.22	<u>Amended and Restated October Promissory Note Issued by the Company (Balmoral Financial Group LLC) (filed as Exhibit 4.18 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on November 8, 2023 and incorporated by reference herein).</u>
4.23	<u>Amended and Restated October Promissory Note Issued by the Company (Camden Capital LLC) (filed as Exhibit 4.19 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on November 8, 2023 and incorporated by reference herein).</u>
4.24	<u>Amended and Restated October Promissory Note Issued by the Company (MDB Merchants Park LLC) (filed as Exhibit 4.20 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on November 8, 2023 and incorporated by reference herein).</u>
4.25	<u>Third Amendment to Senior Secured Convertible Note (April Bridge Financing) (filed as Exhibit 4.21 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on January 16, 2024 and incorporated by reference herein).</u>
4.26	<u>Side Letter to Fourth Amended and Restated Investor Promissory Note Issued by the Company (filed as Exhibit 4.22 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on January 16, 2024 and incorporated by reference herein).</u>
4.27	<u>Fifth Amended and Restated Investor Promissory Note Issued by the Company (filed as Exhibit 4.23 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on January 16, 2024 and incorporated by reference herein).</u>

4.28	<u>Second Amended and Restated October Promissory Note Issued by the Company (AME Equities LLC) (filed as Exhibit 4.24 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on January 16, 2024 and incorporated by reference herein).</u>
4.29	<u>Second Amended and Restated October Promissory Note Issued by the Company (Balmoral Financial Group LLC) (filed as Exhibit 4.25 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on January 16, 2024 and incorporated by reference herein).</u>
4.30	<u>Second Amended and Restated October Promissory Note Issued by the Company (Camden Capital LLC) (filed as Exhibit 4.26 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on January 16, 2024 and incorporated by reference herein).</u>
4.31	<u>Second Amended and Restated October Promissory Note Issued by the Company (MDB Merchants Park LLC) (filed as Exhibit 4.27 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on January 16, 2024 and incorporated by reference herein).</u>
4.32	<u>Stock Issuance Agreement (Benuvia License Agreement) (filed as Exhibit 4.28 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on January 16, 2024 and incorporated by reference herein).</u>
4.33	<u>Amendment No. 1 to Director Promissory Note Issued by the Company (filed as Exhibit 4.29 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on January 16, 2024 and incorporated by reference herein).</u>
4.34	<u>Side Letter to Fifth Amended and Restated Investor Promissory Note Issued by the Company (filed as Exhibit 4.30 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on January 30, 2024 and incorporated by reference herein).</u>
4.35	<u>Sixth Amended and Restated Investor Promissory Note Issued by the Company (filed as Exhibit 4.31 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on January 30, 2024 and incorporated by reference herein).</u>
4.36	<u>Fourth Amendment to Senior Secured Convertible Note (April Bridge Financing) (filed as Exhibit 4.32 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on February 12, 2024 and incorporated by reference herein).</u>
4.37	<u>First Amendment to Senior Secured Convertible Note (September Bridge Financing) (filed as Exhibit 4.33 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on February 12, 2024 and incorporated by reference herein).</u>
4.38	<u>Stock Rescission Agreement (filed as Exhibit 4.34 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on February 12, 2024 and incorporated by reference herein).</u>
4.39	<u>Convertible Note, dated July 24, 2024 (filed as Exhibit 4.1 to Registrant's Current Report on Form 8-K, filed with the SEC on July 29, 2024 and incorporated by reference herein).</u>
10.1+	<u>Channel Therapeutics Corporation 2023 Equity Incentive Plan (filed as Exhibit 10.1 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on January 20, 2023 and incorporated by reference herein).</u>
10.2+	<u>Amended and Restated Employment Agreement (Christian Kopfli) (filed as Exhibit 10.2 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on September 1, 2023 and incorporated by reference herein).</u>
10.3+	<u>Amended and Restated Consultant Agreement (Camden Capital LLC) (filed as Exhibit 10.3 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on June 30, 2023 and incorporated by reference herein).</u>
10.4	<u>Securities Purchase Agreement (April Bridge Financing) (filed as Exhibit 10.4 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on July 20, 2023 and incorporated by reference herein).</u>
10.5	<u>Security Agreement (April Bridge Financing) (filed as Exhibit 10.5 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on July 20, 2023 and incorporated by reference herein).</u>
10.6	<u>Securities Purchase Agreement (September Bridge Financing) (filed as Exhibit 10.6 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on October 16, 2023 and incorporated by reference herein).</u>

10.7	Security Agreement (September Bridge Financing) (filed as Exhibit 10.7 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on September 1, 2023 and incorporated by reference herein).
10.8	Subordination and Intercreditor Agreement (September Bridge Financing) (filed as Exhibit 10.8 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on September 1, 2023 and incorporated by reference herein).
10.9	Securities Purchase Agreement (Series B Preferred Stock) (filed as Exhibit 10.9 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on October 16, 2023 and incorporated by reference herein).
10.10	Registration Rights Agreement (Series B Preferred Stock) (filed as Exhibit 10.10 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on October 16, 2023 and incorporated by reference herein).
10.11+	Employment Agreement (Eric Lang) (filed as Exhibit 10.7 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on June 30, 2023 and incorporated by reference herein).
10.12+	First Amendment to Channel Therapeutics Corporation 2023 Equity Incentive Plan (filed as Exhibit 4.4 to Registrant's Registration Statement on Form S-8, filed with the SEC on April 15, 2024 and incorporated by reference herein).
10.13	Side Letter re Securities Purchase Agreement (Standby Shares) (filed as Exhibit 10.13 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on January 16, 2024 and incorporated by reference herein).
10.14+	Benuvia License Agreement (filed as Exhibit 10.14 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on January 16, 2024 and incorporated by reference herein).
10.15	Consulting Agreement (Francis Knuettel II) (filed as Exhibit 10.3 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on January 20, 2023 and incorporated by reference herein).
10.16	Form of Restricted Stock Unit Agreement under the Channel Therapeutics Corporation 2023 Equity Incentive Plan (filed as Exhibit 4.5 to Registrant's Registration Statement on Form S-8, filed with the SEC on April 15, 2024 and incorporated by reference herein).
10.17	Form of Stock Option Agreement under the Channel Therapeutics Corporation 2023 Equity Incentive Plan (filed as Exhibit 4.6 to Registrant's Registration Statement on Form S-8, filed with the SEC on April 15, 2024 and incorporated by reference herein).
10.18+	Side Letter to Amended and Restated Consultant Agreement (Camden Capital) (filed as Exhibit 10.1 to Registrant's Current Report on Form 8-K, filed with the SEC on May 15, 2024 and incorporated by reference herein).
10.19+	Promissory Note Issued by the Company (Camden Capital) (filed as Exhibit 10.2 to Registrant's Current Report on Form 8-K, filed with the SEC on May 15, 2024 and incorporated by reference herein).
10.20+	Employment Agreement (Francis Knuettel II) (filed as Exhibit 10.3 to Registrant's Current Report on Form 8-K, filed with the SEC on May 15, 2024 and incorporated by reference herein).
10.21+	Form of Restricted Stock Unit Agreement under the Chromocell Therapeutics Corporation 2023 Equity Incentive Plan (filed as Exhibit 4.5 to Registrant's Registration Statement on Form S-8, filed with the SEC on April 15, 2024 and incorporated by reference herein).
10.22+	Form of Stock Option Agreement under the Chromocell Therapeutics Corporation 2023 Equity Incentive Plan (filed as Exhibit 4.6 to Registrant's Registration Statement on Form S-8, filed with the SEC on April 15, 2024 and incorporated by reference herein).
10.23	Securities Purchase Agreement by and between the Company and the July Note Holder, dated July 24, 2024 (filed as Exhibit 10.1 to Registrant's Current Report on Form 8-K, filed with the SEC on July 29, 2024 and incorporated by reference herein).
10.24	Common Stock Purchase Agreement by and between the Company and Tikkun, dated July 26, 2024 (filed as Exhibit 10.2 to Registrant's Current Report on Form 8-K, filed with the SEC on July 29, 2024 and incorporated by reference herein).
10.25	Registration Rights Agreement by and between the Company and Tikkun, dated July 26, 2024 (filed as Exhibit 10.3 to Registrant's Current Report on Form 8-K, filed with the SEC on July 29, 2024 and incorporated by reference herein).

10.26+	Second Amendment to the Chromocell Therapeutics Corporation 2023 Equity Incentive Plan (filed as Exhibit 10.1 to Registrant's Quarterly Report on Form 10-Q, filed with the SEC on November 13, 2024 and incorporated by reference herein).
10.27	Promissory Note dated February 25, 2025 (filed as Exhibit 10.1 to Registrant's Current Report on Form 8-K, filed with the SEC on March 3, 2024 and incorporated by reference herein).
19.1	Insider Trading Policy (filed as Exhibit 19.1 to the Registrant's Annual Report on Form 10-K, filed with the SEC on April 16, 2024 and incorporated by reference herein).
23.1*	Consent of Marcum LLP.
31.1#*	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1#*	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
97.1+	Compensation Recovery Policy (filed as Exhibit 97.1 to the Registrant's Annual Report on Form 10-K, filed with the SEC on April 16, 2024 and incorporated by reference herein).
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Schema
101.CAL	XBRL Taxonomy Calculation Linkbase
101.DEF	XBRL Taxonomy Definition Linkbase
101.LAB	XBRL Taxonomy Label Linkbase
101.PRE	XBRL Taxonomy Presentation Linkbase
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)

* Filed herewith.

+ Indicates management contract or compensatory plan.

The certifications furnished in Exhibits 32.1 and 32.2 hereto are deemed to be furnished with this Report and will not be deemed to be "filed" for purposes of Section 18 of the Exchange Act, except to the extent that the registrant specifically incorporates it by reference.

SIGNATURES

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

Channel Therapeutics Corporation

Date: March 27, 2025

By: /s/ Francis Knuettel II

Name: Francis Knuettel II

Title: Chief Executive Officer and President, Chief Financial Officer, Treasurer and Secretary
(Principal Executive Officer, Principal Financial Officer, Principal Accounting Officer)

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

Date: March 27, 2025

By: /s/ Francis Knuettel II

Francis Knuettel II

Chief Executive Officer and President, Chief Financial Officer, Treasurer, Secretary and Director

Date: March 27, 2025

By: /s/ Ezra Friedberg

Ezra Friedberg

Director

Date: March 27, 2025

By: /s/ Todd Davis

Todd Davis

Director

Date: March 27, 2025

By: /s/ Richard Malamut

Richard Malamut

Director

Date: March 27, 2025

By: /s/ Chia-Lin Simmons

Chia-Lin Simmons

Director

CHANNEL THERAPEUTICS CORPORATION
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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors of
Channel Therapeutics Corporation
Freehold, New Jersey

Opinion on the Financial Statements

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

Explanatory Paragraph – Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 2, the Company has a significant working capital deficiency, 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.

/s/ Marcum LLP

Marcum LLP

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

Hartford, Connecticut
March 27, 2025

Item 1. Financial Statements

CHANNEL THERAPEUTICS CORP
CONSOLIDATED BALANCE SHEETS

	December 31, 2024	December 31, 2023
ASSETS		
CURRENT ASSETS		
Cash	\$ 513,443	\$ 96,391
Prepaid expenses	65,300	—
Due from Chromocell Corporation	40,400	—
Deferred offering costs	750,000	—
TOTAL CURRENT ASSETS	<u>1,369,143</u>	<u>96,391</u>
TOTAL ASSETS	<u>\$ 1,369,143</u>	<u>\$ 96,391</u>
LIABILITIES AND STOCKHOLDERS' DEFICIT		
CURRENT LIABILITIES		
Accounts payable and accrued expenses	\$ 1,897,127	\$ 4,620,925
Accrued compensation	—	645,947
Investor Note, net of debt discount	—	316,324
Loan payable, net of debt discount	2,054,202	202,279
Loan payable - related party, net of debt discount	131,868	750,082
Due to Chromocell Corporation	—	5,386
TOTAL CURRENT LIABILITIES	<u>4,083,197</u>	<u>6,540,943</u>
TOTAL LIABILITIES	<u>4,083,197</u>	<u>6,540,943</u>
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' DEFICIT		
Preferred stock Series A, \$0.0001 par value, 700,000 shares authorized, 0 and 600,000 shares issued and outstanding as of December 31, 2024 and December 31, 2023, respectively	—	60
Preferred stock Series C, \$0.0001 par value, 5,000 shares authorized, 2,600 and 0 shares issued and outstanding as of December 31, 2024 and December 31, 2023, respectively	—	—
Common stock, \$0.0001 par value, 200,000,000 shares authorized, 6,103,813 and 3,906,300 shares issued and outstanding as of December 31, 2024 and December 31, 2023, respectively	613	391
Additional paid in capital	18,760,320	7,074,646
Accumulated deficit	(21,474,987)	(13,519,649)
TOTAL STOCKHOLDERS' DEFICIT	<u>(2,714,054)</u>	<u>(6,444,552)</u>
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	<u>\$ 1,369,143</u>	<u>\$ 96,391</u>

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

CHANNEL THERAPEUTICS CORP
CONSOLIDATED STATEMENTS OF OPERATIONS
FOR THE YEARS ENDED DECEMBER 31, 2024 AND 2023

	Years Ended December 31,	
	2024	2023
OPERATING EXPENSES		
General and administrative expenses	\$ 4,110,045	\$ 2,738,948
Research and development	1,179,436	2,579,418
Professional fees	2,281,968	1,543,918
Total operating expenses	7,571,449	6,862,284
NET LOSS FROM OPERATIONS	(7,571,449)	(6,862,284)
OTHER (EXPENSE) INCOME		
Interest expense	(786,393)	(518,509)
Other income	39,413	—
Gain on default judgement	363,091	—
Total other (expense) income	(383,091)	(518,509)
Net loss before provision for income taxes	(7,955,338)	(7,380,793)
Provision for income taxes	—	—
NET LOSS	\$ (7,955,338)	\$ (7,380,793)
Net loss per common share - basic and diluted	\$ (1.43)	\$ (5.78)
Weighted average number of common shares outstanding during the year - basic and diluted	5,574,473	1,276,543

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

CHANNEL THERAPEUTICS CORP
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' DEFICIT
FOR THE YEARS ENDED DECEMBER 31, 2024 AND 2023

	Preferred A Shares	Preferred A Shares Par	Preferred C Shares	Preferred C Shares Par	Common Shares	Par	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
Balance, December 31, 2022	600,000	\$ 60	—	\$ —	1,111,112	\$ 111	\$ 2,432,148	\$ (6,138,856)	\$ (3,706,537)
Stock-based compensation	—	—	—	—	—	—	1,733,233	—	1,733,233
Shares issued for extension of bridge loan	—	—	—	—	18,892	2	428,398	—	428,400
Shares issued for license	—	—	—	—	384,226	38	2,225,695	—	2,225,733
Shares issued for cash	—	—	—	—	2,525,815	253	255,159	—	255,412
Shares forfeited	—	—	—	—	(133,745)	(13)	13	—	—
Net loss	—	—	—	—	—	—	—	(7,380,793)	(7,380,793)
Balance December 31, 2023	<u>600,000</u>	<u>\$ 60</u>	<u>—</u>	<u>\$ —</u>	<u>3,906,300</u>	<u>\$ 391</u>	<u>\$ 7,074,646</u>	<u>\$ (13,519,649)</u>	<u>\$ (6,444,552)</u>

CHANNEL THERAPEUTICS CORP
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' DEFICIT
FOR THE YEARS ENDED DECEMBER 31, 2024 AND 2023

	Preferred A Shares	Preferred A Shares Par	Preferred C Shares	Preferred C Shares Par	Common Shares	Par	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
Balance, December 31, 2023	600,000	\$ 60	—	\$ —	3,906,300	\$ 391	\$ 7,074,646	\$ (13,519,649)	\$ (6,444,552)
Stock-based compensation	—	—	—	—	—	—	1,455,561	—	1,455,561
Issuance cost from shares issued on extension of bridge loan	—	—	—	—	81,112	9	447,770	—	447,779
Conversion of preferred stock into Common Stock	(600,000)	(60)	—	—	499,429	50	10	—	—
Shares issued for cash in Initial Public Offering	—	—	—	—	1,100,000	110	5,971,890	—	5,972,000
Shares issued for Standby agreement	—	—	—	—	37,500	4	(4)	—	—
Recission of common stock	—	—	—	—	(111,129)	(11)	(91,501)	—	(91,512)
Transfer of liabilities to Chromocell Corp. for Preferred stock	—	—	2,600	—	—	—	2,153,362	—	2,153,362
Conversion of notes into Common Stock	—	—	—	—	253,492	25	1,362,796	—	1,362,821
Restricted Stock Units expense	—	—	—	—	64,498	6	104,478	—	104,484
Shares issued for services	—	—	—	—	192,854	21	239,229	—	239,250
Shares issued for payment of accounts payable	—	—	—	—	10,000	1	7,338	—	7,339
Repurchase of Common Stock	—	—	—	—	(86,196)	(9)	(74,991)	—	(75,000)
Shares issued for cash under equity line of credit, net of issuance costs and for paydown on notes payable and accrued interest	—	—	—	—	155,953	16	109,736	—	109,752
Net loss	—	—	—	—	—	—	—	(7,955,338)	(7,955,338)
Balance December 31, 2024	<u>—</u>	<u>\$ —</u>	<u>2,600</u>	<u>\$ —</u>	<u>6,103,813</u>	<u>\$ 613</u>	<u>\$ 18,760,320</u>	<u>\$ (21,474,987)</u>	<u>\$ (2,714,054)</u>

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

CHANNEL THERAPEUTICS CORP
CONSOLIDATED STATEMENTS OF CASH FLOWS
FOR THE YEARS ENDED DECEMBER 31, 2024 AND 2023

	Years Ended December 31,	
	2024	2023
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (7,955,338)	\$ (7,380,793)
Adjustments to reconcile net loss to net cash used in operating activities		
Amortization of debt discount	692,020	188,119
Issuance cost from shares issued on extension of investor note	—	201,600
Stock-based compensation	1,799,295	1,733,233
Shares issued for license	—	2,225,733
Gain on default judgement	(363,091)	—
Changes in operating assets and liabilities:		
Accounts payable and accrued expenses	1,178,573	1,627,005
Accrued compensation	(282,856)	424,072
Due from Chromocell Corporation	(45,786)	—
Prepaid expenses	(65,300)	—
Deferred offering costs	(750,000)	—
Net Cash Used In Operating Activities	<u>(5,792,483)</u>	<u>(981,031)</u>
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from loan payable, net of debt discount	536,184	201,008
Proceeds from loan payable - related party, net of debt discount	—	565,928
Payment of bridge loan, net of debt discount	(214,757)	—
Common stock issued for cash	5,972,000	255,412
Recission of common stock	(91,512)	—
Repurchase of Common Stock under Stock Repurchase Plan	(75,000)	—
Shares issued for cash under equity line of credit	82,620	—
Net Cash Provided By Financing Activities	<u>6,209,535</u>	<u>1,022,348</u>
NET INCREASE IN CASH	417,052	41,317
CASH AT BEGINNING OF YEAR	<u>96,391</u>	<u>55,074</u>
CASH AT END OF YEAR	<u>\$ 513,443</u>	<u>\$ 96,391</u>
Supplemental cash flow information:		
Cash paid for income taxes	\$ —	\$ —
Cash paid for interest expense	\$ —	\$ —
NONCASH INVESTING AND FINANCING ACTIVITIES:		
Shares forfeited	\$ —	\$ 13
Debt discount from common stock issued for extension of bridge loan	\$ 447,779	\$ 428,400
Conversion of notes to common stock	\$ 1,362,821	\$ —
Transfer of liabilities to Chromocell Corp for Series C Preferred Stock	\$ 2,153,362	\$ —
Accounts payable and accrued expenses converted to loans payable	\$ 1,455,416	\$ —
Accounts payable and accrued expenses converted to loans payable - related party	\$ 131,868	\$ —
Shares issued for payment of accounts payable	\$ 7,339	\$ —
Shares issued for payment of accrued interest	\$ 3,344	\$ —
Shares issued for payment of principal on loan payable	\$ 23,788	\$ —

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

CHANNEL THERAPEUTICS CORP
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1 – ORGANIZATION AND NATURE OF BUSINESS

Company Background

Channel Therapeutics Corporation (“Channel” 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). On October 22, 2024, the Company’s shareholders approved a reincorporation merger of the Company in the State of Nevada with and into Channel Therapeutics Corporation, wholly-owned subsidiary of the Company, with Channel Therapeutics Corporation remaining as the surviving corporation immediately following the reincorporation merger (the “Reincorporation Merger”). The Reincorporation Merger occurred on November 18, 2024.

The Company is a clinical-stage biotech company focused on developing and commercializing new therapeutics to alleviate pain. The Company’s clinical focus is to selectively target the sodium ion-channel known as “NaV1.7”, which has been genetically validated as a pain receptor in human physiology. 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”). The Company’s goal is to develop a novel and proprietary class of NaV blockers that target the body’s peripheral nervous system.

Overview

The Company has a limited operating history and has not generated revenue from its 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 the Company's technologies obsolete, availability of resources for clinical trials, acceptance of technologies into the medical community, and competition from larger, more well-funded companies.

Initial Public Offering

On October 22, 2024, the affirmative vote of a majority of the outstanding shares of Common Stock present in person, by remote communication, if applicable, or represented by proxy at the Annual Meeting approved the Reincorporation Merger. The Reincorporation Merger occurred on November 18, 2024.

Reincorporation Merger and Name Change

On October 22, 2024, the affirmative vote of a majority of the outstanding shares of Common Stock present in person, by remote communication, if applicable, or represented by proxy at the Annual Meeting approved the Reincorporation Merger. The Reincorporation Merger occurred on November 18, 2024.

NOTE 2 – LIQUIDITY AND GOING CONCERN

A fundamental principle of the preparation of financial statements in accordance with GAAP is the assumption that an entity will continue in existence as a going concern, which contemplates continuity of operations and the realization of assets and settlement of liabilities occurring in the ordinary course of business. In accordance with this requirement, the Company has prepared its accompanying consolidated financial statements assuming the Company will continue as a going concern.

During the year ended December 31, 2024, the Company had a net loss of approximately \$8.0 million. As of December 31, 2024, the Company has cash of approximately \$0.5 million and a working capital deficit. During the year ended December 31, 2023, the Company had a net loss of approximately \$8.0 million. As of December 31, 2023, the Company has cash of approximately \$0.5 million and a working capital deficit of approximately \$2.7 million, compared to approximately \$0.1 million in cash and a working capital deficit of approximately \$6.4 million at December 31, 2022.

Based on the Company's current projections, management believes 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 consolidated financial statements. While the Company will continue to invest in its business and the development of CC8464, CT2000, and CT3000, and potentially other molecules, it is unlikely that the Company will generate product or licensing revenue during the next twelve months. During the year ended December 31, 2024, the Company completed its initial public offering, raising \$5.7 million, after deducting the underwriting discounts and commissions and offering expenses, and it is likely the Company will need to raise additional funds through either strategic partnerships or the capital markets. 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.

The consolidated 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 the Company's 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, raise capital, and to control operating expenses.

NOTE 3 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying audited financial statement has been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") and pursuant to the rules and regulations of the SEC.

Revision of previously issued financial statements

During the course of preparing the Company's Annual Report on Form 10-K for the year ended December 31, 2024, the Company identified a misstatement in the prior year financial statements. This misstatement related to the reporting an incorrect number of shares of Common Stock issued for cash in the Company's consolidated statement of changes in stockholders' deficit. This led to an incorrect amount of total common shares outstanding on the Company's consolidated statement of changes in stockholders' deficit and on the Company's consolidated balance sheet. On the Company's consolidated balance sheet as of December 31, 2023, the Company disclosed shares of Common Stock issued and outstanding of 3,914,338. This amount of shares has been revised to 3,906,300, a change of 8,038 shares. On the Company's consolidated statement of changes in stockholders' deficit for the year ended December 31, 2023, the Company disclosed shares of Common Stock issued for cash of 2,533,853. This amount of shares has been revised to 2,525,815, a change of 8,038 shares. Also, on the Company's consolidated statement of changes in stockholders' deficit for the year ended December 31, 2023, the Company disclosed total shares of Common Stock issued and outstanding as of December 31, 2023 of 3,914,338. This amount of shares has been revised to 3,906,300, a change of 8,038 shares.

Emerging Growth Company

The Company is an “emerging growth company,” as defined in Section 2(a) of the Securities Act of 1933, as amended (the “Securities Act”), as modified by the Jumpstart Our Business Startups Act of 2012, as amended (the “JOBS Act”), and it may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies including, but not limited to, not being required to comply with the independent registered public accounting firm attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in its periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

Further, Section 102(b)(1) of the JOBS Act exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies (that is, those that have not had a Securities Act registration statement declared effective or do not have a class of securities registered under the Exchange Act) are required to comply with the new or revised financial accounting standards. The JOBS Act provides that a company can elect to opt out of the extended transition period and comply with the requirements that apply to non-emerging growth companies but any such election to opt out is irrevocable. The Company has elected not to opt out of such extended transition period which means that when a standard is issued or revised and it has different application dates for public or private companies, the Company, as an emerging growth company, can adopt the new or revised standard at the time private companies adopt the new or revised standard. This may make comparison of the Company’s consolidated financial statements with another public company which is neither an emerging growth company nor an emerging growth company which has opted out of using the extended transition period difficult or impossible because of the potential differences in accounting standards used.

Principles of consolidation

The consolidated financial statements include the accounts of Channel Therapeutics Corporation and its wholly owned subsidiary, Chromocell Therapeutics Australia Pty. Ltd. All significant intercompany balances and transactions have been eliminated.

Use of Estimates

The preparation of consolidated 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 consolidated financial statements and the reported amounts of 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 valuation of deferred income taxes.

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, 2024 and December 31, 2023, the Company did not have any cash equivalents.

As of December 31, 2024, the Company had deposits in excess of federally insured limits.

Research and Development

The Company incurs research and development (“R&D”) costs during the process of researching and developing technologies and future offerings. The Company expenses these costs as incurred unless such costs qualify for capitalization under applicable guidance. The Company reviews acquired R&D and licenses to determine if they should be capitalized or expensed under U.S. GAAP standards.

Below is a disaggregation of R&D expenses:

	For the Year Ended December 31, 2024	For the Year Ended December 31, 2023
Consultant	\$ 286,680	\$ 68,900
Lab Materials	1,818	—
Lab Cell Storage	88,662	48,572
Chemistry Manufacturing and Controls (“CMC”)	642,304	—
IP Services	159,972	2,461,946
Total	<u>\$ 1,179,436</u>	<u>\$ 2,579,418</u>

Fair Value Measurements and Fair Value of Financial Instruments

The Company determines fair value based on assumptions that market participants would use in pricing an asset or liability in the principal or most advantageous market. When considering market participant assumptions in fair value measurements, the following fair value hierarchy distinguishes between observable and unobservable inputs, which are categorized in one of the following levels:

- 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 (“ASC 718”), 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, 2024, 870,449 stock options, 55,000 warrants, and 243,100 unvested restricted stock units (“RSUs”) were excluded from dilutive earnings per share as their effects were anti-dilutive. As of December 31, 2023, 197,560 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,” (“ASC 740”) 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 consolidated 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 has filed its tax returns for the year ended December 31, 2023 and after review of the prior year consolidated financial statements and the results of operations through December 31, 2024, the Company has recorded a full valuation allowance on its deferred tax asset.

Recently Issued Accounting Pronouncements

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures, which requires disaggregated information about a reporting entity’s effective tax rate reconciliation, as well as information related to income taxes paid to enhance the transparency and decision usefulness of income tax disclosures. This ASU will be effective for the annual periods beginning after December 15, 2024. The Company is currently evaluating the impacts of adoption of this ASU.

In November 2023, the FASB issued ASU 2023-07, “Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures,” which is intended to improve reportable segment disclosure requirements, primarily through enhanced disclosures about significant segment expenses. The purpose of the amendment is to enable investors to better understand an entity’s overall performance and assess potential future cash flows. The guidance is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024, with early adoption permitted. The guidance is to be applied retrospectively to all prior periods presented in the consolidated financial statements. The Company adopted this ASU in 2024, see Note 9.

NOTE 4 – RELATED PARTY TRANSACTIONS

Employment Agreement

On February 14, 2024, the board of directors of the Company (the “Board”) received a demand letter from an attorney representing Chromocell Holdings and Christian Kopfli, the Company’s former Chief Executive Officer and former Chief Strategy Officer. Mr. Kopfli alleged an improper termination for “cause” and claimed to seek monetary damages in the amount of \$479,169. Of the \$479,169 asserted by Mr. Kopfli, as of December 31, 2024, the Company had accrued \$363,091 in compensation expenses associated with Mr. Kopfli’s prior employment with the Company. However, the Company believed the assertions made by Mr. Kopfli were without merit and commenced a lawsuit against Mr. Kopfli and Chromocell Holdings in the Supreme Court for the State of New York, County of New York on June 7, 2024 (Index No. 652917/2024, the “New York Action”), asserting causes of action against Mr. Kopfli for breach of the Employment Agreement entered into on January 10, 2023 between the Company and Mr. Kopfli, breach of fiduciary duty by Mr. Kopfli, as well as breach of contract against Chromocell Holdings in connection with the Contribution Agreement between the Company and Chromocell Holdings. The Company also asserted a “faithless servant” claim against Mr. Kopfli, seeking a ruling that Mr. Kopfli was not entitled to compensation from the Company. The Company sought monetary damages against Mr. Kopfli and Chromocell Holdings in the New York Action, plus disgorgement of all compensation previously paid or accrued to Mr. Kopfli by the Company.

By Order dated October 3, 2024, the court in the New York Action awarded the Company a default judgment against Mr. Kopfli and Chromocell Holdings on all claims and ordered an assessment of damages against Mr. Kopfli and Chromocell Holdings (currently scheduled to be held in May 2025). As of December 31, 2024, the Company has removed the accrual of \$363,091 in compensation expenses and recorded a gain on default judgement in the same amount.

Camden Consulting LLC

The Company entered into a Consultant Agreement with Camden Capital LLC (“Camden”), 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 agreed to provide the services of Mr. Knuettel, who was to serve as the Company’s Chief Financial and Strategy Officer, Treasurer and Secretary.

Under the Consultant Agreement, Under the Consultant Agreement, Camden 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: (i) an option, awarded as of January 10, 2023, to acquire 22,223 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 2,778 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) a RSU, awarded as of January 10, 2023, of 16,667 shares of the Company’s 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 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 is involuntarily terminated by the Company other than for "Cause" or if Camden terminates the relationship for "Good Reason," Camden 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 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 whereby the RSU for 16,667 shares of Common Stock was cancelled, and the Company agreed to grant Camden an option to acquire 27,777 shares of Common Stock within 30 days of the closing of the IPO. As of June 23, 2023, such RSU for 16,667 shares of the Company's Common Stock had not vested, and no expense was recorded on the Company's consolidated 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.

Effective July 19, 2023, the Board appointed Francis Knuettel II as Interim Chief Executive Officer and as of March 13, 2024, the Board appointed Francis Knuettel II as Chief Executive Officer of the Company, at which time Mr. Knuettel became an employee of the Company. Mr. Knuettel will serve as the Company's Chief Executive Officer until a successor is duly elected and qualified, unless sooner removed. In addition to his role as Chief Executive Officer of the Company, Mr. Knuettel will continue to serve in his capacity as Chief Financial Officer, Treasurer and Secretary of the Company.

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. On December 28, 2023, the Company entered into an amendment to the Director Note, which extended the maturity date to February 29, 2024. On February 21, 2024, the principal and accrued interest on this note converted into 29,167 shares of the Company's Common Stock.

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 Board). All of these investors, except Chromocell Holdings, also participated in the September Bridge Financing. On February 21, 2024, the principal and accrued interest on these notes converted into 130,494 shares of the Company's Common Stock. See Note 5 for terms of these notes.

Due from/to Chromocell Holdings

As of December 31, 2024, the Company had a \$40,400 receivable due from Chromocell Holdings, from which the Company was spun out in August 2022. This amount is comprised of expenses paid by the Company to be reimbursed by Chromocell Holdings. No interest is incurred on these amounts.

As of December 31, 2023, the Company had a \$5,386 liability due to Chromocell Holdings. This amount is comprised of expenses paid by Chromocell Holdings 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 Holdings. Pursuant to the side letter, upon closing of the Company’s IPO: (a) Chromocell Holdings re-assumed all \$1.6 million in direct liabilities previously assumed by the Company in accordance with the Contribution Agreement, (b) Chromocell Holdings waived 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 issued 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 has a liquidation preference of \$1,000 per share. Holders of the Series C Preferred Stock are not entitled to dividends, have no voting rights other than as required by law, and the shares of Series C Preferred Stock are convertible into shares of Common Stock at a price of \$7.50 per share of Common Stock. Following the IPO, at the Company’s option, the shares of Series C Preferred Stock are convertible into shares of Common Stock automatically if, the trading price of the Common Stock exceeds certain thresholds and are redeemable by the Company for cash.

Related Party Note

On May 10, 2024, the Company and Camden Capital LLC, a company controlled by Mr. Knuettel, the Company’s Chief Executive Officer and Chief Financial Officer, entered converted certain payables into a promissory note for \$131,868. The note matures on December 15, 2024, or, if earlier to occur, upon the closing of a public or private offering or other financing or capital-raising transaction of any kind. As of December 31, 2024, the note was in default, though the Company has not received any notice from Mr. Knuettel. The note accrued interest at the rate of 4.86% per annum through December 15, 2024 and 6.86% thereafter. As of December 31, 2024, the note had an outstanding principal of \$131,868 and accrued interest of \$4,242.

Outstanding Principal on Related Party Notes

Note Payable – Related Party	Outstanding Principal	Unamortized Debt Discount	Outstanding Principal, net of Debt Discount
Related Party Note	\$ 131,868	\$ —	\$ 131,868
Total as of December 31, 2024	\$ 131,868	\$ —	\$ 131,868

Note Payable – Related Party	Outstanding Principal	Unamortized Debt Discount	Outstanding Principal, net of Debt Discount
Director Note	\$ 175,000	\$ —	\$ 175,000
September and April Bridge financings	596,928	(21,846)	575,082
Total as of December 31, 2023	\$ 771,928	\$ (21,846)	\$ 750,082

NOTE 5 – NOTES PAYABLE

Investor Note

On February 4, 2022, the Company entered into a note payable for \$450,000 (the “Investor Note”) with a third party. This Investor Note had 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. During the year ended December 31, 2024, the Company issued 81,112 shares of common stock to extend the maturity date of the note, resulting in an additional debt discount of \$447,379. The Company recognized \$581,055 and \$309,094, respectively, of amortization of debt discount included in interest expense on the statement of operations for the years ended December 31, 2024 and 2023 related to the Investor Note. As of December 31, 2024, the debt discount associated with this Investor Note was fully amortized.

On February 27, 2023, the Investor Note 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 June 23, 2023, the Company entered into a 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 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 Investor Note rather than an extinguishment. The Company recorded an expense of \$126,000 from the issuance of the 556 shares of Common Stock based on a share price of \$22.68. The \$22.68 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.

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% monthly (\$9,000 per month) of the face amount of \$450,000 and obligates the holder to subscribe for securities in the IPO in full satisfaction of the Company’s repayment obligations. In addition, pursuant to the Investor Note Side Letters, the Company agreed to register the 8,890 shares of Common Stock (5,556 issued for the June 23, 2023 side letter, and 3,334 issued for the August 17, 2023 side letter) for resale. The Company recorded an expense of \$75,600 from the issuance of the 3,333 shares of Common Stock based on a share price of \$22.68. The \$22.68 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.

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 3,334 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 3,334 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 77,778 shares of Common Stock on the earlier to occur of the IPO or February 29, 2024.

As of December 31, 2024, the Investor Note and the accrued interest on the note has been fully paid off. As of December 31, 2023, there was \$98,036 in accrued interest on the note. Interest expense totaled \$15,517 for the year ended December 31, 2024, compared to \$98,036 the year ended December 31, 2023. The net principal amount of this note was \$316,324 as of December 31, 2023. These notes were exchanged for 93,831 shares of Common Stock at the time of the Company’s IPO.

Director Note

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 had 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.

On December 28, 2023, the Company entered into an amendment to the Director Note, which extended the maturity date to February 29, 2024. The Director Note was exchanged for 29,167 shares of Common Stock at the time of the Company's IPO.

April Bridge Financing

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 year ended December 31, 2023, the Company received \$389,808, 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 consisted of senior secured convertible notes that had a maturity date of October 17, 2023. Such notes accrued interest on the unpaid principal amount at a rate of 8% per annum and automatically converted into shares of Common Stock at the IPO 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 were secured by a security interest in all of the Company's assets (including the Company's 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 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. These notes were exchanged for 87,727 shares of Common Stock at the time of the Company's IPO.

September Bridge Financing

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 consisted of senior secured convertible notes that had a maturity date of March 1, 2024. Such notes accrued interest on the unpaid principal amount at a rate of eight percent (8%) per annum and automatically converted 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 62 shares of Common Stock issuable as further consideration for the September Bridge Financing. The senior secured convertible notes issued in the September Bridge Financing were secured by a security interest in all of the Company's assets (including 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, the Company 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. These notes were exchanged for 42,767 shares of Common Stock at the time of the Company's IPO.

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 matured on November 12, 2023 or, if earlier to occur, upon the closing of the IPO. The October Promissory Notes bore 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. The Company recognized \$24,575 and \$10,425, respectively, of amortization of debt discount included in interest expense on the statements of operations for the years ended December 31, 2024 and 2023. As of December 31, 2024, the October Promissory Notes have been fully paid off in cash.

Bridge Financing Note Amendments and Rescission 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 A.G.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 the IPO. Both notes have an annual interest rate of 8%, which accrues daily, and is calculated on the basis of a 360-day year (consisting of twelve 30 calendar day periods), giving an effective interest rate of 8.3%. During the year ended December 31, 2024, the Company issued 81,112 shares of common stock to extend the maturity date of the note, resulting in an additional debt discount of \$447,379.

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 111,129 shares of Common Stock held by such affiliates of A.G.P. and agreed to refund an aggregate of \$91,512 paid by such affiliates of A.G.P. in consideration therefor within 30 days of the effective date of the Stock Rescission Agreement. At December 31, 2024, all such amounts have been paid pursuant to the Representative Affiliate Transactions and there are no remaining obligations thereto.

May Promissory Note

On May 10, 2024, the Company converted accounts payable with a professional advisor into a promissory note in the amount of \$1,455,416. The note matures on December 15, 2024 or, if earlier to occur, upon the closing of a public or private offering or other financing or capital-raising transaction of any kind. As of December 31, 2024, the note was in default, though the Company has not received any notice from the professional advisor. The note accrued interest at the rate of 4.86% per annum through December 15, 2024 and 6.86% thereafter. As of December 31, 2024, the note had an outstanding principal of \$1,455,416 and accrued interest of \$46,817.

Convertible Note

On July 24, 2024, the Company entered into a securities purchase agreement with an accredited investor (the “July Note Holder”), pursuant to which the Company issued to the July Note Holder a senior unsecured convertible note (the “July Note”) in the aggregate principal amount of \$750,000, which is convertible into shares of Common Stock. The July Note accrues interest at a rate of 6% per annum (which increases to 12% in the event of a default) and matures on August 24, 2025 (the “July Note Maturity Date”). Interest is guaranteed through the July Note Maturity Date regardless of whether the July Note is earlier converted or redeemed. The July Note is convertible by the holder thereof in whole or in part at any time after issuance and prior to the July Note Maturity Date into shares of Common Stock based on a conversion price (the “July Note Conversion Price”) of \$1.506 per share (the “July Note Conversion Shares”), which cannot be reduced below \$0.231 per share, and is subject to customary adjustments for stock splits, stock dividends, recapitalization and other similar transactions. Notwithstanding the foregoing, such conversions are subject to (i) a 4.99% beneficial ownership limitation contained in the Note, which may be increased to 9.99% upon 61 days’ prior written notice to the Company by the July Note Holder, and (ii) the Exchange Cap (as defined below). The Company has agreed to hold a meeting of its stockholders to seek approval of a waiver of the Exchange Cap - no later than ninety (90) days from July 24, 2024. Under the applicable rules of the NYSE American LLC, in no event may the Company issue to July Note Holder and any of its affiliates under the CEF Purchase Agreement (as defined below), or otherwise, more than 1,152,764 shares of Common Stock, which number of shares represents 19.99% of the shares of the Common Stock outstanding immediately prior to the execution of the CEF Purchase Agreement (the “Exchange Cap”).

The July Note is redeemable by the Company in whole or in part at any time after issuance and prior to the July Note Maturity Date in cash at a price equal to 110% of the greater of (i) the July Note Note's outstanding principal amount, plus all accrued but unpaid interest and late charges due under the July Note (the "July Note Conversion Amount") being redeemed as of the date on which such redemption will occur (the "Company Optional Redemption Date") and (ii) the product of (1) the number of July Note Conversion Shares then issuable under the July Note multiplied by (2) the highest closing sale price of the Common Stock on any trading day during the period commencing on the date immediately preceding the date of the Company Optional Redemption Notice (as defined below) and ending on the trading day immediately prior to the date the Company makes the entire payment. The Company may deliver only one notice to exercise its right to require redemption (the "Company Optional Redemption Notice") in any given 20 trading day period and each Company Optional Redemption Notice is irrevocable. At any time prior to the date on which such optional redemption payment is paid in full, the July Note may be converted by the July Note Holder into shares of Common Stock in accordance with the conversion terms thereof.

As of December 31, 2024, there was \$199 in accrued interest and \$127,426 in unamortized debt discount on the note. Interest expense totaled \$19,418 for the year ended December 31, 2024, compared to \$0 for year ended December 31, 2023. The Company recognized \$86,390 and \$0, respectively, of amortization of debt discount included in interest expense on the statements of operations for the years ended December 31, 2024 and 2023. As of December 31, 2024 there as \$726,212 in outstanding principal on this note.

Waiver of Exchange Cap

On October 22, 2024, the affirmative vote of a majority of the outstanding shares of Common Stock present in person, by remote communication, if applicable, or represented by proxy at the Annual Meeting approved the waiver of the Exchange Cap in connection with the July Note and the CEF Purchase Agreement.

Outstanding Principal on Notes

<i>Loan Payable</i>	Outstanding Principal	Unamortized Debt Discount	Outstanding Principal, net of Debt Discount
May Promissory Note	\$ 1,455,416	\$ —	\$ 1,455,416
Convertible Note	726,212	(127,426)	598,786
Total as of December 31, 2024	<u>\$ 2,181,628</u>	<u>\$ (127,426)</u>	<u>\$ 2,054,202</u>

<i>Loan Payable</i>	Outstanding Principal	Unamortized Debt Discount	Outstanding Principal, net of Debt Discount
Investor Note	\$ 205,008	(2,729)	\$ 202,279
Total as of December 31, 2023	<u>\$ 205,008</u>	<u>\$ (2,729)</u>	<u>\$ 202,279</u>

<i>Investor Loan</i>	<u>Outstanding Principal</u>	<u>Unamortized Debt Discount</u>	<u>Outstanding Principal, net of Debt Discount</u>
Investor Note	\$ 450,000	(133,676)	\$ 316,324
Total as of December 31, 2023	<u>\$ 450,000</u>	<u>\$ (133,676)</u>	<u>\$ 316,324</u>

NOTE 6 – STOCKHOLDERS’ EQUITY

Initial Public Offering

On February 21, 2024, the Company completed its IPO and issued 1,100,000 shares of Common Stock at a price of \$6.00 per share. The aggregate net proceeds from the IPO were approximately \$5.9 million after deducting approximately \$0.9 million of underwriting discounts and commissions and offering expenses.

Stock Split

On February 15, 2024, the Company effected a 9-for-1 reverse stock split. All share and per share amounts have been retrospectively adjusted for the reverse stock split.

2023 Plan Amendment

On June 12, 2024, the Board authorized an amendment to the Chromocell Therapeutics Corporation 2023 Equity Incentive Plan (the “2023 Plan”) to increase the number of shares of Common Stock authorized for issuance thereunder by 1,500,000 from 444,444 shares to 1,944,444 shares. On October 22, 2024, the 2023 Plan Amendment was approved by the affirmative vote of a majority of the outstanding shares of Common Stock present in person, by remote communication, if applicable, or represented by proxy at the Annual Meeting.

Share Forfeiture

Pursuant to the terms of the April Bridge Financing, Chromocell Holdings forfeited 133,745 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.

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 4,167 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 a 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.

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 \$0.1008 (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 2,533,853 shares of Common Stock and received aggregate net proceeds of \$255,412, after giving effect to the Representative Affiliate Transactions (as defined below), which it intended to use primarily for general corporate purposes and expenses associated with the IPO.

Rescission Agreement

On February 10, 2024, the Company entered into a Stock Rescission Agreement with certain affiliates of A.G.P. pursuant to which the Company rescinded 111,129 shares of Common Stock held by such affiliates of A.G.P. and agreed to refund an aggregate of \$91,512 paid by such affiliates of A.G.P. in consideration therefor within 30 days of the effective date of the Stock Rescission Agreement. At December 31, 2024, all such amounts have been paid pursuant to the Representative Affiliate Transactions and there are no remaining obligations thereto.

Equity Issuances

On June 12, 2024, the Company issued 50,000 shares of Common Stock to a vendor in considerations for the services provided by the vendor to the Company.

On June 12, 2024, the Company entered into a twelve-month agreement with a vendor to issue up to 7,500 share of Common Stock per month for services performed by such vendor. As of December 31, 2024, the Company has issued 51,187 shares of Common Stock pursuant to this agreement.

On August 12, 2024, the Company issued 10,000 shares of Common Stock to a vendor in exchange for outstanding invoices related to services provided by the vendor to the Company, with such shares issued on October 22, 2024.

On October 22, 2024, the Company issued 50,000 shares of Common Stock to a vendor in considerations for the services provided by the vendor to the Company.

On November 18, 2024, the Company issued 25,000 shares of Common Stock to a vendor in considerations for the services provided by the vendor to the Company.

During the year ended December 31, 2024, the Company issued 16,667 shares of Common Stock to a vendor in considerations for the services provided by the vendor to the Company, with such shares granted on October 22, 2024.

Committed Equity Financing

On July 26, 2024, the Company entered into a Common Stock Purchase Agreement, dated as of July 26, 2024 (the “CEF Purchase Agreement”), with Tikkun Capital LLC (“Tikkun”), providing for a committed equity financing facility, pursuant to which, upon the terms and subject to the satisfaction of the conditions contained in the CEF Purchase Agreement, Tikkun has committed to purchase, at the Company’s direction in its sole discretion, up to an aggregate of \$30,000,000 (the “Total Commitment”) of the shares of Common Stock (the “Purchase Shares”), subject to certain limitations set forth in the CEF Purchase Agreement, from time to time during the term of the CEF Purchase Agreement. Concurrently with the execution of the CEF Purchase Agreement, the Company and Tikkun also entered into a Registration Rights Agreement, dated as of July 26, 2024, pursuant to which the Company agreed to file with the SEC one or more registration statements, to register under the Securities Act, the offer and resale by Tikkun of all of the Purchase Shares that may be issued and sold by the Company to Tikkun from time to time under the CEF Purchase Agreement.

Stock Repurchase Plan

On August 5, 2024, the Board authorized a stock repurchase plan (the “Repurchase Plan”) pursuant to which up to \$250,000 of the Company’s Common Stock may be repurchased prior to December 31, 2024, unless completed sooner or otherwise extended. During the year ended December 31, 2024, the Company repurchased 86,196 shares of Common Stock for \$75,000. The 86,186 shares of Common Stock repurchased by the Company were subsequently cancelled. Open market purchases are intended to be conducted in accordance with applicable Securities and Exchange Commission regulations, including the guidelines and conditions of Rule 10b-18 and Rule 10b5-1 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). The timing and actual number of shares repurchased will depend on a variety of factors including trading price, the Company’s financial performance, corporate and regulatory requirements and other market conditions.

Repurchase Plan Amendment

On October 22, 2024, the Board authorized an amendment (the “Amendment”) to the Repurchase Plan to increase the total value of shares of Common Stock available for repurchase by the Company under the Repurchase Plan by an additional \$500,000, to \$750,000. In addition, the Amendment extended the termination date of the Repurchase Plan from December 31, 2024 to June 30, 2025, prior to which Common Stock may be repurchased, unless completed sooner or otherwise extended.

Chromocell Holdings Share Transfers

On December 18, 2024, 747,187 shares of Common Stock and 2,600 shares of Series C Preferred Stock held by Chromocell Holdings were transferred by the Company to Alexandra Wood (Canada) Inc. (“AWI”) in satisfaction of a default judgement against Chromocell Holdings regarding the default by Chromocell Holdings of a secured promissory note by order of the Supreme Court of the State of New York, County of New York on November 25, 2024 in the matter *Alexandra Wood (Canada) Inc v. Chromocell Corp., Index No. 651735/2024*. AWI subsequently transferred 173,000 shares of Chromocell Holding’s Common Stock that it received such that AWI now owns 574,187 shares of the Common Stock originally issued to Chromocell Holdings in connection with the Contribution Agreement.

Options

During the year ended December 31, 2024, the Company granted a total of 684,000 stock options related to the Company’s common stock. These stock options had a life of 10 years and an exercise price of \$1.30 or \$0.73 per option. During the year ended December 31, 2023, the Company granted a total of 158,670 stock options. These stock options had a life of 10 years and an exercise price of \$22.68 per option.

During the years ended December 31, 2024 and 2023, the fair value of each stock option granted was estimated using the Black-Scholes Option Pricing Model using the following inputs:

	For the Year Ended December 31, 2024	For the Year Ended December 31, 2023
Exercise price	\$ 0.73-1.30	\$ 22.68
Expected dividend yield	0%	0%
Risk free interest rate	4.20%	3.50-3.93%
Expected life in years	10	10
Expected volatility	196-201%	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 1,187,302 shares (on an as converted basis reflecting the conversion of the 600,000 Series A Convertible Preferred Stock held by Chromocell Holdings). As of December 31, 2024, all of the Series A Convertible Preferred Stock shares have been converted. The resulting value per share of common stock was \$37.71. The Company then adjusted this value in accordance with the following:

Value of intellectual property	\$	44.8 million
Common shares outstanding (as converted)		1,187,302
Value per common share	\$	37.71
Illiquidity discount		20%
Minority discount		20%
Fair value of the common stock	\$	22.68

After the completion of the Company's IPO, the trading price of the Company's Common Stock is used as the fair value of the Company's Common Stock.

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 forfeiture rates.

The following is an analysis of the stock option grant activity:

<i>Stock Options</i>	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Life
Outstanding December 31, 2023	197,560	\$ 22.68	9.08
Granted	684,000	\$ 1.26	10.00
Expired	(11,111)	\$ (22.68)	—
Exercised	—	\$ —	—
Outstanding December 31, 2024	870,449	\$ 5.85	9.19
Exercisable December 31, 2024	309,521	\$ 11.14	9.38

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Life
Stock Options			
Outstanding December 31, 2022	50,002	\$ 22.68	9.76
Granted	158,670	\$ 22.68	9.16
Expired	(11,111)	\$ 22.68	—
Exercised	—	\$ —	—
Outstanding December 31, 2023	197,560	\$ 22.68	9.08
Exercisable December 31, 2023	84,131	\$ 22.68	8.98

A summary of the status of the Company's nonvested options as of December 31, 2024, and 2023, and changes during years ended December 31, 2024, and 2023, is presented below:

Non-vested Options	Options	Weighted- Average Exercise Price
Non-vested at December 31, 2023	113,429	\$ 22.68
Granted	684,000	\$ 1.26
Vested	(236,501)	\$ 7.58
Forfeited	—	\$ —
Non-vested at December 31, 2024	560,928	\$ 2.93

Non-vested Options	Options	Weighted- Average Exercise Price
Non-vested at December 31, 2022	45,556	\$ 22.68
Granted	158,670	\$ 22.68
Vested	(90,797)	\$ 22.68
Forfeited	—	\$ —
Non-vested at December 31, 2023	113,429	\$ 22.68

The total number of options granted during the years ended December 31, 2024 and 2023 was 684,000 and 158,670, respectively. The exercise price for these options was \$0.73, \$1.30 or \$22.68 per share. There was an intrinsic value of \$0 and \$0 as of December 31, 2024 and 2023, respectively.

The Company recognized stock-based compensation expense related to option vesting amortization of \$1,455,561 and \$1,733,233 for the years ended December 31, 2024 and 2023, respectively, which is included in general and administrative expenses in the consolidated statements of operations.

As of December 31, 2024, the unamortized stock option expense was \$1,295,319. As of December 31, 2024, the weighted average period for the unamortized stock compensation to be recognized is 1.75 years.

Warrants

The following is an analysis of the stock warrant grant activity:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Life
Stock Warrants			
Outstanding December 31, 2023	—	\$ —	—
Granted	55,000	\$ 7.50	4.99
Expired	—	\$ —	—
Exercised	—	\$ —	—
Outstanding December 31, 2024	55,000	\$ 7.50	4.13
Exercisable December 31, 2024	55,000	\$ 7.50	4.38

A summary of the status of the Company's nonvested warrants as of December 31, 2024, and changes during the year ended December 31, 2024, is presented below:

Non-vested Warrants	Warrants	Weighted-Average Exercise Price
Non-vested at December 31, 2023	—	\$ —
Granted	55,000	\$ 7.50
Vested	(55,000)	\$ 7.50
Forfeited	—	\$ —
Non-vested at December 31, 2024	<u>—</u>	<u>\$ —</u>

The total number of warrants granted during the years ended December 31, 2024 and 2023 was 55,000 and 0, respectively. The exercise price for these warrants was \$7.50 per share and there was an intrinsic value of \$0.

The Company recognized stock-based compensation expense related to warrant vesting amortization of \$0 and \$0 for the years ended December 31, 2024 and 2023, respectively.

On February 21, 2024, the Company issued warrants to purchase up to 55,000 shares of Common Stock to the representative of the underwriters of the IPO (the "Representative"). These warrants have an exercise price of \$7.50, have a cashless exercise provision, are exercisable 180 days following the commencement of sales of the shares of Common Stock of the IPO and have an expiration date of February 21, 2029. No expense was recognized to the warrants issued to such warrants from the IPO as these warrants constituted offering costs of the IPO.

RSUs

A summary of the status of the Company's nonvested RSUs as of December 31, 2024, and changes during the year ended December 31, 2024, is presented below:

Non-vested RSUs	RSUs	Weighted-Average Exercise Price
Non-vested at December 31, 2023	—	\$ —
Granted	356,664	\$ 1.12
Vested	64,498	\$ (1.30)
Forfeited	—	\$ —
Non-vested at December 31, 2024	<u>292,166</u>	<u>\$ 1.08</u>

The total number of RSUs granted during the years ended December 31, 2024 and 2023 was 356,664 and 16,667, respectively. The exercise price for these RSUs was \$0.64 or \$1.30 per share.

On June 23, 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 16,667 shares of common stock was cancelled, and the Company agreed to grant Camden Capital LLC an option to acquire 27,778 shares of common stock within 30 days of the closing of the IPO. As of June 23, 2023, such RSU for 16,667 shares of common stock had not vested, and no expense was recorded on the Company's financial statements.

The Company recognized stock-based compensation expense related to warrant vesting amortization of \$104,484 and \$0 for the years ended December 31, 2024 and 2023, respectively, which is included in general and administrative expenses in the consolidated statements of operations.

NOTE 7 – LEGAL

Demand Letter from Mr. Kopfli’s Attorney

On February 14, 2024, the Board received a demand letter from an attorney representing Chromocell Holdings and the Company’s former Chief Executive Officer and former Chief Strategy Officer, Mr. Christian Kopfli, who was released for “cause” as disclosed elsewhere in this Report. Mr. Kopfli alleged an improper termination for “cause” and claimed to seek monetary damages in the amount of \$479,169. Of the \$479,169 asserted by Mr. Kopfli, as of December 31, 2024, the Company had accrued \$363,091 in compensation expenses associated with Mr. Kopfli’s prior employment with the Company. However, the Company believed the assertions made by Mr. Kopfli are without merit and commenced a lawsuit against Mr. Kopfli and Chromocell Holdings in New York Action, asserting causes of action against Mr. Kopfli for breach of the Employment Agreement entered into on January 10, 2023 between the Company and Mr. Kopfli, breach of fiduciary duty by Mr. Kopfli, as well as breach of contract against Chromocell Holdings in connection with the Contribution Agreement between the Company and Chromocell Holdings. The Company also asserted a “faithless servant” claim against Mr. Kopfli, seeking a ruling that Mr. Kopfli was not entitled to compensation from the Company. The Company sought monetary damages against Mr. Kopfli and Chromocell Holdings in the New York Action, plus disgorgement of all compensation previously paid or accrued to Mr. Kopfli by the Company.

By Order dated October 3, 2024, the court in the New York Action awarded the Company a default judgment against Mr. Kopfli and Chromocell Holdings on all claims, and ordered an assessment of damages against Mr. Kopfli and Chromocell Holdings (currently scheduled to be held in May 2025). As of December 31, 2024, the Company has removed the accrual of \$363,091 in compensation expenses and recorded a gain on default judgement in the same amount.

Parexel Claim

On July 31, 2024, the Company received a demand letter from an attorney representing Parexel International (IRL) Limited (“Parexel”). The letter, which was addressed to both the Company and Chromocell Holdings, purports to be a notice of default of a note (the “Promissory Note”) between Chromocell Holdings and Parexel and seeks the payment of allegedly unpaid principal in the amount of \$682,551 plus interest exceeding \$177,000. The Company denies that it is liable for any of the amounts sought by Parexel; the Company is not a party to the Promissory Note and does not believe it is liable for any amounts allegedly due thereunder. The Company intends to defend itself vigorously in the matter.

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 consolidated 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, 2024 and 2023, 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 consolidated financial statements is as follows:

	2024	2023
Income taxes at U.S. statutory rate	21.00%	19.11%
Income taxes at state rate	—%	9.00%
Change in valuation allowance	(21.00)%	(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, 2024 and 2023 are comprised of the following:

	December 31,	
	2024	2023
Deferred tax assets		
Net operating loss carryforwards	\$ 4,297,287	\$ 2,248,163
Stock-based compensation	470,245	518,174
Accrued compensation	—	181,576
Capitalized organizational costs	—	22,016
Capitalized intellectual property costs	—	620,440
Interest expense limitation	24,664	36,202
Capitalized R&D	799,623	—
Total deferred tax assets	5,591,819	3,626,571
Valuation allowance	(5,591,819)	(3,626,571)
Net deferred tax assets	—	—
Deferred tax liabilities		
Total deferred tax liabilities	—	—
Net deferred taxes	\$ —	\$ —

For the years ended December 31, 2024 and 2023, the Company recorded a full valuation allowance of its deferred tax assets.

The Company has a net operating loss carryforward for federal tax purposes totalling approximately \$16.4 million at December 31, 2024. Approximately \$16.4 million net operating losses incurred in fiscal 2018 through fiscal 2024 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 – SEGMENT DISCLOSURE

The clinical-stage biotech segment 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", which has been genetically validated as a pain receptor in human physiology. 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. This segment is currently pre-revenue.

The accounting policies of the clinical-stage biotech segment are the same as those described in the summary of significant accounting policies.

The chief operating decision maker assesses performance for the clinical-stage biotech segment and decides how to allocate resources based on net loss that also is reported on the statement of operations as consolidated net loss.

The measure of segment assets is reported on the balance sheet as total assets.

The chief operating decision maker uses net loss to evaluate spending in deciding how funds should be allocated in performing the Company's research and development. Net loss is used to monitor budget versus actual results.

The Company has one reportable segment: clinical-stage biotech. This segment performs research and development for biotech products. Since the Company only has one segment, the segment information is the same as the consolidated financials.

The Company's chief operating decision maker is the chief executive officer, with such individual also holding the position of chief financial officer.

NOTE 10 – SUBSEQUENT EVENTS

Bridge Note

On February 25, 2025, the Company issued an unsecured promissory note in the aggregate principal amount of \$325,000 (the "Bridge Note") to 3i, L.P., a Delaware limited partnership (the "Holder"), for a purchase price of \$250,000, pursuant to which the Company promises to pay the Holder or its registered assigns the principal sum of \$325,000 or such amount equal to the outstanding principal amount of the Note together with interest. The Note will bear interest on the outstanding principal amount at an annual rate equal to 6.0%. The Note may be prepaid by the Company without penalty, in whole or in part, upon two days' prior written notice to the Holder. All unpaid principal, together with any then unpaid and accrued interest and other amounts payable under the Note, will otherwise be due and payable on the earliest of: (i) May 25, 2025, (ii) the consummation of a Corporate Event (as defined in the Note), or (iii) when, upon or after the occurrence of an Event of Default (as defined in the Note), such amounts are declared due and payable by the Holder or made automatically due and payable in accordance with the terms of the Note.

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM'S CONSENT

We consent to the incorporation by reference in the Registration Statement of Channel Therapeutics Corporation on Form S-8 (File No. 333-278674), Form S-1 (File No. 333-281070) and Form S-1 (File No. 333-269188) of our report dated March 27, 2025, which includes an explanatory paragraph as to the Company's ability to continue as a going concern, with respect to our audits of the financial statements of Channel Therapeutics Corporation as of December 31, 2024 and 2023, and for the years ended December 31, 2024 and 2023, which report is included in this Annual Report on Form 10-K of Channel Therapeutics Corporation for the year ended December 31, 2024.

/s/ Marcum LLP

Marcum LLP
Hartford, CT
March 27, 2025

**CERTIFICATION
OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002**

I, Francis Knuettel II, certify that:

1. I have reviewed this annual report on Form 10-K of Channel Therapeutics Corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 27, 2025

By: /s/ Francis Knuettel II

Francis Knuettel II
Chief Executive Officer and Chief Financial Officer
(Principal Executive Officer and Principal Financial Officer)

**CERTIFICATION
OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906 OF
THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report of Channel Therapeutics Corporation (the "Company") on Form 10-K for the period ended December 31, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Francis Knuettel II, Chief Executive Officer and Chief Financial Officer of Channel Therapeutics Corporation, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 27, 2025

By: /s/ Francis Knuettel II

Francis Knuettel II
Chief Executive Officer and Chief Financial Officer
(Principal Executive Officer and Principal Financial Officer)
