As submitted confidentially to the Securities and Exchange Commission on September 6, 2022, pursuant to the Jumpstart Our Business Startups Act of 2012. This draft registration statement has not been publicly filed with the Securities and Exchange Commission and all information herein remains strictly confidential.

Registration No. 333-

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

FORM S-1
REGISTRATION STATEMENT
under
The Securities Act of 1933

CHROMOCELL THERAPEUTICS CORPORATION
(Exact name of registrant as specified in its charter)

Delaware	**2836**	**86-3335449**
(State or other jurisdiction of incorporation or organization)	**(Primary Standard Industrial Classification Code Number)**	**(I.R.S. Employer Identification Number)**

675 US Highway Route 1 South
North Brunswick, NJ 08906
732-514-2636
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Christian Kopfli
Chief Executive Officer
675 US Highway Route 1 South
North Brunswick, NJ 08906
Tel. No.: 732-514-2636
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

David E. Danovitch, Esq. **Aaron M. Schleicher, Esq.** **Sullivan & Worcester LLP** **1633 Broadway** **New York, NY 10019** **(212) 660-3060**	**Thomas J. Poletti, Esq.** **Veronica Lah, Esq.** **Manatt, Phelps & Phillips, LLP** **695 Town Center Drive, 14th Floor** **Costa Mesa, CA 92626 (714) 371-2500**

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

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the following box: ☒

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

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

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

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

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Exchange Act. ☐

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

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

PROSPECTUS

SUBJECT TO COMPLETION, DATED SEPTEMBER 6, 2022

UNITS

EACH UNIT CONSISTING OF ONE SHARE OF COMMON STOCK
AND ONE WARRANT TO PURCHASE ONE SHARE OF COMMON STOCK

This is an initial public offering of units (the "Units"), each Unit consisting of one share of common stock, par value $0.0001 per share (the "Common Stock"), of Chromocell Therapeutics Corporation ("Chromocell", the "Company", "we", "us" or "our"), and one warrant to purchase one share of our Common Stock (the "Warrants"). The Warrants included in the units are immediately exercisable following the consummation of this offering, have an exercise price equal to the initial public offering price, and expire five years from the date of issuance. The Common Stock and Warrants are immediately separable and will be issued separately in this offering. The shares of Common Stock and Warrants may be transferred separately immediately upon issuance.

Prior to this offering, there has been no public market for our common stock or warrants. The warrants included in the units are immediately exercisable following the consummation of this offering, have an exercise price equal to the initial public offering price, and expire five years from the date of issuance. We intend to apply for the listing of our common stock and warrants on The Nasdaq Capital Market under the symbols " " and " W," respectively.

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

Investing in shares of our securities involves a high degree of risk. You should review carefully the risks and uncertainties described under the heading "Risk Factors" beginning on page 9 of this prospectus and under similar headings in any amendments or supplements to this prospectus. Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

	Per Unit	*Total*[1]
Initial public offering price	$	$
Underwriting discounts and commissions[2]	$	$
Proceeds, before expenses, to us	$	$

(1) Assumes no exercise of the over-allotment option by the underwriters.
(2) See "Underwriting" for a description of the compensation payable to the underwriters.

We have granted the underwriters an over-allotment option, exercisable for 30 days from the date of this prospectus, which provides them with the right to purchase up to an additional Units, less the underwriting discounts and commissions to cover over-allotments, if any.

The underwriters expect to deliver the securities against payment in New York, New York on , 2022.

Lead Managing Underwriter

The Benchmark Company

The date of this prospectus is , 2022

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ABOUT THIS PROSPECTUS

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

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

Solely for convenience, our trademarks and tradenames referred to in this prospectus and the registration statement of which it forms a part may appear without the ® or ™ symbols, but such references are not intended to indicate in any way that we will not assert, to the fullest extent under applicable law, our rights to these trademarks and tradenames.

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

INDUSTRY AND MARKET DATA

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

BASIS OF PRESENTATION

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

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

In connection with the completion of this offering, we will effect a -for- stock split with respect to our Common Stock. In addition, in connection with completion of this offering, all 600,000 issued and outstanding shares of our Series A Convertible Preferred Stock will automatically convert into shares of Common Stock and Warrants (based on an assumed initial public offering price of $, the midpoint of the price range set forth on the cover page of this prospectus). We refer to these actions as the "IPO Transactions." In this prospectus, we include certain metrics on an "as adjusted" basis to give effect to the IPO Transactions.

PROSPECTUS SUMMARY

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

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

Our Business

Overview

We are a clinical-stage biotech company focused on developing and commercializing new therapeutics to alleviate pain. Our clinical focus is on the selectively targeting the sodium ion-channel known as "NaV1.7", as well as other receptors in the NaV family. NaV1.7 has been genetically validated as a pain receptor in human physiology. Genetic studies have shown that families with a certain inherited NaV1.7 modulation consistently show a pathology of not feeling pain. A NaV1.7 blocker is a chemical entity that modulates the structure of the sodium-channel in a way to prevent the transmission of pain perception to the central nervous system ("CNS"). Our goal is to develop a novel and proprietary class of NaV blockers that target the body's peripheral nervous system and have demonstrated safety in a Phase 1 study. Our lead candidate, CC8464, has a good safety and tolerability profile in Phase 1 clinical trials. We currently plan to begin Phase 2a studies for CC8464 in 2023.

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

Our lead compound, CC8464, is designed to produce pain relief by specifically blocking the NaV1.7 sodium channel. The chemical characteristics of CC8464 restrict its entry into the CNS and limit its effect to the NaV1.7 receptors in the peripheral nervous system, which consists of the nerves outside the brain and spinal cord. Activation of other receptors in the CNS can result in side effects, including addiction and other psychiatric disorders. Since CC8464 is designed to modulate pain signals without activation of receptors in the CNS, it is not expected to produce psychiatric side effects. Based on its characteristics, preclinical studies and the Phase 1 study we have completed to date, we believe that our lead candidate CC8464, if approved, could become an attractive option for both patients and physicians as a treatment for moderate-to-severe pain. If approved, CC8464 could provide pain relief while reducing the incidence of opioid-related adverse events and avoiding abuse and addiction issues associated with currently approved opioid analgesics.

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 approximately 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 were 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 that showed a good safety profile of the compound.

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

Chromocell Therapeutics Corporation (the "Company," "we," "us" and "our") was incorporated in Delaware on March 19, 2021. Our principal executive offices are located at 675 US Route 1 South, North Brunswick, NJ 08906, and our telephone number is (732) 514-2636. Our website is . Information contained on, or that can be accessed through, our website is not incorporated by reference into this prospectus, and you should not consider information on our website to be part of this prospectus.

Implications of Being an Emerging Growth Company

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

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

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

- the last day of the fiscal year on which we have $1.07 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 this offering.

We have elected to take advantage of certain of the reduced disclosure obligations regarding financial statements (such as not being required to provide audited financial statements for the fiscal year ended December 31, 2019) in this prospectus and executive compensation in this prospectus and expect to elect to take advantage of other reduced burdens in future filings.

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

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

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

Summary of Risks Associated with Our Business

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

- we have a limited operating history, have incurred losses since inception and expect to incur losses for the foreseeable future and may never achieve or maintain profitability;
- we will need to raise additional funding in order to receive approval for CC8464 or any other lead candidates that we may develop;
- we are early in our efforts to develop CC8464, and if we are unable to advance development through clinical trials, obtain regulatory approval in the United States or abroad and ultimately commercialize CC8464, or if we experience significant delays in doing so, our business will be materially harmed;
- there is no guarantee that the results from prior clinical and preclinical studies will be indicative of our ability to complete studies or the results to be obtained in the current or future studies and clinical trials;
- CC8464 may cause undesirable side effects or have other properties that could delay or prevent its regulatory approval, limit the commercial potential or result in significant negative consequences following any potential marketing approval;
- we plan to apply for orphan drug designation for CC8464; however, it may not effectively protect us from competition, and we may be unable to obtain similar designations for our future lead candidates. Even if such designation is granted for CC8464 or if Breakthrough Therapy designation, and/or Fast Track designation is granted for CC8464, this may not lead to a faster development, regulatory review or approval process and may not increase the likelihood that any of our lead candidates will receive approval in the United States;

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

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

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

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

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

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

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

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

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

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

- if our listing application for our Common Stock is not approved by Nasdaq, we will not be able to consummate the offering and will terminate this offering. Even if we are approved to list our Common Stock on Nasdaq, failure to maintain such listing could materially adversely affect the value of our Common Stock;

- even if we are able to effect a stock split of our shares of Common Stock to meet Nasdaq's initial listing requirements, we cannot assure you that we will be able to continue to comply with Nasdaq's listing standards. Further, potential investors may not have an opportunity to check the actual post-split market price of our Common Stock prior to confirming their purchases in this offering;

- if you receive shares of Common Stock included in the Units in this offering, you will suffer immediate dilution of your investment, and a significant portion of our shares of Common Stock 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;

- the price of our Common Stock may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock in this offering;

- we will incur increased costs as a result of operating as a smaller reporting public company, and our management will be required to devote substantial time to new compliance efforts;

- we have broad discretion in the use of our cash, including the net proceeds from this offering, and may not use them effectively;

- there is no current public market for Common Stock included in the Units or the Warrants included in the Units, the Warrants included in the Units in this offering are speculative in nature and holders of the Warrants included in the Units will not have rights of holders of our shares of Common Stock until such Warrants are exercised; and

- the other factors set forth under "Risk Factors."

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

THE OFFERING

Units offered by us	Units. Each Unit will consist of one share of our Common Stock and one Warrant to purchase one share of our Common Stock. The Common Stock and Warrants are immediately separable and will be issued separately in this offering. The Units will not be certificated, and the share of Common Stock and the Warrant included in each Unit may be transferred separately, immediately upon issuance. Each Warrant will be immediately exercisable following the consummation of this offering and will expire five years from the date of issuance. Each Warrant will have an exercise price per share equal to the initial public offering price per unit (subject to appropriate adjustment in the event of recapitalization events, stock dividends, stock splits, stock combinations, reclassifications, reorganizations or similar events). The Warrants also provide that in the event of a fundamental transaction we are required to cause any successor entity to assume our obligations under the Warrants. In addition, the holder of the Warrant will be entitled to receive upon exercise of the Warrant the kind and amount of securities, cash or property that the holder would have received had the holder exercised the warrant immediately prior to such fundamental transaction. This prospectus also relates to the offering of the shares of Common Stock issuable upon exercise of the Warrants.
Option to purchase additional Units	We have granted the underwriters a 30-day option to purchase up to an additional Units from us at the initial public offering price, less the underwriting discount.
Common Stock to be outstanding immediately following this offering	shares of Common Stock (or shares if the underwriters' option to purchase additional Units is exercised in full).
Use of proceeds	We estimate that the net proceeds from the sale of our Units in this offering will be approximately $ million (or approximately $ million if the underwriters' option to purchase additional Units is exercised in full), based on an assumed initial public offering price of $ per Unit, the midpoint of the price range set forth on the cover page of this prospectus, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. We intend to use approximately $ million of the net proceeds from this offering to fund our continued research and product development of CC8464. We intend to use the remaining net proceeds from this offering, if any, for general corporate purposes. See "Use of Proceeds."
Lock-up	In connection with our initial public offering, we, our directors, executive officers, and our principal stockholders have agreed not to offer, issue, sell, contract to sell, encumber, grant any option for the sale of or otherwise dispose of any of our securities for a period of six months following the closing of the offering of the Units. See "Underwriting."

Representative's Warrants	We will issue to The Benchmark Company, as representative of the underwriters or its designees, at the closing of this offering warrants purchasing the number of shares of common stock equal to 3% of the aggregate number of shares of common stock sold in this offering. The representative's warrant will be exercisable immediately and will expire five years after the effective date of the registration statement for this offering. The exercise price of the representative's warrant will equal % of the public offering price per share. See "Underwriting."
Risk factors	See "Risk Factors" and other information included in this prospectus for a discussion of factors you should consider carefully before deciding to invest in our securities.
Transfer agent and registrar; Warrant agent	Our transfer agent and registrar for our Common Stock and our Warrant agent is , located at .
Proposed Nasdaq symbols	We intend to apply to list our Common Stock and Warrants on Nasdaq under the symbols " " and " W", respectively.

Unless we specifically state otherwise or the context otherwise requires, the share information in this prospectus is based on an aggregate of 10,000,000 shares of Common Stock outstanding as of , 2022, and:

- gives effect to the IPO Transactions, which include: (i) a 1-for- stock split of Common Stock; and (ii) the issuance of shares of Common Stock upon conversion of all issued and outstanding shares of Series A Preferred Stock, assuming an initial public offering price of $ per Unit, the midpoint of the price range set forth on the cover page of this prospectus;
- gives effect to the issuance of Units in this offering, each Unit consisting of one share of Common Stock and one Warrant;
- assumes no exercise of the underwriters' option to purchase up to an additional Units from us in this offering;
- assumes no exercise of the Warrants included in the Units sold in this offering;
- assumes no exercise of the Warrants issued upon conversion of all issued and outstanding shares of our Series A Preferred Stock, assuming an initial public offering price of $ per Unit, the midpoint of the price range set forth on the cover page of this prospectus;
- assumes no exercise of the Underwriters' Warrants issued in this offering;
- assumes no exercise of the Advisor Warrants (as defined in "Underwriting") issued in this offering; and
- does not reflect shares of Common Stock that are reserved for future grants or sale under our new omnibus equity incentive plan, which amount includes .

SUMMARY HISTORICAL FINANCIAL DATA

The following tables summarize our financial data as of and for the periods indicated. The statements of operations data for the years ended December 31, 2021 and 2020, and the balance sheet data as of December 31, 2021, are derived from the audited financial statements included elsewhere in this prospectus. These historical results have been prepared on a carve-out basis and are not necessarily indicative of results that may be expected in the future. Please see "Basis of Presentation" in the forepart of this prospectus for more information.

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

	For the Year Ended December 31,	
	2021	**2020**
Statements of Operations Data:		
REVENUE		
Grant revenue	-	199,934
Total Revenue	-	199,934
OPERATING EXPENSES		
General and administrative expenses	496,667	1,323,120
Research and development	209,047	138,585
Professional fees	133,282	92,096
Total Operating Expenses	838,996	1,553,801
NET LOSS FROM OPERATIONS	(838,996)	(1,353,867)
OTHER INCOME (EXPENSE)		
Interest expenses	(253)	(1,676)
Gain on forgiveness of PPP loan	243,862	-
Gain of sale of NOL tax credit	-	694,959
Total Other Income	243,609	693,283
Net loss before provision for income taxes	(595,387)	(660,584)
Provision for Income Taxes	-	-
NET INCOME (LOSS)	(595,387)	(660,584)
Pro forma net income per common share, basic[(1)] (unaudited)		
Pro forma net income per common share, diluted[(1)] (unaudited)		
Weighted-average shares used to compute pro forma net income per common share, basic[(1)]		
Weighted- average shares used to compute pro forma net income per common share, diluted[(1)]		
Balance Sheet Data:		
Total assets	-	71,872
Total liabilities	3,680,267	3,649,813
Parent's net deficit	(3,680,267)	(3,577,941)
Total liabilities and parent's net deficit	-	71,872

(1) Gives effect to the transactions contemplated by the Contribution Agreement and the IPO Transactions, as if each occurred on January 1, 2021.

RISK FACTORS

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

Risks Related to Our Business

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 lead candidates, conducting preclinical and clinical studies of CC8464 for erythromelalgia ("EM") and other pain indications. We have not yet demonstrated the ability to successfully complete a large-scale, pivotal clinical trial, obtain marketing approval, manufacture a commercial scale product, arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, predictions about our future success or viability may not be as accurate as they could be if we had a history of successfully developing and commercializing pharmaceutical products.

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

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

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

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

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

We have had net losses since inception, and we had an accumulated deficit of approximately $3.7 million as of December 31, 2021, which includes a net loss of approximately $0.6 million for the year ended December 31, 2021. As a result, these conditions have raised substantial doubt regarding our ability to continue as a going concern beyond one year of the filing of our financial statements. 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, licensing arrangements and government grants. Our ability to achieve significant profitability depends on our ability to successfully complete the development of, and obtain the regulatory approvals necessary to commercialize, CC8464 and/or additional lead candidates. We expect that it will take several years, if ever, before we have a commercialized lead candidate. The net losses we incur may fluctuate significantly from quarter to quarter.

If we are required by the FDA, the European Medicines Agency ("EMA"), or other regulatory authorities, including, among others, China's National Medical Products Administration, Japan's Pharmaceuticals and Medical Devices Agency, and the Australian National Health and Medical Research Council's Therapeutics Goods Administration, to perform studies in addition to those currently expected, or if there are any delays in completing our clinical trials or the development of CC8464 and/or other lead candidates, 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;
- initiate additional clinical trials and preclinical studies for any additional lead candidates that we may pursue in the future;
- prepare a U.S. New Drug Application ("NDA") for filing with the FDA, a marketing authorization application, and approvals in certain other countries;
- oversee the manufacturing of material for clinical trials or potential commercial sales;
- develop a lead candidate portfolio;
- establish a business development operation to in- our out-license certain assets;
- establish a sales, marketing and distribution infrastructure to commercialize any lead candidate 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 lead candidates and technologies.

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

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

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

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

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

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

Identifying potential lead candidates 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 candidates, if approved, may not achieve commercial success. Our lead candidate's revenues, if any, will be derived from or based on sales of lead candidates 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 our lead candidates. 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 our lead candidates. 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.

Risks Related to Development, Clinical Testing, and Regulatory Approval

We are early in our efforts to develop CC8464. 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 lead candidate we may develop) 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.

Our lead candidate, 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.

There is no guarantee that results of our potential future clinical trials will be positive or that we will be able to complete this or any potential future clinical trials on the anticipated timelines or at all. Furthermore, research and discoveries by us or others may identify serious adverse events, undesirable side effects or other unexpected properties of our current and future lead candidates, 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 lead candidate for more limited indications than requested or they may impose significant limitations in the form of narrow indications, warnings or post-approval safety monitoring program. These regulatory authorities may require precautions or contra-indications with respect to conditions of use or they may grant approval subject to the performance of costly post-marketing clinical trials. In addition, regulatory authorities may not approve the labeling claims that are necessary or desirable for the successful commercialization of CC8464. Any of the foregoing scenarios could materially harm the commercial prospects for CC8464 and materially and adversely affect our business, financial condition, results of operations and prospects.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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. Other regulatory regimes that may impact us include: the EU's European Medicines Agency, China's National Medical Products Administration, Japan's Pharmaceuticals and Medical Devices Agency, and the Australian National Health and Medical Research Council's Therapeutics Goods Administration. These are not the only regulatory regimes to which we may be subject in the event we are able to execute on our objectives.

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

Even if we obtain regulatory approval for CC8464 or any of our other lead candidates, CC8464 or our other lead candidates will remain subject to regulatory oversight.

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

In addition, product manufacturers and their facilities are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP requirements and adherence to commitments made in the NDA or foreign marketing application. If we, or a regulatory authority, discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured or disagrees with the promotion, marketing or labeling of that product, a regulatory authority may impose restrictions relative to that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing.

If we fail to comply with applicable regulatory requirements following approval of CC8464 or any future lead candidate, 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 lead candidates; or
- refuse to allow us to enter into supply contracts, including government contracts.

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

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

Even if we obtain and maintain approval for our lead candidates 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 lead candidate in the United States by the FDA does not ensure approval of such lead candidate by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. Sales of CC8464 or other future lead candidates 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 lead candidate, comparable regulatory authorities of foreign countries also must approve the manufacturing and marketing of the lead candidate 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 lead candidate 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 lead candidates, if approved, is also subject to approval. We intend to submit a marketing authorization application to the EMA for approval of CC8464in 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 lead candidate 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 lead candidates 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 lead candidates 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 lead candidates may be withdrawn. If we fail to comply with the regulatory requirements, our target market will be reduced and our ability to realize the full market potential of CC8464 or our future lead candidates 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, it may not effectively protect us from competition, and we may be unable to obtain similar designations for our future lead candidates. 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 candidates before us, we may not be able to have competing products approved by the applicable regulatory authority for a significant period of time.

In connection with the application for our lead candidate, CC8464, for the treatment of EM, we also plan to seek orphan drug designation from the FDA. Under the Orphan Drug Act of 1983, the FDA may designate a lead candidate 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 lead candidate 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 lead candidate from competition because different drugs can be approved for the same condition. In the United States, even after an orphan drug is approved, the FDA may subsequently approve another drug for the same condition if the FDA concludes that the latter drug is not the same drug or is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. In the EU, marketing authorization may be granted to a similar medicinal product for the same orphan indication if:

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

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

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

As with our application for "orphan drug" designation for CC8464 from the FDA, there is no assurance that any of our other lead candidates will receive a similar designation from the FDA or that we will receive Breakthrough Therapy or Fast Track designations for any of our lead candidates (including CC8464). Further, even if we do receive favorable designations from the FDA, the receipt of any of these designations for a lead candidate 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 lead candidate or indication and fail to capitalize on lead candidates or indications that may be more profitable or for which there is a greater likelihood of success.

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

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

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

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

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

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

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

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

Risks Related to Manufacturing

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

Before we can begin to commercially manufacture CC8464 or any of our lead candidates, 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 lead candidate that we may develop.

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

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

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

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

Risks related to Commercialization of Our Lead Candidates

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Moreover, increasing efforts by government and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for new products approved and, as a result, they may not cover or provide adequate payment for our lead candidates. 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 lead candidates and may fail to capitalize on programs or lead candidates that may be a greater commercial opportunity or for which there is a greater likelihood of success.

Beyond the development and commercialization of CC8464, the future success of our business depends upon our ability to identify, develop and commercialize lead candidates based on the platform technology. CC8464 was discovered in our labs using our technologies. Research programs to identify new lead candidates will require to invest substantial technical, financial and human resources. We may fail to identify other potential lead candidates for clinical development for several reasons. For example, our research may be unsuccessful in identifying potential lead candidates or our potential lead candidates 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 lead candidates 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 lead candidate, we may relinquish valuable rights to that lead candidate 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 lead candidate. Alternatively, we may allocate internal resources to a lead candidate 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 lead candidate or fail to develop a potentially successful lead candidate, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

If we are successful in executing our business strategy, we will need to expand our managerial, operational, financial and other systems and resources to manage our operations, continue our research and development activities and, in the longer term, build a commercial infrastructure to support commercialization of any of our lead candidates that are approved for sale. Future growth would impose significant added responsibilities on members of management. It is likely that our management, finance, development personnel, systems and facilities currently in place may not be adequate to support this future growth. Our need to effectively manage our operations, growth and lead candidates 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. Currently, Christian Kopfli is our Chief Executive Officer, and Mr. Francis Knuettel II is our Chief Financial Officer, Treasurer and Corporate Secretary. These executives 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 Mr. Kopfli or Mr. Knuettel could have a material adverse effect on our business, financial condition, and results of operations.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets, including conditions that are outside of our control, such as the impact of health and safety concerns, including SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2) ("COVID-19") pandemic and the Omicron COVID-19 variant, as well as the recent inflation in the United States, foreign and domestic government sanctions imposed on Russia as a result of its recent invasion of Ukraine, and other disruptions to global supply chains. Each of these events has caused or may continue to result in extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn, whether due to inflationary pressures or otherwise, could result in a variety of risks to our business, including weakened demand for our lead candidates 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.

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

Public health crises such as pandemics or similar outbreaks could adversely impact our business. In December 2019, COVID-19 surfaced in Wuhan, China and has since spread worldwide, including to New Jersey where our primary office and laboratory space is located. The COVID-19 pandemic is evolving, and to date has led to the implementation of various responses, including government-imposed quarantines, travel restrictions and other public health safety measures. During our 2021 fiscal year, in response to the COVID-19 pandemic, we reduced staff and slowed down development activities as capital and testing options available to us were more limited. The extent to which COVID-19 will impact our future operations or those of our third-party partners, including our clinical trial operations, will also depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration of the pandemic, adverse impacts of the Omicron COVID-19 variant or other COVID-19 variants, new information that will emerge concerning the severity of COVID-19 and the actions to contain COVID-19 or treat its impact, among others.

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

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

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 lead candidates 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 lead candidates or drugs caused injuries, we will incur substantial liabilities. lead of merit or eventual outcome, liability claims may result in:

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

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

Risks Related to Our Intellectual Property

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

Our success depends, in large part, on our ability to obtain and maintain patent protection in the United States and other countries with respect to CC8464, additional lead candidates 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 China, Japan and Europe. It is possible that some of our pending patent applications in foreign jurisdictions will not result in issued patents in a timely fashion or at all, and even if we are granted the patents we are currently pursuing in foreign jurisdictions, the patents may not be issued in a form that will provide us with the full scope of protection that we desire, they may not prevent competitors or other third parties from competing with us, and/or they may not otherwise provide us with a competitive advantage. Our competitors, or other third parties, may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner. For example, there is no assurance that the CC8464 Patent, or any other patent that we may be granted, will prevent third parties from developing competing technologies. Moreover, our patent estate, including the CC8464 Patent, does not preclude third parties from obtaining intellectual property rights that could interfere with our freedom to use our platform for other indications. Even assuming patents issue from our pending and future patent applications, changes in either the patent laws or interpretation of the patent laws in the United States and foreign jurisdictions may diminish the value of our patents or narrow their scope of protection.

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

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

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

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

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

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

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

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

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

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

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

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

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

Moreover, the patent positions of companies engaged in the development and commercialization of pharmaceuticals are particularly uncertain. We cannot assure you that our efforts to seek patent protection for CC8464 and future lead candidates 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 lead candidates 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 preexisting obligations to their universities to assign intellectual property rights, which university rights generally are superior to assignment rights that we might receive from such individuals.

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

Risks Related to this Offering of Units and Ownership of our Common Stock and Warrants

Certain of our directors and members of management will maintain the ability to substantially influence all matters submitted to stockholders for approval.

Immediately following this offering, (i) Flamands, an entity controlled by Ezra Friedberg, one of our directors, will beneficially own % of our Common Stock (or % of our Common Stock if the underwriters' option to purchase additional Units is exercised in full) and (ii) Christian Kopfli, through Chromocell Holdings, will beneficially own % of our Common Stock (or % of our Common Stock if the underwriters' option to purchase additional Units is exercised in full). As a result, Flamands, Chromocell Holdings, Ezra Friedberg and Christian Kopfli will have significant influence with respect to our management, business plans and policies, including the appointment and removal of our officers, decisions on whether to raise future capital, and amending our charter and bylaws, which govern the rights attached to our Common Stock. In addition, for so long as they continue to beneficially own a significant percentage of our stock, it could cause or prevent a change of control of the Company or a change in the composition of our board of directors and could preclude any unsolicited acquisition of us. The concentration of ownership could deprive you of an opportunity to receive a premium for your shares of Common Stock as part of a sale of our Company and ultimately might affect the market price of our Common Stock.

Nasdaq may delist our Common Stock and Warrants 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 Nasdaq, such as the corporate governance requirements or the minimum closing bid price requirement, The Nasdaq Stock Market LLC may take steps to delist our Common Stock and Warrants. 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 and Warrants when you wish to do so. In the event of a delisting, we would take actions to restore our compliance with Nasdaq's listing requirements, but we can provide no assurance that any such action taken by us would allow our Common Stock and Warrants to become listed again, stabilize the market price or improve the liquidity of our Common Stock, prevent our Common Stock from dropping below Nasdaq'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 Nasdaq, we could face significant material adverse consequences, including:

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

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

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

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

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

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

Our certificate of incorporation and our bylaws provide that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the DGCL, our certificate of incorporation or our bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. Notwithstanding the foregoing, the exclusive forum provision does not apply to suits brought to enforce any liability or duty created by the Securities Act, the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or any other claim for which the federal courts have exclusive jurisdiction. Unless we consent in writing to the selection of an alternative forum, the United States federal district courts shall, to the fullest extent permitted by applicable law, be the sole and exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. The choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. Alternatively, if a court were to find the choice of forum provision contained in our certificate of incorporation and our bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could materially and adversely affect our business, financial condition, and results of operation.

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

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

After giving effect to the IPO Transactions and sale of Units in this offering, we will have outstanding shares of Common Stock. All of the shares sold as part of the Units in this offering will be immediately tradable without restriction under the Securities Act of 1933, as amended, or the Securities Act, except for any shares held by "affiliates," as that term is defined in Rule 144 under the Securities Act, or Rule 144.

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

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

In the future, we may issue additional shares of Common Stock or other equity or debt securities convertible into Common Stock in connection with 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 Common Stock to decline.

If you purchase Units in this offering, you will suffer immediate dilution of your investment.

The public offering price of the Units will be substantially higher than the net tangible book value per share of our Common Stock. Therefore, if you purchase Units in this offering, you will pay a price per Unit that substantially exceeds our net tangible book value per share of Common Stock after this offering. To the extent outstanding warrants, options or other convertible securities may be exercised, you will incur further dilution. Based on the assumed public offering price of $ per Unit, which is the midpoint of the price range set forth on the cover page of this prospectus, you will experience immediate dilution of $ per share, representing the difference between the assumed public offering price of the Units and our as adjusted net tangible book value per share of $ after giving effect to the IPO Transactions and sale of Units this offering. See "Dilution."

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

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

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

The offering price for the Units sold in this offering will be determined by negotiation between the representative of the underwriters and us. This price may not reflect the market price of our Common Stock following this offering. In addition, the market price of our Common Stock is likely to be highly volatile due to many factors, including:

- our ability to successfully proceed to and conduct clinical trials;
- results of clinical trials of our lead candidates 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 lead candidates or clinical development programs;
- the results of our efforts to discover, develop, acquire or in-license additional lead candidates;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- our inability to obtain or delays in obtaining adequate product supply for any approved product or inability to do so at acceptable prices;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or stockholder litigation;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions; and
- the other factors described in this “Risk Factors” section.

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

No public market for our Common Stock or the Warrants to purchase shares of our Common Stock included as part of the units in this offering currently exists, and an active trading market may not develop or be sustained following this offering.

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

Provisions of the Warrants offered by this prospectus could discourage an acquisition of us by a third party.

In addition to the discussion of the provisions of our certificate of incorporation, our bylaws, certain provisions of the Warrants offered by this prospectus could make it more difficult or expensive for a third party to acquire us. The Warrants prohibit us from engaging in certain transactions constituting "fundamental transactions" unless, among other things, the surviving entity assumes our obligations under the Warrants. These and other provisions of the Warrants offered by this prospectus could prevent or deter a third party from acquiring us even where the acquisition could be beneficial to you.

The Warrants included in the Units in this offering are speculative in nature.

Following this offering, the market value of the Warrants included in the Units, if any, is uncertain and there can be no assurance that the market value of the Warrants included in the Units will equal or exceed their imputed offering price. In the event that our Common Stock price does not exceed the exercise price of the Warrants included in the Units during the period when such Warrants are exercisable, such Warrants may not have any value. Furthermore, each Warrant included in the Units will expire five years from its original issuance date.

Holders of the Warrants included in the Units will not have rights of holders of our shares of Common Stock until such Warrants are exercised.

The Warrants included in the Units in this offering do not confer any rights of share ownership on their holders, but rather merely represent the right to acquire shares of our Common Stock at a fixed price. Until holders of such Warrants acquire shares of our Common Stock upon exercise of such Warrants, holders of such Warrants will have no rights with respect to our shares of Common Stock underlying such Warrants.

We have broad discretion in the use of our cash, including the net proceeds from this offering, and may not use them effectively.

Our management will have broad discretion in the application of our cash, including the net proceeds from this offering, and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our Common Stock or Warrants. 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 or Warrants to decline and delay the development of CC8464 and any other lead candidates that we may develop. Pending their use, we may invest our cash, including the net proceeds from this offering, in a manner that does not produce income or that loses value. See "Use of Proceeds."

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

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

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

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

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

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

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

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

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

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

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

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

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

- the initiation, timing, progress and results of preclinical and clinical trials for CC8464 and any other lead candidates, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available and our research and development programs;
- the timing, scope or results of regulatory filings and approvals, including timing of final FDA marketing and other regulatory approval of CC8464;
- our ability to achieve certain accelerated or orphan drug designations from the FDA;
- our estimates regarding the potential market opportunity for CC8464;
- our research and development programs for our lead candidates;
- our plans and ability to successfully develop and commercialize our lead candidates, including CC8464;
- our ability to identify and develop new lead candidates;
- 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 candidates 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 candidates;
- our competitive position;
- our intellectual property position and our ability to protect our intellectual property and enforce our intellectual property rights;
- our financial performance;
- developments and projections relating to our competitors and our industry;
- our ability to establish and maintain collaborations or obtain additional funding;
- our expectations related to the use of proceeds from this offering;

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

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

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

USE OF PROCEEDS

We estimate that the net proceeds from our issuance and sale of of our Units in this offering will be approximately $ million (or $ million if the underwriters exercise in full their option to purchase additional Units), assuming an initial public offering price of $ per Unit, the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

Each $1.00 increase (decrease) in the assumed initial public offering price of $ per Unit, the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the net proceeds to us from this offering by approximately $ million, assuming that the number of Units offered by us, as set forth on the cover page of this prospectus, remains the same. Similarly, each 1.0 million increase (decrease) in the number of Units offered by us, as set forth on the cover of this prospectus, would increase (decrease) the net proceeds to us by $ million, assuming the assumed initial public offering price per Unit remains the same.

We intend to use approximately $ million of the net proceeds from this offering as follows:

- approximately $ million to prepare and conduct a Phase 2a proof-of-concept study of CC8464 for EM;
- approximately $ million to prepare and conduct a dose escalation study for CC8464 to establish a safe dose escalation regime to avoid a high incidence rate of rashes;
- approximately $ million to develop and produce additional drug products for clinical trials of CC8464; and
- approximately $ million to proceed with additional long-term toxicology studies required for FDA approval of CC8464.

We intend to use the remaining net proceeds from this offering, if any, for general corporate purposes.

The expected net proceeds of this offering will not be sufficient for us to fund any of our lead candidates, including CC8464, through regulatory approval, and we will need to raise substantial additional capital to complete the development and commercialization of our lead candidates, as well as to establish commercial supply and a sales organization.

The amounts and timing of our actual expenditures will depend on numerous factors, including the progress of our preclinical and clinical trials and other development and commercialization efforts for CC8464 and our other lead candidates, as well as the amount of cash used in our operations. Although we have no present intention or commitment to do so, we may use a portion of the net proceeds for the acquisition of, or investment in, technologies, intellectual property or businesses that complement our business.

Our expected use of net proceeds from this offering represents our current intentions based upon our present plans and business condition. As of the date of this prospectus, we cannot predict with complete certainty all of the particular uses for the net proceeds to be received upon the completion of this offering or the actual amounts that we will spend on the uses set forth above. We may find it necessary or advisable to use the net proceeds for other purposes, and our management will retain broad discretion over the allocation of the net proceeds of this offering. Pending the uses described above, we plan to invest the net proceeds from this offering in short- and intermediate-term, interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government.

DIVIDEND POLICY

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

CAPITALIZATION

The following table sets forth our cash and our capitalization as of , 2022:

- on an actual basis;
- on an as adjusted basis, after giving effect to the IPO Transactions, which include: (i) a 1-for- stock split of Common Stock; and (ii) the issuance of shares of Common Stock and Warrants upon conversion of all issued and outstanding shares of Series A Preferred Stock, assuming an initial public offering price of $ per Unit; and
- on a further as adjusted basis, after giving effect to the IPO Transactions described above, the sale of Units in this offering at an assumed public offering price of $ per Unit, and the application of the net proceeds therefrom as described in "Use of Proceeds," after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us (a portion of which were paid prior to , 2022).

You should read this table together with the sections of this prospectus captioned "Use of Proceeds," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Description of Capital Stock" and our consolidated financial statements and related notes included elsewhere in this prospectus.

	As of , 2022 (unaudited)[1]		
(in thousands, except share and per share amounts)	**Actual**	**As Adjusted**	**As Further Adjusted**
Cash	$		
Current Liabilities			
Stockholders' equity:			
Common Stock; $0.0001 par value per share; 100,000,000 shares authorized, zero shares issued and outstanding, actual; 100,000,000 shares authorized and shares issued and outstanding, as adjusted; and 100,000,000 shares authorized and shares issued and outstanding, as further adjusted			
Preferred Stock: $0.0001 par value per share; 10,000,000 shares authorized, 600,000 shares of Series A Convertible Preferred Stock issued and outstanding, actual; 10,000,000 shares authorized and zero shares issued and outstanding, as adjusted; and 10,000,000 shares authorized and zero shares issued and outstanding, as further adjusted			
Additional paid-in capital			
Accumulated deficit			
Total stockholders' (deficit) equity			
Total capitalization	$		

(1) On an actual, as adjusted basis and as further adjusted basis, reflects approximately $ million in offering expenses paid on or prior to , 2022.

DILUTION

If you invest in our securities, your ownership interest will be immediately diluted to the extent of the difference between the initial public offering price per Unit and the as further adjusted net tangible book value per share of our Common Stock immediately after this offering. As adjusted net tangible book value dilution per share represents the difference between the amount per Unit paid by purchasers of Units in this offering, after giving effect to the IPO Transactions, which include (i) a 1-for- stock split of Common Stock and (ii) the issuance of shares of Common Stock upon conversion of all issued and outstanding shares of Series A Preferred Stock, assuming an initial public offering price of $ per Unit, and the as adjusted net tangible book value per share of Common Stock immediately after the completion of this offering.

As of , 2022, our as adjusted net tangible book value was approximately $, or $ per share of Common Stock.

After giving effect to our sale of Units in this offering at an assumed public offering price of $ per Unit, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, our as further adjusted net tangible book value as of , 2022 would have been $ million, or $ per share. This represents an immediate increase in as adjusted net tangible book value of $ per share to our existing stockholders and an immediate dilution of $ per share to new investors participating in this offering.

The following table illustrates this dilution on a per share basis:

Assumed initial public offering price per Unit		$
Historical as adjusted net tangible book value per share as of , 2022	$	
As further adjusted net tangible book value per share immediately after this offering[(1)]		
Dilution in net tangible book value per share to new investors in this offering[(1)]		$

(1) Each $1.00 increase (decrease) in the assumed initial combined public offering price of $ per Unit, the midpoint of the price range set forth on the cover page of this prospectus, would increase our as further adjusted net tangible book value per share after this offering by $ per share and the dilution per share to new investors participating in this offering by $ per share, assuming that the number of shares of Common Stock and accompanying Warrants offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting underwriting discounts and estimated offering expenses payable by us. Similarly, each 1.0 million increase (decrease) in the number of shares of Common Stock and accompanying Warrants offered by us would increase (decrease) the as further adjusted net tangible book value per share after this offering by $ per share and the dilution per share to new investors participating in this offering by $ per share, assuming that the assumed initial combined public offering price remains the same, after deducting underwriting discounts and estimated offering expenses payable by us.

If the underwriters exercise in full their option to purchase up to additional Units to cover over-allotments, if any, the as adjusted net tangible book value per share after giving effect to this offering would be $ per share, representing an immediate increase (decrease) to existing stockholders of $ per share and immediate dilution to new investors participating in this offering of $ per share, assuming that the assumed initial combined public offering price remains the same, after deducting underwriting discounts and estimated offering expenses payable by us.

The following table summarizes, on an as adjusted basis as of , 2022 after giving effect to the IPO Transactions, which include (i) a 1-for- stock split of Common Stock; and (ii) the issuance of shares of Common Stock upon conversion of all issued and outstanding shares of Series A Preferred Stock, assuming an initial public offering price of $ per Unit, the differences between the number of shares of Common Stock purchased from us, the total cash consideration and the average price per share paid to us by existing stockholders and by new investors purchasing shares Units in this offering at an assumed public offering price of $ per Unit, the midpoint of the price range set forth on the cover page of this prospectus, before deducting estimated underwriting discounts and estimated offering expenses payable by us:

	Shares Purchased		Total Consideration		Average Price Per Share
	Number	Percent	Amount	Percent	
Existing stockholders		%	$	%	$
New public investors		%	$	%	$
Total		%	$	100%	

If the underwriters exercise their option to purchase additional Units in full, the number of shares of Common Stock held by existing stockholders will be reduced to % of the total number of shares of Common Stock to be outstanding after this offering, and the number of shares of Common Stock held by investors participating in this offering will be further increased to % of the total number of shares of Common Stock to be outstanding after this offering, based on all of the assumptions described above in this section.

To the extent any outstanding options to purchase Common Stock are exercised or to the extent that we issue new securities which result in the issuance of additional shares of Common Stock, new investors would experience further dilution.

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

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

Overview

We are a clinical-stage biotech company focused on developing and commercializing new therapeutics to alleviate pain by selectively targeting the sodium ion-channel known as "NaV1.7", as well as other receptors in the NaV family. NaV1.7 has been genetically validated as a pain receptor in human physiology. Our goal is to develop a novel and proprietary class of NaV blockers that target the body's peripheral nervous system and have demonstrated safety in a Phase 1 study. Our lead candidate, CC8464, has demonstrated a good safety and tolerability profile in Phase 1 clinical trials. We currently plan to begin Phase 2a studies for CC8464 in 2023.

We were incorporated in Delaware on March 19, 2021. On August 10, 2022, we entered into that certain Contribution Agreement (the "Contribution Agreement") with Chromocell Corporation, a Delaware corporation ("Chromocell Holdings"). Pursuant to the Contribution Agreement, effective July 12, 2022 (the "Contribution Date"), 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. Prior to the Contribution Date, we had only nominal assets and liabilities. Accordingly, the financial statements presented in this prospectus for periods prior to the Contribution Date have been prepared on a "carve-out" basis from the financial statements of Chromocell Holdings to represent our financial position and performance as if it had existed on a stand-alone basis. The financial statements presented in this prospectus for periods from and after the Contribution Date reflect our financial position and performance as a stand-alone entity.

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

In connection with the completion of this offering, we will effect a -for- stock split with respect to our common stock, par value $0.0001 per share (the "Common Stock"). In addition, in connection with completion of this offering, all 600,000 issued and outstanding shares of our Series A Convertible Preferred Stock will automatically convert into shares of Common Stock and Warrants (based on an assumed initial public offering price of $, the midpoint of the price range set forth on the cover page of this prospectus). We refer to these actions as the "IPO Transactions."

Going Concern

For the year ended December 31, 2021 and 2020, respectively, we had a net loss of $0.6 million and $0.7 million, respectively, and will require significant additional capital in order to operate in the normal course of business and fund clinical studies. As a result, these conditions have raised substantial doubt regarding our ability to continue as a going concern beyond one year of the filing of our financial statements. While we believe in the viability of management's strategy to raise funds and control costs during the development stage, there can be no assurances to that effect. Our ability to continue as a going concern is dependent upon the ability to complete clinical studies and implement our business plan, raise capital, generate sufficient revenues and to control operating expenses.

Results of Operations

Comparison of the Fiscal Years Ended December 31, 2021 and 2020

The following table summarizes our results of operations for the fiscal years ended December 31, 2021 and 2020:

	December 31,		$	%
	2021	2020	Change	Change
Revenues	$ -	$ 199,934	$ (199,934)	(100)%
General and administrative expenses	496,667	1,323,120	(826,453)	(62)%
Research and development expenses	209,047	138,585	70,462	51%
Professional expenses	133,282	92,096	41,186	45%
Operating expenses	838,996	1,553,801	(714,805)	(46%)
Loss from operations	(838,996)	(1,353,866)	514,871	38%
Other income (loss)	243,609	693,283	(449,674)	(65)%
Net loss	$ (595,387)	(660,584)	65,197	10%

Revenue

For the years ended December 31, 2021 and 2020, the Company incurred revenue of zero and $199,934, respectively, representing a decrease of $199,934 or 100%. The decrease is due to a decrease in grant revenue.

Operating Expenses

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

General and Administrative Expenses

Our general and administrative expenses for the years ended December 31, 2021 and 2020 were $496,667 and $1,323,120, respectively, representing a decrease of $826,453, or 62%. The decrease is primarily due to a reduction in compensation expenses as the Company adjusted to COVID by reducing staff and slowing down development activities as capital and testing options for the Company were more limited during the pandemic.

Research and Development Expenses

For the years ended December 31, 2021 and 2020, the Company incurred research and development expenses of $209,047 and $138,585, respectively, representing an increase of $70,462 or 51%. The increase is primarily due to an increase in maintenance and filing expenses associated with growth in the Company's patent portfolio.

Professional Fees

Professional fees for the years ended December 31, 2021 and 2020 were $133,282 and $92,096, respectively, representing an increase of $41,186, or 45%. The increase is primarily due to a greater accounting and legal services expenses in preparation for the initial public offering.

Other Income

For the years ended December 31, 2021 and 2020, we recognized $243,609 and $693,283 in other income, respectively. Other income for the year ended December 31, 2021 was primarily comprised of a gain on forgiveness of a PPP loan in the amount of $243,862 and for the year ended December 31, 2020 was primarily comprised of an NOL tax credit of $694,959.

Liquidity

Sources of Liquidity and Capital

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

Cash totaled $0 million and $0 million as of December 31, 2021 and 2020, respectively. Our net loss totaled $0.6 million and $0.7 million for the years ended December 31, 2021 and 2020, respectively. As of December 31, 2021 and 2020, we had an accumulated deficit of approximately $3.7 million and $3.6 million, respectively, and had a working capital deficit of $2.6 million and $3.6 million, respectively.

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

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

Future Funding Requirements

Our primary use of cash is to repay assumed liabilities associated with the execution of the Contribution Agreement on July 12, 2022 and to fund operating expenses.

Pursuant to the Contribution Agreement, the Company agreed to assume $1,556,323 of liabilities directly associate with assets acquired, and agreed to make a cash payment to Chromocell Holdings in an aggregate amount of $597,038 for certain expenses. These two amounts substantially comprise the accounts payable on the Company's balance sheet.

With respect to the Company's future expected operations expenses, the primary expense drivers will be research and development and management overhead, including costs of being a public company. Of these, it is expected that research and development will be the largest expense and comprise approximately $5 - 6 million in the twenty-four months following the offering, which will be utilized for the Company's escalation study and Phase II drug trial costs. We have based the research and development costs on current trial parameters and expectations on certain existing tax credits, and there is no certainty that the trial parameters or tax credits available to the Company will remain as they are, which could lead to changes in our research and development expenditures. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable, accrued expenses and prepaid expenses.

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

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

We may also raise additional funding through strategic relationships, public or private equity or debt financings, credit facilities, grants or other arrangements. If such funding is not available or not available on terms acceptable to us, our current development plan and plans for expansion of our general and administrative infrastructure may be curtailed. If we raise additional funds through the issuance of preferred stock, convertible debt securities or other debt financing, these securities or other debt could contain covenants that would 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 fiscal years ended December 31, 2021 and 2020:

	December 31, 2021	December 31, 2020	$ Change	% Change
Net Loss	$ (595,387)	$ (660,584)	$ 65,197	10%
Cash Flow from Operating Activities	(1,593,011)	3,625,773)	2,032,762	56%
Cash Flow from Investing Activities	-	-	-	-
Cash Flow from Financing Activities	1,593,011	3,625,773	(2,032,762)	(56)%
Net Increase (Decrease) in Cash	-	-	-	-

Net Cash (Used) Provided by Operating Activities

For the year ended December 31, 2021, we incurred a net loss of $595,387. Net cash flows used in operating activities was $1,593,011 for the year ended December 31, 2021.

For the year ended December 31, 2020, we incurred a net loss of $660,584. Net cash flows used in operating activities was $3,625,773 for the year ended December 31, 2020.

Net Cash (Used) Provided by Investing Activities

The Company neither received or used cash in investing activities during the years ended December 31, 2021 and 2020.

Net Cash Provided by Financing Activities

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

For the year ended December 31, 2020, net cash flows provided by financing activities were $3,625,773, cash transfers from the Company to Chromocell Holdings in the amount of $3,383,980 and proceeds from PPP loan of $241,793.

Off-Balance Sheet Arrangements

During the years ended December 31, 2021 or 2020, we did not have, and we do not currently have, any off-balance sheet arrangements, as defined under applicable SEC rules.

Critical Accounting Estimates

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

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

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

JOBS Act

On April 5, 2012, the JOBS Act was enacted. Section 107 of the JOBS Act provides that an “emerging growth company” can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act, for complying with new or revised accounting standards. In other words, an “emerging growth company” can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies.

We have chosen to take advantage of the extended transition periods available to emerging growth companies under the JOBS Act for complying with new or revised accounting standards until those standards would otherwise apply to private companies provided under the JOBS Act.

We are in the process of evaluating the benefits of relying on other exemptions and reduced reporting requirements provided by the JOBS Act. Subject to certain conditions set forth in the JOBS Act, as an “emerging growth company,” we intend to rely on certain of these exemptions, including without limitation, (i) providing an auditor’s attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act and (ii) complying with any requirement that may be adopted by the Public Company Accounting Oversight Board (“PCAOB”) regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis. We will remain an “emerging growth company” until the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of $1.07 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of the completion of this offering; (iii) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the Securities and Exchange Commission.

Recently Issued and Adopted Accounting Pronouncements

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

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

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

BUSINESS

Overview

We are a clinical-stage biotech company focused on developing and commercializing new therapeutics to alleviate pain by selectively targeting the sodium ion-channel known as "NaV1.7", as well as other receptors in the NaV family. NaV1.7 has been genetically validated as a pain receptor in human physiology. Genetic studies have shown that families with a certain inherited NaV1.7 modulation consistently show a pathology of not feeling pain. A NaV1.7 blocker is a chemical entity that modulates the structure of the sodium-channel in a way to prevent the transmission of pain perception to the CNS. Our goal is to develop a class of NaV blockers that target the body's peripheral nervous system and have demonstrated safety in a Phase 1 study. Our lead candidate, CC8464, has demonstrated a good safety and tolerability profile in Phase 1 clinical trials. We currently plan to begin Phase 2a studies for CC8464 in 2023.

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

Our lead compound, CC8464, is designed to produce pain relief by specifically blocking the NaV1.7 sodium channel. The chemical characteristics of CC8464 restrict its entry into the CNS and limit its effect to the NaV1.7 receptors in the peripheral nervous system, which consists of the nerves outside the brain and spinal cord. Since CC8464 is designed to modulate pain signals without activation of receptors in the CNS, it is not expected to produce psychiatric side effects. Based on its characteristics, preclinical studies and the Phase 1 study we have completed to date, we believe that our lead candidate CC8464, if approved, could become an attractive option for both patients and physicians as a treatment for moderate-to-severe pain. If approved, CC8464 would provide pain relief while significantly reducing the incidence of opioid-related adverse events and abuse and addiction issues associated with currently approved opioid analgesics.

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 pain and pain-related symptoms in EM. Based on genetic studies, a scientific consensus emerged that NaV1.7 could be critical in mediating pain in EM. Our first aim is to assess CC8464's potential as a drug for EM.

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

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

- ***Leverage our differentiated research and discovery approach to expand our pipeline.*** We plan to continue to build our 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, several related sodium channels, e.g., NaV1.8 or NaV1.6, may be involved in pain sensation. While NaV1.7 is the most validated pain receptor, we believe that blockers against other sodium channels may complement CC8464 as our primary pain blocking candidate.

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

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

Our Lead Candidate: CC8464 for the Treatment of EM

CC8464 is our lead candidate for the treatment of EM. EM is an orphan disease without an effective treatment, in particular for severe cases.

Background on EM

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

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

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

Prevalence

According to Transparency Market Research:

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

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

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

Existing Treatment Options

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

CC8464's Mechanisms of Action

According to the National Institutes of Health, mutations of NaV1.7 are a leading cause for EM. It is less clear whether other sodium-channels or causes other than genetic mutations influence the development of EM.

CC8464 Current Study Results

CC8464 has undergone a Phase 1 study. The result showed that CC8464 has a good overall tolerability and safety profile but may cause rashes in certain patients. The occurrence of rashes is not uncommon in the class of molecules to which CC8464 belongs. A dose-escalation-regime is a standard method to mitigate rashes as a side effect and the FDA has approved drugs with such prescriptions. We believe that a dose-escalation-regime could reduce the occurrence of rashes to a tolerable level for CC8464. We plan to conduct a dose-escalation-study to validate the concept and establish a safe prescription regime for patients.

Our Addressable Market

Based on a study published in the *International Journal of Vascular Medicine*, our lead product for the treatment of EM, CC8464, may be relevant for approximately 50,000 patients in the US today.

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

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

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

Our Lead Drug Candidate and Pipeline

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

CC8464's FDA Orphan Drug Designation

We are considering submitting a request to the FDA for Orphan Drug Designation, which could lead to approval for such designation and provide marketing exclusivity, as well as reduced FDA review periods and regulatory fees. We may apply for similar orphan designations in additional jurisdictions, including Europe and Japan, as well as additional regulatory classifications, such as FDA Breakthrough Therapy Designation, that confer an advantage during development.

CC8464 Manufacturing

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

Intellectual Property

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

We have adopted a strategy of seeking patent protection in the United States and in other jurisdictions globally that we deem appropriate with respect to certain of our technologies relating to our products and process. As of February 11, 2022, we have received an issued patent from the USPTO directed to the composition and use of CC8464. We have obtained patents and are actively prosecuting additional applications in the U.S. as well as international patent applications in the E.U., Japan, China and other relevant markets.

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

Our Competition

The biotechnology and pharmaceutical industries are highly competitive. Several pharmaceutical companies that are developing either topical applications for EM or other molecules that modulate NaV1.7 and therefore have the potential to mitigate EM. These companies and new entrants may potentially compete with our products in the future with novel delivery technologies. The advanced clinical development of CC8464, if approved by the FDA, provides a viable pathway to realize our commercialization plans. The market exclusivity associated with Orphan Designation plus the CC8464 market exclusivity associated with our issued patent and pending patent applications are key elements of our commercialization strategy.

Our Facilities

Chromocell Holdings leases a combined laboratory, office and warehouse space in the NJ Biotech Center that the Company uses in its research and development efforts. Chromocell Holdings may extend its current lease (675 US Route 1 South, North Brunswick, NJ 08906), which ends in 2022.

Employees and Human Capital Resources

As of December 31, 2021, we had two full-time employees and eight 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.

Legal Proceedings

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

Government Regulation

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

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

- completion of extensive preclinical studies in accordance with applicable regulations, including studies conducted in accordance with GLP requirements;
- completion of the manufacture, under cGMP conditions of the drug substance, drug product, and labeling and packaging that the sponsor intends to use in human clinical trials along with required analytical and stability testing;
- submission to the FDA of an IND, which must become effective before clinical trials may begin and must be updated annually and amended when certain changes are made;
- approval by an institutional review board ("IRB") or independent ethics committee ("IEC") at each clinical trial site before each trial may be initiated;
- performance of adequate and well-controlled clinical trials in accordance with applicable IND regulations, GCP requirements, including informed consent, financial disclosure by investigators and other clinical trial-related regulations, to establish the safety 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, the lead candidate 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 safety 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 lead candidate 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 lead candidate 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 lead candidate 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 lead candidate 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 safety 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 safety and efficacy of a product's use or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the investigational drug, to the satisfaction of the FDA. The FDA must approve an NDA before a drug may be marketed in the United States.

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

Further, under PDUFA, each NDA must be accompanied by a substantial user fee. For fiscal year 2021, the application fee for each application containing clinical data is $2,875,842. PDUFA also imposes an annual program fee for each approved prescription drug, which has been set at $336,432 for fiscal year 2021. The FDA adjusts the PDUFA user fees on an annual basis. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on applications for products designated as orphan drugs, unless the product also includes a non-orphan indication.

The FDA also may require submission of a Risk Evaluation and Mitigation Strategy ("REMS") if it believes that a risk evaluation and mitigation strategy is necessary to ensure that the benefits of the drug outweigh its risks. A REMS can include use of risk evaluation and mitigation strategies like medication guides, physician communication plans, assessment plans, and/or elements to assure safe use ("ETASU") such as restricted distribution methods, patient registries, special monitoring or other risk-minimization tools.

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

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

After evaluating the NDA and all related information, including the advisory committee recommendation, if any, and inspection reports regarding the manufacturing facilities and clinical trial sites, the FDA may issue an approval letter, or, in some cases, a Complete Response Letter. A Complete Response Letter indicates that the review cycle of the application is complete, and the application is not ready for approval. A Complete Response Letter generally contains a statement of specific conditions that must be met in order to secure final approval of the NDA, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the Complete Response Letter without first conducting required inspections, testing submitted product lots, and/or reviewing proposed labeling. In issuing the Complete Response Letter, the FDA may require additional clinical or preclinical testing or recommend other actions, such as requests for additional information or clarification, that the applicant might take in order for the FDA to reconsider the application. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indication(s).

Even if the FDA approves a product, depending on the specific risk(s) to be addressed it may limit the approved indications for use of the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including phase 4 clinical trials, be conducted to further assess a product's safety 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 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 lead candidates, 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 lead candidate and the specific indication for which it is being studied. The sponsor of a new drug product may request the FDA to designate the drug as a Fast Track product at any time during the clinical development of the product, but ideally no later than the pre-NDA meeting because many of the features of Fast Track designation will not apply after that time. Fast Track designation provides increased opportunities for sponsor interactions with the FDA during preclinical and clinical development, in addition to the potential for rolling review once a marketing application is filed. Rolling review means that the FDA may review portions of the marketing application before the sponsor submits the complete application.

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

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

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

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

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

The Accelerated Approval pathway is usually contingent on a sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the product's clinical benefit. As a result, a lead candidate 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 lead candidates 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 lead candidate 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 lead candidate 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 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 and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study.

U.S. Post-Approval Requirements for Drugs

Drugs approved by FDA are subject to continuing regulation by the FDA, including, among other things, requirements relating to manufacturing establishment registration and product listing, recordkeeping, periodic reporting, product sampling and distribution, reporting of adverse experiences with the product, field alerts regarding issues with distributed product, promotion and advertising compliance, which include restrictions on promoting products for unapproved uses or patient populations (known as "off-label use") and limitations on industry-sponsored scientific and educational activities. Although physicians may prescribe approved products for off-label uses, manufacturers may not market or promote such uses. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, as well as other advertising and promotion requirements, including not only by company employees but also by agents of the company or those speaking on the company's behalf, and a company that is found to have improperly promoted may be subject to significant liability, including investigation by federal and state authorities. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, untitled letters, corrective advertising, and potential civil and criminal penalties, including liabilities under the FCA where products are 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 our future lead candidates, some of our United States patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Amendments"). The Hatch-Waxman Amendments permit restoration of the patent term of up to five years as compensation for patent term lost during the FDA regulatory review process for a drug that has not been previously approved for commercial marketing. Patent-term restoration, however, cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date and only those claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. The patent-term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA plus the time between the submission date of an NDA and the approval of that application, except that the review period is reduced by any time during which the applicant failed to exercise due diligence. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may apply for restoration of patent term for our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant NDA.

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

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

Other Regulatory Matters

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

Healthcare Laws

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

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

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

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

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

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

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

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

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

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

Insurance Coverage and Reimbursement

In the United States and markets in other countries, patients who are prescribed treatments for their conditions and providers performing healthcare services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Thus, even if a lead candidate 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 lead candidate does not assure that other payors will also provide coverage for the lead candidate. No uniform policy of coverage and reimbursement for products exists among third-party payors, and coverage and reimbursement levels for products can differ significantly from payor to payor.

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

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

Current and Future Healthcare Reform Legislation

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Government Regulation of Drugs Outside of the United States

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

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

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

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

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

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

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

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

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

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

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

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

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

Government Regulation of Data Collection outside of the United States

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

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

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

MANAGEMENT

Executive Officers and Directors

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

Name	Age	Position
Executive Officers		
Christian Kopfli, Esq.	57	President and Chief Executive Officer and Director
Francis Knuettel II	56	Chief Financial Officer, Chief Strategy Officer, Treasurer and Secretary
Non-Employee Directors		
Ezra Friedberg	52	Director
Daniel O'Connor	57	Director

Biographic Information - Executive Officers

Christian Kopfli, Esq. has served as our Chief Executive Officer and as a director since our inception. Mr. Kopfli co-founded Chromocell Holdings in 2002, serving initially as General Counsel before becoming Chief Executive Officer of Chromocell Holdings in 2005, a position he currently still holds. Prior to joining Chromocell Holdings, he served as an Associate at Davis Polk & Wardwell, working in its New York City, Tokyo and Frankfurt offices. At Davis Polk, Mr. Kopfli worked extensively in mergers and acquisitions, capital markets and private equity transactions.

Francis Knuettel II has served as our Chief Financial Officer, Chief Strategy Officer, Treasurer and Secretary since June 2022. Prior to that, from December 2020 to April 2022, he served as Chief Executive Officer and director of Unrivaled Brands, a California-based operator of cannabis assets in California and Oregon, where he grew 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 from August 2018 to January 2019. During Mr. Knuettel's career, he has helped raise more than $300 million via venture equity and debt, public equity and debt offerings in the United States and Canada, convertible debt, PIPEs, bridge loans and other instruments. In addition, he has managed more than 15 mergers and acquisition transactions of companies as both buyer and seller and has handled large-scale licensing transactions with fortune 50 companies. Mr. Knuettel also holds numerous board positions at both public and private companies, including 180 Life Sciences (Nasdaq: ATNF), ECOM Medical, Murphy Canyon Acquisition Corp. (Nasdaq: MURF) and Relativity Acquisition Corp. (Nasdaq: RACY). 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.

Biographical Information - Non-Employee Directors

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

Daniel J. O'Connor has served as a director since July 2022. Between September 2017 and June 2021, Mr. O'Connor served as the Chief Executive Officer, President and Director of OncoSec Medical Incorporated, a NJ based biotech company focusing on intratumoral cancer immunotherapy. Prior to OncoSec, Mr. O'Connor served as the President and CEO of Advaxis Inc., where he successfully up-listed the company to NASDAQ, implemented a turnaround strategy that resulted in more than $300 million raised in funding and licensing deals and established major partnerships with companies such as Amgen Inc., Merck & Co. and Bristol Myers Squibb. Under his leadership, the company advanced four new cancer immunotherapy drug candidates into clinical trials and several PD-1 combination clinical studies with Keytruda® and Opdivo®, which ultimately transformed Advaxis into a patient-focused, leading cancer immunotherapy company. Earlier in his career, Mr. O'Connor was the General Counsel and Senior Vice President for ImClone Systems where he helped lead the clinical development, launch and commercialization of ERBITUX®, and positioned ImClone for sale to Eli Lilly in 2008. Mr. O'Connor served as General Counsel at PharmaNet (today, Syneos Health) and was part of the senior leadership team that grew PharmaNet from a start-up clinical research organization (CRO) into a well-established leader in clinical research. Mr. O'Connor is a founding member the Board of Directors for Seelos Therapeutics (NASDAQ: SEEL) and was previously the Chairman of its Audit Committee. Mr. O'Connor was also a member of the Board of Trustees of BioNJ from 2015 to 2021 and previously served as its Vice Chairman and Chairman of its Nominating Committee for several years. In 2015, Ernst & Young named Mr. O'Connor Entrepreneur of the Year® in New Jersey. Also in 2015, he was the "Highly Commended" award winner for the 8th Vaccine Industry Excellence Award (ViE) Best Biotech CEO. In 2017, he was appointed by the governor of New Jersey to serve on the New Jersey Biotechnology Task Force. The Task Force was created to improve communication between State government and the industry to find ways to help retain and attract biotechnology companies to New Jersey. In 2018, he received Irish American Magazine Healthcare & Life Sciences 50 Honoree. In May, 2021, he was named a finalist for the Ernst & Young Entrepreneur of the Year® in New Jersey. He is a 1995 graduate of the Penn State University's Dickinson School of Law in Carlisle, Pennsylvania and previously served as a Trusted Advisor to its Dean. Mr. O'Connor graduated from the United States Marines Corps Officer Candidate School in 1988 and was commissioned as a Lieutenant in the U.S. Marines, attaining the rank of Captain and was deployed to Saudi Arabia for Operation Desert Shield. Prior to his career in drug development, Mr. O'Connor was a former criminal prosecutor in Somerset County, New Jersey.

Board Composition

Board of Directors

Upon completion of this offering, our board of directors will consist of five 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 Nasdaq 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, Nasdaq 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 Nasdaq 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 Nasdaq 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 are independent, as defined under applicable Nasdaq rules. In making such determination, our board of directors considered the relationships that each such non-employee director has with our company and all other facts and circumstances that our board of directors deemed relevant in determining his or her independence, including the beneficial ownership of our capital stock by each non-employee director and the transactions involving them described in the section entitled "Certain Relationships and Related-Party Transactions."

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

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

Committees of Our Board of Directors

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

Audit Committee

Our audit committee is composed of and . is the chairperson of our audit committee. and each meet the requirements for independence under the current Nasdaq 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 is an "audit committee financial expert" as defined in Item 407(d)(5)(ii) of Regulation S-K promulgated under the Securities Act. This designation does not impose any duties, obligations or liabilities that are greater than are generally imposed on members of our audit committee and our board of directors. Our audit committee is responsible for, among other things:

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

Compensation Committee

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

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

Nominating and Corporate Governance Committee

Our nominating and corporate governance committee is composed of and . 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 Nasdaq 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.

Codes of Business Conduct and Ethics

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

Non-Employee Director Compensation

Prior to this offering, 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. We did not pay any compensation, other than equity awards, to any of our non-employee directors in 2021. We plan to reimburse our directors for expenses associated with attending meetings of our board of directors and its committees although we have not previously done so.

Prior to this offering, we intend to adopt and ask our stockholders to approve the initial terms of our non-employee director compensation program. Our board of directors is still in the process of considering the non-employee director compensation policy.

EXECUTIVE COMPENSATION

Our sole named executive officer for 2021 was Christian Kopfli, our Chief Executive Officer, President and Chief Financial Officer. In June 2022, our board of directors appointed Francis Knuettel II as Chief Financial Officer, Chief Strategy Officer, Treasurer and Secretary.

Summary Compensation Table

The following table provides information regarding the compensation of our sole named executive officer during the years ended December 31, 2021 and 2020.

Name and Principal Position	Year	Salary	Bonus	Option Awards	Non-Equity Incentive Plan Compensation	All Other Compensation	Total
Christian Kopfli Chief Executive Officer, President and Chief Financial Officer	2021	$ 264,000	$ --	$ --	$ --	$ --	$ 264,000
	2020	$ 66,605[1]	$ --	$ --	$ --	$ --	$ 66,605

(1) Represents the portion of Mr. Kopfli's salary attributable to his services to the Company during the year ended December 31, 2020.

Executive Employment Arrangements

As of the date of this filing, we have not entered into an employment agreement with any of our executive officers.

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, 2021.

	Option Awards					Stock Awards			
Name and Principal Position	Number of Securities Underlying Unexercised Options Exercisable	Number of Securities Underlying Unexercised Options Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options	Option Exercise Price	Option Expiration Date	Number of Shares or Units of Stock Unvested	Market Value of Shares of Units of Stock Unvested	Equity Incentive Plan Awards: Number of Unearned Unvested Shares	Equity Incentive Plan Awards: Market or Payout Value of Unearned Unvested Shares
Christian Kopfli Chief Executive Officer, President and Chief Financial Officer	---	---	---	$ ---	---	---	$ ---	---	$ ---

Equity Incentive Plans

The 2022 Plan

Our board of directors intends to adopt and submit for stockholder approved the 2022 Plan prior to the consummation of this offering. The 2022 Plan will terminate on in accordance with its terms, however, awards outstanding under the 2022 Plan will continue to be governed by their existing terms.

Share Reserve. We intend to reserve shares of our Common Stock for issuance under the 2022 Plan. Unissued shares of Common Stock subject to awards that expire, are forfeited, or are cancelled, shares of Common Stock reacquired by us and shares of Common Stock withheld in payment of the purchase price or exercise price of an award or in satisfaction of withholding taxes will again become available for issuance under the 2022 Plan.

Administration. Our board of directors, or a committee thereof, will administer the 2022 Plan upon its adoption; however, following this offering, the compensation committee of our board of directors will generally administer the 2022 Plan. The administrator has complete discretion to make all decisions relating to the 2022 Plan and outstanding awards.

Eligibility. Employees, non-employee members of our board of directors and consultants will be eligible to participate in the 2022 Plan. However, only employees are eligible to receive incentive stock options.

Types of Awards. The 2022 Plan will provide for the following types of awards granted with respect to shares of our Common Stock:

- incentive and nonstatutory stock options to purchase shares of our Common Stock;
- direct award or sale of shares of our Common Stock, including restricted shares; and
- restricted stock units.

Options. The exercise price for options granted under the 2022 Plan will be determined by our board of directors, but may not be less than 100% of the fair market value of our Common Stock on the grant date. Optionees may pay the exercise price in cash or cash equivalents or by one, or any combination of, the following forms of payment, as permitted by the administrator in its sole discretion:

- Surrender of shares of Common Stock that the optionee already owns;
- Delivery of a full-recourse promissory note, with the option shares pledged as security against the principal and accrued interest on the note;
- An immediate sale of the option shares through a company-approved broker, if the shares of our Common Stock are publicly traded;
- Surrendering a number of vested shares of Common Stock subject to the option having an aggregate fair market value no greater than the aggregate exercise price of such shares, or the sum of such exercise price plus all or a portion of the minimum amount required to be withheld under applicable law; or
- Other methods permitted by the DGCL.

Options vest as determined by the administrator. In general, we will grant options that vest over a three-year period. Options will expire at the time determined by the administrator, but in no event more than ten years after they are granted, and generally expire earlier if the optionee's service terminates.

Restricted Shares. Restricted shares may be awarded or sold under the 2022 Plan in return for cash or cash equivalents or, as permitted by the administrator in its sole discretion, in exchange for services rendered to us, by delivery of a full-recourse promissory note or through any other means permitted by applicable law. Restricted shares will vest as determined by the administrator.

Restricted Stock Units. Restricted stock units may be awarded or sold under the 2022 Plan. No cash consideration shall be required of the recipient in connection with the grant of restricted stock units. Settlement of vested restricted stock units may be made in the form of cash, shares of our Common Stock, or any combination of both, as determined by the administrator. Restricted stock units will vest as determined by the administrator.

Corporate Transactions. In the event that we are a party to a merger or consolidation or in the event of a sale of all or substantially all of our stock or assets, awards granted under the 2022 Plan will be subject to the agreement governing such transaction or, in the absence of such agreement, in the manner determined by the administrator. Such treatment may include, without limitation, one or more of the following with respect to outstanding awards:

- The continuation, assumption or substitution of an award by the surviving entity or its parent;
- Cancellation of the vested portion of the award in exchange for a payment equal to the excess, if any, of the value of the shares subject to the award over any exercise price per share applicable to the award;
- Cancellation of the award without payment of any consideration;
- Suspension of the optionee's right to exercise the option during a limited period of time preceding the completion of the transaction; or
- Termination of any right the optionee has to exercise the option prior to vesting in the shares subject to the option.

The administrator is not obligated to treat all awards in the same manner. The administrator has the discretion, at any time, to provide that an award under the 2022 Plan will vest on an accelerated basis in connection with a corporate transaction or to amend or modify an award so long as such amendment or modification is not inconsistent with the terms of the 2022 Plan or would not result in the impairment of a participant's rights without the participant's consent.

Changes in Capitalization. In the event of certain specified changes in the capital structure of our Common Stock, such as a stock split, reverse stock split, stock dividend, reclassification or any other increase or decrease in the number of issued shares of stock effective without receipt of consideration by us, proportionate adjustments will automatically be made in (i) each of the number and kind of shares available for future grants under the 2022 Plan, (ii) the number and kind of shares covered by each outstanding award, (iii) the exercise price per share subject to each outstanding option and (iv) any repurchase price applicable to shares of Common Stock granted under the 2022 Plan. In the event of an extraordinary cash divided that has a material effect on the fair market value of our Common Stock, a recapitalization, spin-off or other similar occurrence, the administrator at its sole discretion may make appropriate adjustments to one or more of the items described above.

Amendments or Termination. The administrator may at any time amend, suspect or terminate the 2022 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 2022 Plan will terminate automatically ten years after the later of the date when our board of directors adopts 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 2022 Plan upon termination will remain outstanding and will continue to be governed by their existing terms.

Limitations on Liability and Indemnification Matters

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

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

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

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

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

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

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

Rule 10b5-1 Sales Plans

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

CERTAIN RELATIONSHIPS AND RELATED PARTY AND OTHER TRANSACTIONS

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

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

On August 10, 2022, effective July 12, 2022, the Company and Chromocell Holdings entered into the Contribution Agreement effecting (1) the contribution by Chromocell Holdings to the Company of assets related to Chromocell Holding's Therapeutics Business, including all intellectual property related to Chromocell Holding's NaV1.7 program and its clinical-stage CC8464 lead compound, (2) assumption by the Company of direct-liabilities related to Chromocell Holding's historical Therapeutics Business in the amount of $1,556,323 as well as expenses of $597,038 and (3) the issuance by the Company to Chromocell Holdings of 10,000,000 shares of its common stock and 600,000 shares of its Series A Convertible Preferred Stock.

Review, Approval or Ratification of Transactions with Related Parties

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

PRINCIPAL STOCKHOLDERS

The following table sets forth information regarding beneficial ownership of our Common Stock as of , 2022, by:

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

We have determined beneficial ownership in accordance with the rules of the SEC and the information is not necessarily indicative of beneficial ownership for any other purpose. Unless otherwise indicated below, to our knowledge, the persons and entities named in the table have sole voting and sole investment power with respect to all shares of Common Stock that they beneficially own, subject to community property laws where applicable. In computing the number of shares of our Common Stock beneficially owned by a person and the percentage ownership of that person, we deemed outstanding shares of our Common Stock subject to options or warrants held by that person that are currently exercisable or exercisable within 60 days of , 2022. We did not deem these shares outstanding, however, for the purpose of computing the percentage ownership of any other person.

Percentage computations are based on approximately shares of our Common Stock outstanding as of , 2022 (after giving effect to the IPO Transactions), and shares outstanding immediately following this offering (or shares if the underwriters exercise in full their option to purchase additional Units).

Unless otherwise indicated, the address of each beneficial owner listed on the table below is c/o Chromocell Therapeutics Corporation, 675 US Route 1 South, North Brunswick Township, NJ 08906.

	Shares Beneficially Owned Prior to this Offering		Shares Beneficially Owned After this Offering Assuming No Exercise of the Underwriter's Option		Shares Beneficially Owned After this Offering Assuming Full Exercise of the Underwriter's Option	
Name of Beneficial Owner	**Number**	**%**	**Number**	**%**	**Number**	**%**
Named Executive Officers and Directors						
Christian Kopfli[1]		%		%		%
Ezra Friedberg[2]		%		%		%
Daniel J. O'Connor		%		%		%
All executive officers and directors as a group (persons)		**%**		**%**		%
5% Stockholders						
Flamands International Holdings LLC[3][4]		%		%		%
Chromocell Corporation[4]		%		%		%

[1] Mr. Kopfli serves on the board of directors of Chromocell Corporation and, accordingly, may be deemed to beneficially own the shares of Common Stock held by Chromocell Corporation.

[2] Mr. Friedberg serves as manager of Flamands International Holdings, LLC and, accordingly, may be deemed to beneficially own the shares of Common Stock held by Flamands International Holdings, LLC.

[3] The business address of Flamands International Holdings, LLC is 434 West 33rd Street #741, New York, NY 10001.

[4] In August 2022, Chromocell Holdings sold 5,999,667 shares of the common stock it owns of the Company to Flamands resulting in a change of control of the Company. The agreement provides Flamands an option to acquire an additional 667,000 shares of the common stock Chromocell Holdings owns of the Company prior to the public filing of a registration statement relating to the Company's initial public offering.

DESCRIPTION OF CAPITAL STOCK

Upon the completion of this offering, our authorized capital stock will consist of shares of Common Stock and shares of blank check preferred stock, $0.0001 par value per share. The following description summarizes the most important terms of our capital stock after giving effect to the IPO Transactions. Because it is only a summary, it does not contain all the information that may be important to you. For a complete description, you should refer to our certificate of incorporation and bylaws, each as amended to date, which will be included as exhibits to the registration statement of which this prospectus forms a part.

Common Stock

Authorized Shares

The Company has authorized for issuance an aggregate of shares of Common Stock. As of , 2022, 10,000,000 shares of Common Stock were issued and outstanding.

Dividend Rights

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

Voting Rights

Holders of our Common Stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders. We have not provided for cumulative voting for the election of directors. Our certificate of incorporation will establish a classified board of directors, divided into three classes with staggered three-year terms. Only one class of directors will be elected at each annual meeting of our stockholders, with the other classes continuing for the remainder of their respective three-year terms.

No Preemptive or Similar Rights

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

Liquidation Rights

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

Preferred Stock

Our board of directors has the authority, without further action by our stockholders, to issue up to shares of preferred stock in one or more classes or series and to fix the designations, rights, preferences, privileges and restrictions thereof, without further vote or action by the stockholder. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting, or the designation of, such class or series, any or all of which may be greater than the rights of Common Stock. The issuance of our preferred stock could adversely affect the voting power of holders of Common Stock and the likelihood that such holders will receive dividend payments and payments upon our liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing a change in control of the Company or other corporate action. Immediately after completion of this offering, no shares of preferred stock will be outstanding, and we have no present plan to issue any shares of preferred stock.

Warrants to Be Issued in this Offering

The following summary of certain terms and provisions of the warrants offered hereby is not complete and is subject to, and qualified in its entirety by, the provisions of the warrant agent agreement between us and as warrant agent, and the form of warrant, both of which are filed as exhibits to the registration statement of which this prospectus is a part. Prospective investors should carefully review the terms and provisions set forth in the warrant agent agreement, including the annexes thereto, and form of warrant.

Exercisability

The warrants are immediately exercisable at any time following the consummation of this offering and at any time up to the date that is five years after their original issuance. The warrants will be exercisable, at the option of each holder, in whole or in part by delivering to us a duly executed exercise notice and, at any time a registration statement registering the issuance of the shares of common stock underlying the warrants under the Securities Act is effective and available for the issuance of such shares, or an exemption from registration under the Securities Act is available for the issuance of such shares, by payment in full in immediately available funds for the number of shares of common stock purchased upon such exercise. If a registration statement registering the issuance of the shares of common stock underlying the warrants under the Securities Act is not effective or available and an exemption from registration under the Securities Act is not available for the issuance of such shares, the holder may, in its sole discretion, elect to exercise the warrant through a cashless exercise, in which case the holder would receive upon such exercise the net number of shares of common stock determined according to the formula set forth in the warrant. No fractional shares of common stock will be issued in connection with the exercise of a warrant. In lieu of fractional shares, we will pay the holder an amount in cash equal to the fractional amount multiplied by the exercise price.

We will not effect the exercise of any portion of these warrants, and the holder will not have the right to exercise any portion of the warrants, and any such exercise shall be null and void and treated as if never made, to the extent that after giving effect to such exercise, the holder together with its affiliates and certain other persons specified in these warrants collectively would own beneficially in excess of 4.99% (or, upon election by a holder prior to the issuance of any warrants, 9.99%) of the shares of common stock outstanding immediately after giving effect to such exercise.

Exercise Price

The exercise price per whole share of common stock purchasable upon exercise of the warrants is $ per share (based on an initial public offering price of $ per unit, the midpoint of the range set forth on the cover of this prospectus). The exercise price is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our common stock and also upon any distributions of assets, including cash, stock or other property to our stockholders.

Transferability

Subject to applicable laws, the warrants may be offered for sale, sold, transferred or assigned without our consent.

Exchange Listing

We intend to apply to list our warrants for trading on The NASDAQ Capital Market under the symbol " W". No assurance can be given that our listing application will be approved or that a trading market will develop

Warrant Agent

The warrants will be issued in registered form under a warrant agent agreement between as warrant agent, and us. The warrants shall be represented only by one or more global warrants deposited with the warrant agent, as custodian on behalf of The Depository Trust Company (DTC) and registered in the name of Cede & Co., a nominee of DTC, or as otherwise directed by DTC.

Fundamental Transactions

In the event of a fundamental transaction, as described in the warrants and generally including any reorganization, recapitalization or reclassification of our Common Stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of more than 50% of our outstanding common stock, or any person or group becoming the beneficial owner of 50% of the voting power represented by our outstanding common stock, the holders of the warrants will be entitled to receive upon exercise of the warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the warrants immediately prior to such fundamental transaction

Rights as a Stockholder

Except as otherwise provided in the warrants or by virtue of such holder's ownership of shares of our common stock, the holder of a warrant does not have the rights or privileges of a holder of our common stock, including any voting rights, until the holder exercises the warrant.

Governing Law

The warrants and the warrant agent agreement are governed by New York law.

Stock Options

The Company intends to adopt the 2022 Plan prior to the consummation of this offering, to provide for the grant of both incentive stock options and nonqualified stock options. The 2022 Plan will terminate on , in accordance with its terms.

Options granted under the 2022 Plan will generally expire 10 years from the date of the grant. Options will be granted with an exercise price not less than the fair market value of the underlying Common Stock on the date of the grant. Unless otherwise specified by the board of directors, all grants will vest fully over a three-year period, provided that the employee continues to be employed. Unless otherwise provided for by the board of directors, vesting will terminate once the optionee is no longer an employee. If an employee leaves the Company prior to fully vesting their option awards, the remaining unvested portion will be considered forfeited, and the earlier recognition of the unvested shares will be reversed during the period of forfeiture.

Anti-Takeover Provisions

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

Delaware Law

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

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

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

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

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

Certificate of Incorporation and Bylaws Provisions

Our certificate of incorporation and our bylaws, as in effect immediately prior to the completion of this offering, include a number of provisions that could deter hostile takeovers or delay or prevent changes in control of our company, including the following:

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

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

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

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

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

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

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

- *Choice of Forum*. Our certificate of incorporation will provide that the Court of Chancery of the State of Delaware will be the exclusive forum for: any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the DGCL, our certificate of incorporation or our bylaws; any action to interpret, apply, enforce or determine the validity of our certificate of incorporation or our bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. The enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable.

Transfer Agent and Registrar

Upon the completion of this offering, the transfer agent and registrar for our Common Stock will be . The transfer agent's address is , and its telephone number is . Our shares of Common Stock, including the shares of Common Stock included in the Units or issued upon exercise of the Warrants, will be issued in uncertificated form only, subject to limited circumstances.

Market Listing

We intend to apply to list our Common Stock and Warrants on the Nasdaq Capital Market under the symbols " " and " W", respectively.

SHARES ELIGIBLE FOR FUTURE SALE

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

After giving effect to the IPO Transactions and sale of Units in this offering, we will have outstanding shares of Common Stock. All of the shares sold as part of the Units in this offering will be immediately tradable without restriction under the Securities Act of 1933, as amended, or the Securities Act, except for any shares held by "affiliates," as that term is defined in Rule 144 under the Securities Act, or Rule 144.

The remaining outstanding shares of our Common Stock will be deemed "restricted securities" as defined in Rule 144. Restricted securities may be sold in the public market only if they are registered under the Securities Act or if they qualify for an exemption from registration under Rule 144 or Rule 701 promulgated under the Securities Act, which rules are summarized below. In addition, all of our security holders have entered into lock-up agreements with the underwriters under which they have agreed, subject to specific exceptions, not to sell any of shares of Common Stock for at least 180 days following the date of this prospectus, as described below.

Lock-Up Agreements

All of our directors, executive officers and our security holders are subject to lock-up agreements that, subject to certain exceptions, prohibit them from directly or indirectly offering, pledging, selling, contracting to sell, selling any option or contract to purchase, purchasing any option or contract to purchase, granting any option, right or warrant to purchase or otherwise transferring or disposing of any shares of Common Stock, options to acquire shares of Common Stock or any securities convertible into or exercisable or exchangeable for Common Stock, whether now owned or hereafter acquired, or entering into any swap or any other agreement or any transaction that transfer, in whole or in part, directly or indirectly, the economic consequence of ownership, for a period of six months following the closing of this offering, without the prior written consent of the underwriters. These agreements are described in the section entitled "Underwriting."

Rule 144

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

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

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

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

Rule 701

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

Equity Incentive Options

We intend to file a registration statement on Form S-8 under the Securities Act covering all of the shares of Common Stock subject to outstanding options and the shares of Common Stock reserved for issuance under our 2022 Plan and future incentive stock plans. We expect to file a registration statement covering such shares issuable under the 2022 Plan as soon as permitted under the Securities Act. However, the shares of Common Stock registered on Form S-8 may be subject to the volume limitations and the manner of sale, notice and public information requirements of Rule 144 and will not be eligible for resale until expiration of the lock-up agreements to which they are subject.

MATERIAL U.S. FEDERAL INCOME TAX CONSIDERATIONS

The following is a summary of the material U.S. federal income tax considerations relating to the purchase, ownership and disposition of our Units, common stock and warrants purchased in this Offering, which we refer to collectively as our securities, but is for general information purposes only and does not purport to be a complete analysis of all the potential tax considerations. The holder of a unit generally should be treated, for U.S. federal income tax purposes, as the owner of the underlying one share of common stock and one warrant to purchase one share of common stock that underlie the unit, as the case may be. As a result, the discussion below with respect to actual holders of common stock and warrants should also apply to holders of units (as the deemed owners of the underlying common stock and warrants that comprise the units). This summary is based upon the provisions of the Internal Revenue Code of 1986, as amended (the "Code"), existing and proposed U.S. Treasury regulations promulgated thereunder, administrative rulings and judicial decisions, all as of the date hereof. These authorities may be changed, possibly retroactively, so as to result in U.S. federal income and estate tax consequences different from those set forth below. There can be no assurance that the Internal Revenue Service (the "IRS") will not challenge one or more of the tax consequences described herein, and we have not obtained, and do not intend to obtain, an opinion of counsel or ruling from the IRS with respect to the U.S. federal income tax considerations relating to the purchase, ownership or disposition of our securities.

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

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

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

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

Allocation of Purchase Price and Characterization of a Unit

No statutory, administrative or judicial authority directly addresses the treatment of a unit or instruments similar to a unit for U.S. federal income tax purposes and, therefore, that treatment is not entirely clear. The acquisition of a unit should be treated for U.S. federal income tax purposes as the acquisition of one share of common stock and one warrant to purchase one share of common stock. For U.S. federal income tax purposes, each holder of a unit must allocate the purchase price paid by such holder for such unit between such one share of common stock and one warrant to purchase one share of common stock based on their relative fair market values at the time of issuance. Under U.S. federal income tax law, each investor must make his or her own determination of such value based on all the relevant facts and circumstances. Therefore, we strongly urge each investor to consult his or her tax adviser regarding the determination of value for these purposes. The price allocated to each share of common stock and each warrant should be the stockholder's tax basis in such share or warrant, as the case may be. Any disposition of a unit should be treated for U.S. federal income tax purposes as a disposition of the one share of common stock and one warrant to purchase one share of common stock comprising the unit, and the amount realized on the disposition should be allocated between the one share of common stock and one warrant to purchase one share of common stock based on their respective relative fair market values (as determined by each such unit holder on all the relevant facts and circumstances) at the time of disposition. The separation of the common stock and warrants comprising units should not be a taxable event for U.S. federal income tax purposes.

The foregoing treatment of the common stock and warrants and a holder's purchase price allocation are not binding on the IRS or the courts. Because there are no authorities that directly address instruments that are similar to the units, no assurance can be given that the IRS or the courts will agree with the characterization described above or the discussion below. Accordingly, each prospective investor is urged to consult its own tax advisors regarding the tax consequences of an investment in a unit (including alternative characterizations of a unit). The balance of this discussion assumes that the characterization of the units described above is respected for U.S. federal income tax purposes.

Consequences to U.S. Holders

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

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

Distributions

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

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

Constructive Distributions

The terms of the warrants allow for changes in the exercise price of the warrants under certain circumstances. A change in exercise price of a warrant that allows holders to receive more shares of common stock on exercise may increase a holder's proportionate interest in our earnings and profits or assets. In that case, such holder may be treated as though it received a taxable distribution in the form of our common stock. A taxable constructive stock distribution would generally result, for example, if the exercise price is adjusted to compensate holders for distributions of cash or property to our stockholders.

Not all changes in the exercise price that result in a holder's receiving more common stock on exercise, however, would be considered as increasing a holder's proportionate interest in our earnings and profits or assets. For instance, a change in exercise price could simply prevent the dilution of a holder's interest upon a stock split or other change in capital structure. Changes of this type, if made pursuant to bona fide reasonable adjustment formula, are not treated as constructive stock distributions for these purposes. Conversely, if an event occurs that dilutes a holder's interest and the exercise price is not adjusted, the resulting increase in the proportionate interests of our stockholders could be treated as a taxable stock distribution to our stockholders.

Any taxable constructive stock distributions resulting from a change to, or a failure to change, the exercise price of the warrants that is treated as a distribution of common stock would be treated for U.S. federal income tax purposes in the same manner as distributions on our common stock paid in cash or other property, resulting in a taxable dividend to the recipient to the extent of our current or accumulated earnings and profits (with the recipient's tax basis in its common stock or warrants, as applicable, being increased by the amount of such dividend), and with any excess treated as a return of capital or as capital gain. U.S. holders should consult their own tax advisors regarding whether any taxable constructive stock dividend would be eligible for tax rates applicable to long-term capital gains or the dividends-received deduction described below under "Consequences to U.S. Holders—Distributions," as the requisite applicable holding period requirements might not be considered to be satisfied.

Sale, Exchange or Other Taxable Disposition of Common Stock

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

Sale, Exchange, Redemption, Lapse or Other Taxable Disposition of a Warrant

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

Any taxable constructive stock distributions resulting from a change to, or a failure to change, the exercise price of the warrants that is treated as a distribution of common stock would be treated for U.S. federal income tax purposes in the same manner as distributions on our common stock paid in cash or other property, resulting in a taxable dividend to the recipient to the extent of our current or accumulated earnings and profits (with the recipient's tax basis in its common stock or warrants, as applicable, being increased by the amount of such dividend), and with any excess treated as a return of capital or as capital gain. U.S. holders should consult their own tax advisors regarding whether any taxable constructive stock dividend would be eligible for tax rates applicable to long-term capital gains or the dividends-received deduction described below under "Consequences to U.S. Holders—Distributions," as the requisite applicable holding period requirements might not be considered to be satisfied.

Sale, Exchange or Other Taxable Disposition of Common Stock

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

Sale, Exchange, Redemption, Lapse or Other Taxable Disposition of a Warrant

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

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

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

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

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

- shares of our common stock or our warrants, as applicable, constitute U.S. real property interests by reason of our status as a "United States real property holding corporation" (a USRPHC) for U.S. federal income tax purposes at any time within the shorter of the five-year period preceding the non-U.S. holder's disposition of, or the non- U.S. holder's holding period for, our common stock or warrants, as applicable.

We believe that we are not currently and will not become a USRPHC for U.S. federal income tax purposes, and the remainder of this discussion so assumes. However, because the determination of whether we are a USRPHC depends on the fair market value of our U.S. real property relative to the fair market value of our other business assets, there can be no assurance that we will not become a USRPHC in the future. Even if we become a USRPHC, however, as long as our common stock is regularly traded on an established securities market, such common stock will be treated as U.S. real property interests only if the non-U.S. holder actually or constructively hold more than five percent of such regularly traded common stock at any time during the shorter of the five-year period preceding the non-U.S. holder's disposition of, or the non-U.S. holder's holding period for, our common stock. In addition, provided that our common stock is regularly traded on an established securities market, a warrant will not be treated as a U.S. real property interest with respect to a non-U.S. holder if such holder did not own, actually or constructively, warrants whose total fair market value on the date they were acquired (and on the date or dates any additional warrants were acquired) exceeded the fair market value on that date (and on the date or dates any additional warrants were acquired) of 5% of all our common stock.

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

Federal Estate Tax

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

Backup Withholding and Information Reporting

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

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

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

Foreign Account Tax Compliance

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

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

UNDERWRITING

We and the underwriters named below have entered into an underwriting agreement with respect to the units being offered. Subject to certain conditions, each underwriter has severally agreed to purchase the number of units indicated in the following table. The Benchmark Company, LLC ("Benchmark") is acting as the representative of the underwriters.

Underwriters	Number of Units
The Benchmark Company, LLC	
Total	

The underwriters are committed to take and pay for all of the units being offered, if any are taken, other than the units covered by the option described below unless and until this option is exercised. The underwriting agreement also provides that if an underwriter defaults, the purchase commitments of non-defaulting underwriters may also be increased or the offering may be terminated.

The underwriters have an option to buy up to additional shares of common stock included in the units and/or additional warrants to purchase shares of common stock included in the units from us in any combination thereof to cover sales of shares by the underwriters which exceed the number of shares specified in the table above. The underwriters have 30 days from the date of this prospectus to exercise this over-allotment option. If any shares and/or additional warrants are purchased with this over-allotment option, the underwriters will purchase shares and/or additional warrants in approximately the same proportion as shown in the table above. If any additional shares of common stock and/or additional warrants are purchased, the underwriters will offer the additional shares and additional warrants, respectively. on the same terms as those on which the shares and warrants are being offered.

The following table shows the per unit and total underwriting discounts and commissions to be paid to the underwriters by us assuming both no exercise and full exercise of the underwriters' over-allotment option:

	Without Over-Allotment Exercise	With Over-Allotment Exercise
Per Unit[(1)]	$	$
Total	$	

(1) The underwriters will receive a discount of 4% of the public offering price.

Units sold by the underwriters to the public will initially be offered at the initial public offering price set forth on the cover of this prospectus. Any units sold by the underwriters to securities dealers may be sold at a discount of up to $ per unit from the initial public offering price. After the initial offering of the units, the representative may change the offering price and the other selling terms. The offering of the units by the underwriters is subject to receipt and acceptance and subject to the underwriters' right to reject any order in whole or in part. Sales of units made outside of the United States may be made by affiliates of the underwriters.

Expense Reimbursement

We have agreed to pay or reimburse the underwriters for certain of their actual out-of-pocket fees and expenses, including "road show," diligence, filing fees and communication expenses associated with the review of this offering by the Financial Industry Regulatory Authority, Inc., and legal fees up to a maximum of $112,500. We have also agreed to pay the costs of background checks on our senior management in an amount of up to $7,500.

Non-accountable Expense Allowance

In connection with and upon closing of this offering, the Company shall pay to the underwriters a non-accountable expense allowance equal to one percent (1%) of the gross proceeds received by the Company from the sale of the units.

Underwriters' Warrants

In addition, pursuant to the underwriting agreement, we will issue the Underwriters' Warrants to the underwriters to purchase a number of shares of Common Stock equal to 4% of the total number of Units sold in this offering at an exercise price equal to 100% of the per Unit offering price of the Units sold in this offering. The Underwriters' Warrants may be purchased in cash or via cashless exercise, will be exercisable for a five-year period commencing six months following the commencement of sales of the Units registered on the registration statement of which this prospectus is a part and will terminate on the five-year anniversary of their issuance. The Underwriters' Warrants and the shares of Common Stock issuable upon exercise of the Underwriters' Warrants will be deemed compensation by FINRA, and therefore will be subject to FINRA Rule 5110(e)(1)(A). In accordance with FINRA Rule 5110(e)(1)(A), neither the Underwriters' Warrants nor any of the shares of Common Stock issued upon exercise of such warrants may be sold, transferred, assigned, pledged or hypothecated, or be the subject of any hedging, short sale, derivative, put or call transaction that would result in the effective economic disposition of such securities by any person, for a period of 180 days immediately following the commencement of sales of the Units registered on the registration statement of which this prospectus is a part, subject to certain exceptions.

Lock-up Agreements

We have agreed with the underwriters that we will not, without the prior consent of the representative, directly or indirectly sell, offer, contract or grant any option to sell, pledge, transfer, or otherwise dispose of or enter into any transaction which may result in the disposition of any common stock or securities convertible into, exchangeable or exercisable for any common stock for a period of six months after the closing of this offering.

In addition, each of our executive officers and directors and our primary stockholders have agreed with the underwriters not to directly or indirectly sell, offer, contract or grant any option to sell, pledge, transfer (excluding intra-family transfers, transfers to a trust for estate planning purposes or to beneficiaries of officers, directors and shareholders upon their death), or otherwise dispose of or enter into any transaction which may result in the disposition of any common stock or securities convertible into, exchangeable or exercisable for any common stock, without the prior written consent of the representative, for a period of six months after the closing date of this offering.

Stabilization

In connection with this offering, the underwriters may engage in transactions that stabilize, maintain or otherwise affect the price of our common stock. Specifically, the underwriters may over-allot in connection with this offering by selling more units than they are obligated to purchase under the underwriting agreement, creating a short position in our securities. The short position may be either a covered short position or a naked short position. In a covered short position, the number of securities over-allotted by the underwriters is not greater than the number of securities that they may purchase in the over-allotment option. In a naked short position, the number of securities involved is greater than the number of securities in the over-allotment option. To close out a short position or to stabilize the price per security the underwriters may bid for, and purchase, securities in the open market. The underwriters may also elect to reduce any short position by exercising all or part of the over-allotment option. In determining the source of securities to close out the short position, the underwriters will consider, among other things, the price of the security available for purchase in the open market as compared to the price at which it may purchase the security through the over-allotment option. If the underwriters sell more than could be covered by the over-allotment option, a naked short position, the position can only be closed out by buying securities in the open market. A naked short position is more likely to be created if the underwriters are concerned that there could be downward pressure on the price of the securities in the open market after pricing that could adversely affect investors who purchase in the offering.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representative has repurchased securities sold by or for the account of such underwriter in stabilizing or short covering transactions.

Finally, the underwriters may bid for, and purchase, securities in market making transactions, including "passive" market making transactions as described below.

The foregoing transactions may stabilize or maintain the market price of our securities at a price that is higher than the price that might otherwise exist in the absence of these activities. The underwriters are not required to engage in these activities, and may discontinue any of these activities at any time without notice. These transactions may be effected on a national securities exchange or otherwise.

In connection with this offering, the underwriters and selling group members, if any, or their affiliates may engage in passive market making transactions in common stock on a national securities exchange immediately prior to the commencement of sales in this offering, in accordance with Rule 103 of Regulation M under the Exchange Act. Rule 103 generally provides that:

- a passive market maker may not effect transactions or display bids for our common stock in excess of the highest independent bid price by persons who are not passive market makers; net purchases by a passive market maker on each day are generally limited to 30% of the passive market maker's average daily trading volume in our common share during a specified two-month prior period or 200 shares, whichever is greater, and must be discontinued when that limit is reached; and

- passive market making bids must be identified as such.

Passive market making may stabilize or maintain the market price of our common stock at a level above that which might otherwise prevail and, if commenced, may be discontinued at any time.

Indemnification

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act and liabilities arising from breaches of representations and warranties contained in the underwriting agreement, or to contribute to payments that the underwriters may be required to make in respect of those liabilities.

Determination of Public Offering Price

Prior to this offering, there has not been a public market for our shares and warrants. The public offering price of the units offered by this prospectus has been determined by negotiation between us and the underwriters. Among the factors considered in determining the public offering price of the units were:

- our history and our prospects;

- our financial information and historical performance;

- the industry in which we operate;

- the status and development prospects for our products and services;

- the experience and skills of our executive officers; and
- the general condition of the securities markets at the time of this offering.

The offering price stated on the cover page of this prospectus should not be considered an indication of the actual value of the securities. That price is subject to change as a result of market conditions and other factors, and we cannot assure you that the securities can be resold at or above the public offering price.

Listing

We have applied to list our common stock and the warrants included in the units on the Nasdaq Capital Market under the symbols " " and " W," respectively, upon our satisfaction of the exchange's initial listing criteria, including the completion of this offering.

Electronic Distribution

A prospectus in electronic format may be made available on websites or through other online services maintained by the underwriters of this offering, or by its affiliates. Other than the prospectus in electronic format, the information on the underwriters' website and any information contained in any other website maintained by an underwriter is not part of this prospectus or the registration statement of which this prospectus forms a part, has not been approved and/or endorsed by us or the underwriters in their capacity as underwriters, and should not be relied upon by investors.

Other Relationships

The underwriters have informed us that they do not expect to confirm sales of our units offered by this prospectus to any accounts over which they exercise discretionary authority.

Some of the underwriters and their affiliates may in the future engage in investment banking and other commercial dealings in the ordinary course of business with us or our affiliates. They may in the future receive customary fees and commissions for these transactions. In addition, in the ordinary course of their business activities, the underwriters and their affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers. Such investments and securities activities may involve securities and/or instruments of ours or our affiliates. The underwriters and their affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or financial instruments and may hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

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

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

Advisory Arrangement

The Company has separately retained A.G.P./Alliance Global Partners ("A.G.P.") as a financial advisor in connection with this offering. Further to such financial advisory agreement, A.G.P. will not be rendering services to the Company as an underwriter, syndicate member or placement agent in connection with this Offering. Such financial advisory services are separate from those services to be performed by the underwriters in connection with this offering. The Company has agreed to pay A.G.P. a separate cash fee equal to three percent (3.00%) of the gross proceeds from the sale of the securities in this Offering and issue to A.G.P. warrants equal to two percent (2%) of the Units issued in this offering (with terms and conditions identical to the Underwriter Warrants).

Selling Restrictions

This prospectus does not constitute an offer to sell to, or a solicitation of an offer to buy from, anyone in any country or jurisdiction (i) in which such an offer or solicitation is not authorized, (ii) in which any person making such offer or solicitation is not qualified to do so or (iii) in which any such offer or solicitation would otherwise be unlawful. No action has been taken that would, or is intended to, permit a public offer of the units or possession or distribution of this prospectus or any other offering or publicity material relating to the units in any country or jurisdiction (other than the U.S.) where any such action for that purpose is required. Accordingly, each underwriter has undertaken that it will not, directly or indirectly, offer or sell any units or have in its possession, distribute or publish any prospectus, form of application, advertisement or other document or information in any country or jurisdiction except under circumstances that will, to the best of its knowledge and belief, result in compliance with any applicable laws and regulations and all offers and sales of units by it will be made on the same terms.

Switzerland

This prospectus is not intended to constitute an offer or solicitation to purchase or invest in the securities described herein. The securities may not be publicly offered, directly or indirectly, in Switzerland within the meaning of the Swiss Financial Services Act, or FinSA, and will not be listed on the SIX Swiss Exchange or on any other exchange or regulated trading facility in Switzerland. Neither this prospectus nor any other offering or marketing material relating to the securities constitutes a prospectus as such term is understood pursuant to the FinSA, and neither this prospectus nor any other offering or marketing material relating to the securities may be publicly distributed or otherwise made publicly available in Switzerland.

European Economic Area

In relation to each Member State of the European Economic Area (each a "Relevant State"), no securities have been offered or will be offered pursuant to this offering to the public in that Relevant State prior to the publication of a prospectus in relation to the securities which has been approved by the competent authority in that Relevant State or, where appropriate, approved in another Relevant State and notified to the competent authority in that Relevant State, all in accordance with the Prospectus Regulation, except that the securities may be offered to the public in that Relevant State at any time:

(a) to any legal entity which is a qualified investor as defined under Article 2 of the Prospectus Regulation;

(b) to fewer than 150 natural or legal persons (other than qualified investors as defined under Article 2 of the Prospectus Regulation), subject to obtaining the prior consent of the representative for any such offer; or

(c) in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of the securities shall require the company or any underwriter to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation.

For the purposes of this provision, the expression an "offer to the public" in relation to the securities in any Relevant State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase or subscribe for any securities, and the expression "Prospectus Regulation" means Regulation (EU) 2017/1129.

United Kingdom

No securities have been offered or will be offered pursuant to this offering to the public in the United Kingdom prior to the publication of a prospectus in relation to the securities which has been approved by the Financial Conduct Authority, except that the shares may be offered to the public in the United Kingdom at any time:

(a) to any legal entity which is a qualified investor as defined under Article 2 of the UK Prospectus Regulation;

(b) to fewer than 150 natural or legal persons (other than qualified investors as defined under Article 2 of the UK Prospectus Regulation), subject to obtaining the prior consent of the representative for any such offer; or

(c) in any other circumstances falling within Section 86 of the UK's Financial Services and Markets Act 2000, as amended, or FSMA.

provided that no such offer of the shares shall require the company or any underwriter to publish a prospectus pursuant to Section 85 of the FSMA or supplement a prospectus pursuant to Article 23 of the UK Prospectus Regulation.

For the purposes of this provision, the expression an "offer to the public" in relation to the securities in the United Kingdom means the communication in any form and by any means of sufficient information on the terms of the offer and any securities to be offered so as to enable an investor to decide to purchase or subscribe for any securities and the expression "UK Prospectus Regulation" means Regulation (EU) 2017/1129 as it forms part of domestic law by virtue of the European Union (Withdrawal) Act 2018.

The communication of this prospectus and any other document or materials relating to the issue of the securities offered hereby is not being made, and such documents and/or materials have not been approved, by an authorized person for the purposes of section 21 of the FSMA. Accordingly, such documents and/or materials are not being distributed to, and must not be passed on to, the general public in the UK. The communication of such documents and/or materials as a financial promotion is only being made to and directed at persons outside the UK and those persons in the UK who have professional experience in matters relating to investments and who fall within the definition of investment professionals (as defined in Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended (the "Financial Promotion Order")), or who fall within Article 49(2)(a) to (d) of the Financial Promotion Order, or who are any other persons to whom it may otherwise lawfully be made under the Financial Promotion Order (all such persons together being referred to as "relevant persons"). In the UK, the securities offered hereby are only available to, and any investment or investment activity to which this prospectus relates will be engaged only with, relevant persons. Any person in the UK that is not a relevant person should not act or rely on this prospectus or any of its contents. Each underwriter has represented, warranted and agreed that it has only communicated or caused to be communicated and will only communicate or cause to be communicated an invitation or inducement to engage in investment activity (within the meaning of Section 21 of the FSMA) received by it in connection with the issue or sale of the securities in circumstances in which Section 21(1) of the FSMA does not apply to the company; and it has complied with and will comply with all applicable provisions of the FSMA with respect to anything done by it in relation to the securities in, from or otherwise involving the UK.

The Company has separately retained A.G.P./Alliance Global Partners ("A.G.P.") as a financial advisor in connection with this offering. A.G.P., further to such financial advisory agreement, will not be rendering services to the Company as an underwriter, syndicate member or placement agent in connection with this offering and such financial advisory services are separate from hose services to be performed by Benchmark in connection with the offering as further described herein. The Company has agreed to pay A.G.P. a separate cash fee equal to three percent (3.00%) of the gross proceeds from the sale of the securities in this offering and warrants equal to two percent (2%) of the Units issued in this offering (with terms and conditions identical to the Underwriter Warrants) in connection with such financial advisory services which is not and shall not be considered to be part of Benchmark's compensation in connection with services to be rendered by Benchmark as described herein.

LEGAL MATTERS

The validity of the shares of Common Stock included in the Units offered hereby and issuable upon the exercise of the Warrants included in the Units offered hereby will be passed upon for us by Sullivan & Worcester LLP, New York, New York. The underwriters are being represented by Manatt, Phelps & Philips, LLP, Costa Mesa, California, in connection with this offering.

EXPERTS

The carve-out financial statements of Chromocell Therapeutics Corporation as of December 31, 2021 and 2020, and for each of the two years in the period ended December 31, 2021, appearing in this prospectus have been audited by Marcum LLP, independent registered public accounting firm, as set forth in their report thereon (which contains an explanatory paragraph relating to substantial doubt about the ability of Chromocell Therapeutics Corporation to continue as a going concern as described in Note 2 to the carve-out financial statements), appearing elsewhere in this prospectus, and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the Units offered by this prospectus. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement, some of which is contained in exhibits to the registration statement as permitted by the rules and regulations of the SEC. For further information with respect to us and Units, Common Stock and Warrants, we refer you to the registration statement, including the exhibits filed as a part of the registration statement. Statements contained in this prospectus concerning the contents of any contract or any other document are not necessarily complete. If a contract or document has been filed as an exhibit to the registration statement, please see the copy of the contract or document that has been filed. Each statement in this prospectus relating to a contract or document filed as an exhibit is qualified in all respects by the filed exhibit. The SEC maintains an Internet website that contains reports, proxy statements and other information about issuers, like us, that file electronically with the SEC. The address of that website is www.sec.gov.

As a result of this offering, we will become subject to the information and reporting requirements of the Exchange Act and, in accordance with this law, will file periodic reports, proxy statements and other information with the SEC. These periodic reports, proxy statements and other information will be available for inspection and copying at the SEC's public reference facilities and the website of the SEC referred to above. We also maintain a website at . Upon completion of this offering, you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. Information contained on our website is not a part of this prospectus and the inclusion of our website address in this prospectus is an inactive textual reference only.

Chromocell Therapeutics Corporation
Index to Carve-Out Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of Directors of
Chromocell Therapeutics Corporation
North Brunswick, New Jersey

Opinion on the Financial Statements

We have audited the accompanying carve-out balance sheets of Chromocell Therapeutics Corporation (the "Company") as of December 31, 2021 and 2020, the related carve-out statements of operations, changes in parent's net deficit and cash flows for each of the two years in the period ended December 31, 2021, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2021 and 2020, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2021, in conformity with accounting principles generally accepted in the United States of America.

Explanatory Paragraph – Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 2, the Company has incurred significant losses and needs to raise additional funds to meet its obligations and sustain its operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB and in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Emphasis of Matter

As discussed in Note 1 the financial statements have been prepared on a "carve-out" basis from the financial statements of Chromocell Holdings to reflect the assets, liabilities, revenues and expenses of Chromocell Therapeutics Corporation as well as allocations deemed reasonable by management to present the results of operations, financial position and cash flows of Chromocell Therapeutics Corporation on a standalone basis and may not reflect Chromocell Therapeutics Corporation results of operations, financial position and cash flows had the Company operated as a standalone company during the periods presented. Our Opinion is not modified with respect to this matter.

/s/ Marcum llp

Marcum llp

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

Houston, Texas
September 6, 2022

CHROMOCELL THERAPEUTICS CORPORATION
CARVE-OUT BALANCE SHEETS

	December 31, 2021	December 31, 2020
ASSETS		
CURRENT ASSETS		
Security Deposit	$ -	$ 71,872
TOTAL CURRENT ASSETS	$ -	$ 71,872
TOTAL ASSETS	$ -	$ 71,872
LIABILITIES AND PARENT'S NET DEFICIT		
CURRENT LIABILITIES		
Accounts payable and accrued expenses	$ 2,580,317	$ 3,408,020
PPP loan	-	241,793
TOTAL CURRENT LIABILITIES	2,580,317	3,649,813
Advance from Chromocell Corporation	1,099,950	-
TOTAL LIABILITIES	3,680,267	3,649,813
COMMITMENTS AND CONTINGENCIES		
PARENT'S NET DEFICIT		
Parent's net deficit	(3,680,267)	(3,577,941)
TOTAL PARENT'S NET DEFICIT	(3,680,267)	(3,577,941)
TOTAL LIABILITIES AND PARENT'S NET DEFICIT	$ -	$ 71,872

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

CHROMOCELL THERAPEUTICS CORPORATION
CARVE-OUT STATEMENTS OF OPERATIONS

	For the Year Ended December 31, 2021	For the Year Ended December 31, 2020
REVENUE		
Grant revenue	$ -	$ 199,934
Total Revenue	-	199,934
OPERATING EXPENSES		
General and administrative expenses	496,667	1,323,120
Research and development	209,047	138,585
Professional fees	133,282	92,096
Total Operating Expenses	838,996	1,553,801
NET LOSS FROM OPERATIONS	(838,996)	(1,353,867)
OTHER INCOME (LOSS)		
Interest expense	(253)	(1,676)
Gain on forgiveness of PPP loan	243,862	-
Gain on sale of NOL tax credit	-	694,959
Total Other Income (Loss)	243,609	693,283
Net loss before provision for income taxes	(595,387)	(660,584)
Provision for Income Taxes	-	-
NET LOSS	$ (595,387)	$ (660,584)

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

CHROMOCELL THERAPEUTICS CORPORATION
CARVE-OUT STATEMENTS OF CHANGES IN PARENT'S NET DEFICIT

	For the Year Ended December 31, 2021	For the Year Ended December 31, 2020
Parent's net deficit, beginning of year	$ (3,577,941)	$ (6,301,337)
Net loss	(595,387)	(660,584)
Net contributions from parent	493,061	3,383,980
Parent's net deficit, end of year	$ (3,680,267)	$ (3,577,941)

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

CHROMOCELL THERAPEUTICS CORPORATION
CARVE-OUT STATEMENTS OF CASH FLOWS

	For the Year Ended December 31, 2021	For the Year Ended December 31, 2020
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (595,387)	$ (660,584)
Adjustments to reconcile net loss to net cash used in operating activities		
Gain on forgiveness of PPP loan	(241,793)	-
Changes in operating assets and liabilities:		
Security deposit	71,872	-
Accounts payable and accrued expenses	(827,703)	(2,965,189)
Net Cash Used in Operating Activities	(1,593,011)	(3,625,773)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from PPP loan	-	241,793
Net Contribution from Chromocell Corporation	493,061	3,383,980
Advance from Chromocell Corporation	1,099,950	-
Net Cash Provided by Financing Activities	1,593,011	3,625,773
NET INCREASE (DECREASE) IN CASH	-	-
CASH AT BEGINNING OF PERIOD	-	-
CASH AT END OF PERIOD	$ -	$ -
Supplemental cash flow information:		
Cash paid for income taxes	$ -	$ -
Cash paid for interest expense	$ -	$ -

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

NOTE 1 – ORGANIZATION AND NATURE OF BUSINESS

Company Background

Chromocell Therapeutics Corporation ("Chromocell" or the "Company") was incorporated in the State of Delaware on March 19, 2021.On August 10, 2022, the Company entered into that certain Contribution Agreement (the "Contribution Agreement") with Chromocell Corporation, a Delaware corporation ("Chromocell Holdings"), pursuant to which, effective July 12, 2022 (the "Contribution Date"), Chromocell Holdings contributed all assets and liabilities related to Chromocell Holdings' historical therapeutic business, including all patents, pre-clinical and Phase I study results and data, and trade secrets related to the CC8464 compound to the Company.

Prior to the Contribution Date, the Company had only nominal assets and liabilities. Since this was a spin off transaction in accordance with Accounting Standards Codification ("ASC") 805, "Business Combinations", the Company recognized the contributed assets from Chromocell Holdings at their carrying amounts on the Contribution Date. Chromocell Holdings had two lines of business, the therapeutics business, which was transferred to the Company (the "Therapeutics Business") and a flavors business, which remains with Chromocell Holdings.

Accordingly, the financial statements presented in this prospectus for periods prior to the Contribution Date have been prepared on a "carve-out" basis from the financial statements of Chromocell Holdings to represent the Company's financial position and performance as if it had existed on a stand-alone basis.

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

The Company is a development stage life sciences company which improves consumer products and patient lives through breakthrough science and technologies. The Company is focused on the discovery and development of therapeutics through the use of pioneering Chromovert® technology. Chromovert technology enables the Company to use rare cells ideally suited for effective high-throughput screening. The Company's therapeutics pipeline is currently focused on analgesics and rare diseases, where Chromovert technology has proven highly effective in the rapid identification of potential new drug candidates.

The Company has a limited operating history and has not generated revenue from intended operations. The Company's business and operations are sensitive to general business and economic conditions in the U.S. and worldwide along with local, state, and federal governmental policy decisions. A host of factors beyond the Company's control could cause fluctuations in these conditions. Adverse conditions may include changes in the biotechnology regulatory environment, technological advances that render our technologies obsolete, availability of resources for clinical trials, acceptance of technologies into the medical community, and competition from larger, more well-funded companies.

On January 30, 2020, the World Health Organization declared the COVID-19 novel coronavirus outbreak a "Public Health Emergency of International Concern" and on March 10, 2020, declared it to be a pandemic. Actions taken around the world to help mitigate the spread of the coronavirus include restrictions on travel, and quarantines in certain areas, and forced closures for certain types of public places and businesses. The COVID-19 coronavirus and actions taken to mitigate it have had and are expected to continue to have an adverse impact on the economies and financial markets of many countries, including the geographical area in which the Company operates. While it is unknown how long these conditions will last and what the financial impact will be to the Company, it is reasonably possible that future capital raising efforts and additional development of our technologies may be negatively affected.

NOTE 2 – GOING CONCERN ANALYSIS

Management Plans

During the year ended December 31, 2021, the Company had a net loss of $595,387 and cash of $0 at December 31, 2021. The Company will be conducting medical research and development, and the time at which the Company will begin generating revenue is unknown. These factors indicate substantial doubt about the Company's ability to continue as a going concern for the twelve months following the issuance of these financial statements. The accompanying financial statements have been prepared assuming that the Company will continue as a going concern.

The financial statements included in this report do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the matters discussed herein. While the Company believes in the viability of our strategy to generate sufficient revenue, control costs, and raise additional funds, when necessary, there can be no assurances to that effect. The Company's ability to continue as a going concern is dependent upon the ability to implement the business plan, generate sufficient revenues and to control operating expenses.

Liquidity and Capital Resources

At December 31, 2021, the Company had $0.0 million in cash and cash equivalents and a working capital deficit of approximately $2.6 million, compared to approximately $0.0 million in cash and cash equivalents and a working capital deficit of approximately $3.6 million at December 31, 2020.

Based on the Company's current projections, management believes that due to the lack of cash, revenue and accounts receivables it will be unable to fund its operations through at least the next twelve months, unless the Company can raise additional funds through an initial public offering. While the Company will continue to invest in its business and the development of CC8464, and potentially other molecules, and it is unlikely that the Company will generate product or licensing revenue during the next twelve months, so the Company will need to raise funds though the initial public offering or via private investors or both; However, there is no assurance that the Company will be able to raise such additional funds on acceptable terms, if at all. If the Company raises additional funds by issuing securities, existing stockholders may be diluted.

If adequate funds are not available, the Company may be required to curtail its operations or other business activities or obtain funds through arrangements with strategic partners or others that may require the Company to relinquish rights to certain technologies or potential markets.

NOTE 3 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

Chromocell has not constituted a separate legal entity or group and stand-alone financial statements have not previously been prepared for theCompany. These carve-out financial statements for Chromocell for the years ended December 31, 2021 and 2020 include all of Chromocell's operations which have been conducted within Chromocell Holdings, which also has other activities.

These financial statements have been prepared on a stand-alone basis derived from the financial statements and related accounting records ofChromocell Holdings. The accompanying carve-out combined financial statements present the historical financial position, results of operations, changes in net assets and cash flows of the Company as it was historically conducted, as more fully described below in Footnote 4. The financial information in these financial statements does not necessarily include all the expenses that would have been incurred had the Company operated as a separate stand-alone entity and may not reflect results of operations, financial position and cash flows had the Company been a stand-alone company during the years ended December 31, 2021 and 2020 or in the future.

The Company's financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") and the rules and regulations of the Securities and Exchange Commission ("SEC").

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. Significant estimates made by management include, but are not limited to, estimating the useful lives of patent assets, realization of long-lived assets, valuation of deferred income taxes, unrealized tax positions and business combination accounting.

Grant Revenue

In 2020, the Company received a government grant to drive its research and development efforts. Through these government grants, the government provided funding for the Company to perform research and development activities. The Company believes the government entities funding these grants are interested in the Company advancing its underlying technologies through research activities and not providing incentives for hiring employees or building facilities that would suggest that the grant monies are not for specific research activities.

In determining how to classify the monies received under government grants, the Company acknowledges that there is no specific guidance under U.S. GAAP, so the Company has relied on FASB Concept 6 for the classification of this grant revenue. FASB Concept 6, "Elements of Financial Statements", discusses the definitions of revenues, expenses, gains, and losses and gives broad guidance but does not distinguish precisely between revenues and gains or between expenses and losses. Revenues and gains are similar, and expenses and losses are similar, but some differences are significant in conveying information about an enterprise's performance. Revenues and expenses result from an entity's ongoing major or central operations and activities, from activities such as producing or delivering goods, rendering services, lending, insuring, investing, and financing. In contrast, gains and losses result from incidental or peripheral transactions of an enterprise with other entities and from other events and circumstances affecting it. Some gains and losses may be considered "operating" gains and losses and may be closely related to revenues and expenses. Distinctions between revenues and gains and between expenses and losses in a particular entity depend to a significant extent on the nature of the entity, its operations, and its other activities. Items that are revenues for one kind of entity may be gains for another, and items that are expenses for one kind of entity may be losses for another. For the presentation of these grants in the Company's financial statements, the Company believes that recognizing the government grant proceeds as a component of revenue is a better reflection of the economics of the arrangements as the Company earns the funding through the performance of research and development which is one of the Company's primary business activities or central to its operations. The Company believes that presenting research and development funding from government grants, as revenue provides consistency in our financial reporting. The Company also believes that this presentation clearly presents to users of its financial statements in one line the Company's sources of funding from these grants. The Company notes that there are no contingencies associated with the receipt of or ability to retain the funds under the grant, other than undertaking and performing the related research and development activities. The revenue is recorded as the qualifying costs are incurred and all qualifying cost were incurred in the year ended December 31, 2020.

The Company records funds received pursuant to a government grant as revenue and recognized $0 and $199,934 in revenue as qualifying expenses were incurred under the funding agreement for the year ended December 31, 2021 and 2020, respectively.

Research and Development

We incur research and development costs during the process of researching and developing our technologies and future offerings. We expense these costs as incurred unless such costs qualify for capitalization under applicable guidance.

Below is a disaggregation of R&D expenses:

	As of December 31,	
	2021	**2020**
Consulting expense	$ 120,480	$ 87,876
Patent and legal expense	14,679	36,838
Lab materials	73,888	13,871
Total	$ 209,047	$ 138,585

Fair Value Measurements and Fair Value of Financial Instruments

The Company adopted FASB ASC Topic 820, Fair Value Measurements ("ASC Topic 820"). ASC Topic 820 clarifies the definition of fair value, prescribes methods for measuring fair value, and establishes a fair value hierarchy to classify the inputs used in measuring fair value as follows:

- Level 1 Inputs are unadjusted quoted prices in active markets for identical assets or liabilities available at the measurement date.
- Level 2 Inputs are unadjusted quoted prices for similar assets and liabilities in active markets, quoted prices for identical or similar assets and liabilities in markets that are not active, inputs other than quoted prices that are observable, and inputs derived from or corroborated by observable market data.
- Level 3 Inputs are unobservable inputs which reflect the reporting entity's own assumptions on what assumptions the market participants would use in pricing the asset or liability based on the best available information.

The Company did not identify any assets or liabilities that are required to be presented on the balance sheets at fair value in accordance with ASC Topic 820.

Due to the short-term nature of all financial assets and liabilities, their carrying value approximates their fair value as of the balance sheet dates.

Income Taxes

The Company accounts for income taxes pursuant to the provision of ASC 740 "Accounting for Income Taxes," which requires, among other things, an asset and liability approach to calculating deferred income taxes. The asset and liability approach requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of temporary differences between the carrying amounts and the tax bases of assets and liabilities. A valuation allowance is provided to offset any net deferred tax assets for which management believes it is more likely than not that the net deferred asset will not be realized.

The Company follows the provision of the ASC 740 related to Accounting for Uncertain Income Tax Position. When tax returns are filed, it is more likely than not that some positions taken would be sustained upon examination by the taxing authorities, while others are subject to uncertainty about the merits of the position taken or the amount of the position that would be ultimately sustained. In accordance with the guidance of ASC 740-10, the benefit of a tax position is recognized in the financial statements in the period during which, based on all available evidence, management believes it is most likely that not that the position will be sustained upon examination, including the resolution of appeals or litigation processes, if any. Tax positions taken are not offset or aggregated with other positions.

Tax positions that meet the more-likely-than-not recognition threshold are measured as the largest amount of tax benefit that is more than 50% likely of being realized upon settlement with the applicable taxing authority. The portion of the benefits associated with tax positions taken that exceeds the amount measured as described above should be reflected as a liability for uncertain tax benefits in the accompanying balance sheet along with any associated interest and penalties that would be payable to the taxing authorities upon examination. The Company believes its tax positions will more likely than not be upheld upon examination. As such, the Company has not recorded a liability for uncertain tax benefits.

The federal and state income tax returns of the Company are subject to examination by the Internal Revenue Service and state taxing authorities, generally for three years after they were filed. The Company is in the process of filing the tax returns for the 2021 year. After review of the prior year financial statements and the results of operations through December 31, 2021, the Company has recorded a full valuation allowance on its deferred tax asset.

Recent Accounting Pronouncements

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

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

NOTE 4 – CARVE-OUT CRITERIA AND ASSUMPTIONS

The carve-out statements of comprehensive income, as set forth above and which was the subject of the statement contained herein, reflect direct revenues and expenses and allocations of indirect expenses related to certain support functions that are provided on a centralized basis by Chromocell Holdings. These expenses, assets, and liabilities have been allocated to the Company on the basis of direct usage when identifiable, with others allocated based on relevant data criteria.

- Employment related expenses – allocated all Therapeutics direct salaries and an allocation of headquarters salaries based on headcounts.
- General and administrative expenses and Professional fees – allocated all direct Therapeutics related expenses and corporate expense have been allocated to reflect the utilization of those corporate services by the Company.
- Research and development expenses – all Research and development expenses are direct Therapeutics related expenses.
- Rent and related expenses and security deposits – applied a ratio based on floor space used by Therapeutics.
- Grant income – fully allocated to Therapeutics.
- Long lived assets – Long lived assets are owned by Chromocell Holdings Inc and under shared use by its components including the Company. Operating expenses are allocated that reflect the usage of the long-lived asset by the Company.
- Accounts payable and accrued expenses – allocated all direct Therapeutics related liabilities and an allocation corporate expense reflecting the utilization of those corporate services by the Company.

- PPP loan and PPP loan forgiveness – Allocated to reflect the utilization of the proceeds by the Company.
- NOL Tax Credit – For the gain on the sale of an NOL tax credit in 2020, generated in 2018 and derived under New Jersey state tax law, the portion allocated to Therapeutics was predicated on the ratio of net income between Flavors and Therapeutics in 2018.

Chromocell Holdings uses a centralized approach to cash management of its operations. Any cash excess over comprehensive income earned by the Company were transferred to Chromocell Holdings through "net parent investment." Accordingly, none of the Chromocell Holdings cash and cash equivalents, have been assigned to the Company in the carve-out combined financial statements.

As these carve-out financial statements present a portion of the business of Chromocell Holdings, which does not constitute a separate legal entity for the purposes of carve-out financial statements, the net assets of the Chromocell Holdings have been presented as Parent's net (deficit) investment. Except for the PPP loan, Chromocell Holdings third-party bank loans, related party loans and the related interest expense, have not been included in the carve-out financial statements for any of the periods presented. Chromocell is not the legal obligor on those loans, and they were not directly attributable to the Chromocell Operations.

As the lease is held by Chromocell Corporation, Therapeutics does not have the right to control the use of the space being leased and only shares the space. As such, there is no lease liability or right of use asset recorded for Therapeutics.

Management believes the assumptions underlying the carve-out combined financial statements, including the assumptions regarding allocation of expenses, are reasonable.

NOTE 5 – RELATED PARTY TRANSACTIONS

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

On August 10, 2022, effective July 12, 2022, the Company and Chromocell Holdings entered into the Contribution Agreement effecting (1) the contribution by Chromocell Holdings to the Company of assets related to Chromocell Holding's Therapeutics Business, including all intellectual property related to Chromocell Holding's NaV1.7 program and its clinical-stage CC8464 lead compound, (2) assumption by the Company of direct-liabilities related to Chromocell Holding's historical Therapeutics Business in the amount of $1,556,323 as well as expenses of $597,038 and (3) the issuance by the Company to Chromocell Holdings of 10,000,000 shares of its common stock and 600,000 shares of its Series A Convertible Preferred Stock.

Change of control

In August 2022, Chromocell Holdings sold 5,999,667 shares of the common stock it owns of the Company to Flamands resulting in a change of control of the Company. The agreement provides Flamands an option to acquire an additional 667,000 shares of the common stock Chromocell Holdings owns of the Company prior to the public filing of a registration statement relating to the Company's initial public offering. The Company was not a party to the sale, and as of the date these financial statements were issued, the option has not been exercised.

NOTE 6 – FINANCING ARRANGEMENTS

On April 22, 2020, Chromocell Holdings entered into a PPP loan of which $241,793 was allocated to the Company. This note accrued interest at a rate of 1% per annum. This loan is due on April 22, 2022. At December 31, 2021 and 2020, the loan had accrued interest of $0 and $1,676. During the year ended December 31, 2021, this loan was fully forgiven, with a total of $241,793 in principal forgiven and $1,929 in interest forgiven being allocated to the Company.

NOTE 7 – COMMITMENT AND CONTINGENCIES

The following table shows the allocation of rent to the Company on a non-cancelable lease of $1,618 per month as of December 31, 2021:

	Payment Due by Year					
	Total	**2022**	**2023**	**2024**	**2025**	**2026**
Lease	$ 19,230	$ 19,230	$ -	$ -	$ -	$ -

NOTE 8 – INCOME TAX

The Company follows the asset and liability method of accounting for income taxes under ASC 740, "Income Taxes." Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial statements carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that included the enactment date. Valuation allowances are established, when necessary, to reduce deferred tax assets to the amount expected to be realized.

ASC 740 prescribes a recognition threshold and a measurement attribute for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. For those benefits to be recognized, a tax position must be more likely than not to be sustained upon examination by taxing authorities. The Company recognizes accrued interest and penalties related to unrecognized tax benefits as income tax expense. There were no unrecognized tax benefits and no amounts accrued for interest and penalties as of December 31, 2020. The Company is currently not aware of any issues under review that could result in significant payments, accruals or material deviation from its position. The Company is subject to income tax examinations by major taxing authorities since inception. The Company used the separate return method for the preparation of the income tax provision.

For the years ended December 31, 2021 and 2020, there was no income tax provision recorded. The tax benefit was added to the net operating loss to which a full valuation allowance was applied.

A reconciliation of income tax expense (benefit) computed at the statutory federal income tax rate to income taxes as reflected in the financial statements is as follows:

	2021	2020
Income taxes at U.S. statutory rate	19.11%	19.11%
Income taxes at state rate	9.00	9.00
Change in valuation allowance	(28.11)	(28.11)
Total provision for income taxes	-%	-%

Deferred taxes are recognized for temporary differences between the basis of assets and liabilities for financial statement and income tax purposes. The significant components of the Company's deferred tax assets and liabilities as of December 31, 2021 and 2020 are comprised of the following:

	Years Ended December 31,	
	2021	2020
Deferred tax assets		
Net operating loss carryforwards	$ 2,726,414	$ 2,627,019
Total deferred tax assets	2,726,414	2,627,019
Valuation allowance	(2,726,414)	(2,627,019)
Net deferred tax assets	-	-
Deferred tax liabilities		
Total deferred tax liabilities	-	-
Net deferred taxes	$ -	$ -

For the years ended December 31, 2021 and 2020, the Company recorded a valuation allowance of its deferred tax assets.

The Company has a net operating loss carryforward for federal tax purposes totaling approximately $4.1 million at December 31, 2021. Approximately $4.1 million net operating losses incurred in fiscal 2018 through fiscal 2021 that do not expire and can be utilized to offset up to 80% of future taxable income under the Tax Cuts and Jobs Act.

During the year ended December 31, 2020, Chromocell Holdings received a tax credit of $1,031,096, with $694,959 being allocated to Therapeutics, from the State of New Jersey as part of the Technology Business Tax Certificate Transfer Program. This program allows certain New Jersey businesses to sell a portion of their state net operating loss to unrelated corporations. The net operating loss that was sold was generated in the 2018 fiscal year.

UNITS

CHROMOCELL THERAPEUTICS CORPORATION

PROSPECTUS

The Benchmark Company

The date of this prospectus is , 2022

Through and including , 2022 (25 days after the date of this prospectus), all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to their unsold allotments or subscriptions.

PART II

INFORMATION NOT REQUIRED IN THE PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution.

The following table sets forth the costs and expenses, other than the underwriting discounts and commissions, payable by the registrant in connection with the sale of our Units being registered. All amounts are estimates except for the Securities and Exchange Commission ("SEC") registration fee, the Financial Industry Regulatory Authority, Inc. ("FINRA") filing fee and the Nasdaq Capital Market ("Nasdaq") listing fee.

	Amount Paid or to be Paid
SEC registration fee	$
FINRA filing fee	
Nasdaq listing fee	
Printing and engraving expenses	
Legal fees and expenses	
Accounting fees and expenses	
Transfer agent and registrar fees and expenses	
Miscellaneous expenses	
Total	$

Item 14. Indemnification of Directors and Officers.

We are incorporated under the laws of the State of Delaware. Section 102 of the General Corporation Law of the State of Delaware permits a corporation to eliminate the personal liability of directors of a corporation to the corporation or its stockholders for monetary damages for a breach of fiduciary duty as a director, except where the director breached his duty of loyalty, failed to act in good faith, engaged in intentional misconduct or knowingly violated a law, authorized the payment of a dividend or approved a stock repurchase in violation of Delaware corporate law or obtained an improper personal benefit.

Section 145 of the DGCL provides that a corporation has the power to indemnify a director, officer, employee or agent of the corporation and certain other persons serving at the request of the corporation in related capacities against expenses (including attorneys' fees), judgments, fines and amounts paid in settlements actually and reasonably incurred by the person in connection with an action, suit or proceeding to which he is or is threatened to be made a party by reason of such position, if such person acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the corporation, and, in any criminal action or proceeding, had no reasonable cause to believe his conduct was unlawful, except that, in the case of actions brought by or in the right of the corporation, no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery or other adjudicating court determines that, despite the adjudication of liability but in view of all of the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Court of Chancery or such other court shall deem proper.

As permitted by the DGCL, our certificate of incorporation and bylaws to be in effect upon the closing of this offering provide that: (i) we are required to indemnify our directors and officers to the fullest extent permitted by the DGCL; (ii) we may, in our discretion, indemnify our employees and agents as set forth in the DGCL; (iii) we are required, upon satisfaction of certain conditions, to advance all expenses incurred by our directors and officers in connection with certain legal proceedings; (iv) the rights conferred in the bylaws are not exclusive; and (v) we are authorized to enter into indemnification agreements with our directors, officers, employees and agents.

We intend to enter into indemnification agreements with our directors and executive officers that require us to indemnify them against expenses, judgments, fines, settlements and other amounts that any such person becomes legally obligated to pay (including with respect to a derivative action) in connection with any proceeding, whether actual or threatened, to which such person may be made a party by reason of the fact that such person is or was a director or officer of us or any of our affiliates, provided such person acted in good faith and in a manner such person reasonably believed to be in, or not opposed to, our best interests. We maintain a directors' and officers' liability insurance policy. The policy insures directors and officers against unindemnified losses arising from certain wrongful acts in their capacities as directors and officers and reimburses us for those losses for which we have lawfully indemnified the directors and officers. The policy contains various exclusions.

In addition, the underwriting agreement to be filed as Exhibit 1.1 to this Registration Statement provides for indemnification by the underwriters of us and our officers and directors for certain liabilities arising under the Securities Act of 1933, as amended (the "Securities Act") or otherwise.

Item 15. Recent Sales of Unregistered Securities.

Pursuant to that certain Contribution Agreement entered into with each of Chromocell Holdings, we issued to Chromocell Holdings10,000,000 shares of Common Stock and 600,000 shares of Series A Convertible Preferred Stock. Each of the foregoing issuances was made in a transaction not involving a public offering pursuant to an exemption from the registration requirements of the Securities Act in reliance upon Section 4(a)(2) of the Securities Act, or Regulation D or Rule 701 promulgated under the Securities Act.

Item 16. Exhibits and Financial Statement Schedules.

(a) Exhibits.

We have filed the exhibits listed on the accompanying Exhibit Index of this registration statement, which Exhibit Index is incorporated herein by reference.

(b) Financial Statement Schedules.

All other schedules have been omitted because the information required to be presented in them is not applicable or is shown in the financial statements or notes.

Item 17. Undertakings.

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

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

The undersigned Registrant hereby undertakes that:

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

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

EXHIBIT INDEX

Exhibit No.	Description
1.1*	Form of Underwriting Agreement
2.1*	Contribution Agreement
3.1*	Certificate of Incorporation, as currently in effect
3.2*	Certificate of Designation of Series A Convertible Preferred Stock, as currently in effect
3.3*	Form of Certificate of Incorporation to be effective upon the closing of this offering
3.4*	Bylaws, as currently in effect
3.5*	Form of Bylaws to be effective upon the closing of this offering
4.1*	Form of Common Stock Certificate
4.2*	Form of Warrant
4.3*	Form of Underwriters' Warrant
4.4*	Form of Advisor Warrant
4.5*	Form of Warrant Agent Agreement
5.1*	Opinion of Sullivan & Worcester LLP
10.1*	Chromocell Therapeutics Corporation 2022 Stock Option and Stock Issuance Plan
23.1*	Consent of Marcum LLP, independent registered public accounting firm
23.2*	Consent of Sullivan & Worcester LLP (included in Exhibit 5.1)
24.1*	Power of Attorney (included on signature page)
107*	Filing Fee Table

* To be filed by amendment.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the city of North Brunswick, State of New Jersey, on , 2022.

CHROMOCELL THERAPEUTICS CORPORATION

By: _____
Name: Christian Kopfli
Title: President, Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that each person whose individual signature appears below hereby authorizes and appoints Christian Kopfli with full power of substitution and resubstitution and full power to act, as his true and lawful attorney-in-fact and agent to act in his name, place and stead, and to execute in the name and on behalf of each person, individually and in each capacity stated below, and to file any and all amendments to this registration statement, any related registration statement filed pursuant to Rule 462(b) under the Securities Act of 1933, as amended, and any or all pre- or post-effective amendments thereto, and to file the same, with all exhibits thereto, and all other documents in connection therewith, with the U.S. Securities and Exchange Commission, granting unto said attorney-in-fact and agent, and full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully for all intents and purposes as he might or could do in person, hereby ratifying and confirming that said attorney-in-fact and agent, or any substitute, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed by the following persons in the capacities indicated below:

Signature	Title	Date
Christian Kopfli	Director, President and Chief Executive Officer (Principal Executive Officer)	, 2022
Francis Knuettel II	Chief Financial Officer, Chief Strategy Officer, Treasurer and Secretary (Principal Financial Officer and Principal Accounting Officer)	, 2022
Ezra Friedberg	Director	, 2022
Daniel O'Connor	Director	, 2022