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

**FORM S-3
REGISTRATION STATEMENT**
*Under
The Securities Act of 1933*

SOLENO THERAPEUTICS, INC.
(Exact name of Registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

77-0523891
(I.R.S. Employer
Identification Number)

**203 Redwood Shores Parkway, Suite 500
Redwood City, CA 94065
(650) 213-8444**
(Address, including zip code, and telephone number, including area code, of Registrant's principal executive offices)

**Anish Bhatnagar
Chief Executive Officer
Solenio Therapeutics, Inc.
203 Redwood Shores Parkway, Suite 500
Redwood City, CA 94065
(650) 213-8444**
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

**Elton Satusky
Jesse Schumaker
Wilson Sonsini Goodrich & Rosati,
Professional Corporation
650 Page Mill Road
Palo Alto, CA 94304
(650) 493-9300**

Approximate date of proposed sale to the public: From time to time after this Registration Statement becomes effective.

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box.

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, other than securities offered only in connection with dividend or interest reinvestment plans, 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, 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 registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box.

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company, or an emerging growth company. See 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

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

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered (1)	Amount to be Registered (2)	Proposed Maximum Offering Price Per Security (2)	Proposed Maximum Aggregate Offering Price (3)(4)	Amount of Registration Fee
Common Stock \$0.001 par value	—	—	—	—
Warrants	—	—	—	—
Total (5)	—	—	\$100,000,000	\$7,626.69

- (1) The securities registered hereunder include such indeterminate (a) number of shares of common stock and (b) number of warrants to purchase common stock. There are also being registered hereunder an indeterminate number of shares of common stock as may be issued upon conversion, exercise or exchange of the warrants from time to time by the registrant. Any securities registered hereunder may be sold separately. Pursuant to Rule 416 under the Securities Act of 1933, as amended (the "Securities Act"), the securities being registered hereunder shall also include such indeterminate number of shares of common stock as may be issuable with respect to the securities being registered hereunder as a result of stock splits, stock dividends or similar transactions.
- (2) The registrant is hereby registering an indeterminate amount and number of each identified class of securities up to a proposed maximum aggregate offering price of \$100,000,000, which may be offered from time to time at indeterminate prices, including securities that may be purchased by underwriters. Of this amount, securities having a proposed maximum aggregate offering price of \$100,000,000 were registered by the registrant pursuant to a prior registration statement (File No. 333-232068), originally filed on June 11, 2019 and declared effective on July 23, 2019, of which approximately \$27,090,001 of such securities have not yet been issued and sold. Pursuant to Rule 415(a)(6) under the Securities Act, the registrant hereby includes on this registration statement such securities remaining unissued and unsold under such prior registration statement. The registration fee with respect to the securities that have not yet been issued or sold under the prior registration statement is approximately \$3,283.31, and the registration fee due hereunder is being offset against the previously paid registration fee with respect to such unissued and unsold securities, pursuant to Rule 457(p) under the Securities Act. The registrant has estimated the proposed maximum aggregate offering price solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities Act. Securities registered hereunder may be sold separately, together or as units with other securities registered hereunder.
- (3) The proposed maximum per share and aggregate offering prices per class of securities will be determined from time to time by the registrant in connection with the issuance by the registrant of the securities registered under this registration statement and is not specified as to each class of security pursuant to General Instruction II.D of Form S-3 under the Securities Act.
- (4) Calculated pursuant to Rule 457(o) under the Securities Act, based on the proposed maximum aggregate offering price.
- (5) The proposed maximum offering price will be determined by the registrant in connection with the issuance of the securities. In no event will the aggregate offering price of all securities issued by the registrant from time to time pursuant to this Registration Statement exceed \$100,000,000 or the equivalent thereof in one or more foreign currencies, foreign currency units or composite currencies. Separate consideration may or may not be received for any shares of common stock so issued upon conversion, exchange or redemption of the warrants.

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 Commission, acting pursuant to said section 8(a), may determine.

The information in this 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 prospectus is not an offer to sell these securities, and the selling stockholders are not soliciting offers to buy these securities, in any state where the offer or sale of these securities is not permitted.

SUBJECT TO COMPLETION, DATED JANUARY 14, 2021

PROSPECTUS



SOLENO THERAPEUTICS, INC.

\$100,000,000

**Common Stock
Warrants**

We may offer and sell from time to time, in one or more series or issuances and on terms that we will determine at the time of the offering, any combination of the securities described in this prospectus, up to an aggregate amount of \$100,000,000.

This prospectus provides a general description of the securities we may offer. Each time we sell securities, we will provide specific terms of any offering in a supplement to this prospectus. We may also authorize one or more free writing prospectuses to be provided to you in connection with these offerings. Any prospectus supplement and any related free writing prospectus may also add, update, or change information contained in this prospectus. You should carefully read this prospectus, the applicable prospectus supplement and any related free writing prospectus, as well as the documents incorporated or deemed to be incorporated by reference in this prospectus before you purchase any of the securities offered hereby. This prospectus may not be used to consummate a sale of securities by us unless accompanied by the applicable prospectus supplement.

These securities may be offered and sold in the same offering or in separate offerings; to or through underwriters, dealers, and agents; or directly to institutional purchasers. The names of any underwriters, dealers, or agents involved in the sale of our securities, their compensation and any overallotment options held by them will be described in the applicable prospectus supplement. For a more complete description of the plan of distribution of these securities, see the section entitled "Plan of Distribution" beginning on page 18 of this prospectus.

Our Common Stock, \$0.001 par value per share ("Common Stock"), is listed on the Nasdaq Capital Market under the symbol "SLNO." We will provide information in any applicable prospectus supplement regarding any listing of securities other than shares of our Common Stock on any securities exchange.

Investing in our securities involves a high degree of risk. You should carefully read and consider the risk factors described in, and incorporated by reference under, "[Risk Factors](#)" beginning on page 6 of this prospectus and in the applicable prospectus supplement before investing in any securities.

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.

This prospectus is dated , 2021

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ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement on Form S-3 that we filed with the United States Securities and Exchange Commission (the “SEC”), using a “shelf” registration process. Under this shelf process, we may, from time to time, offer and sell any combination of the securities described in this prospectus in one or more offerings up to a total amount of \$100,000,000.

This prospectus provides you with a general description of the securities we may offer. Each time we sell securities under this shelf registration, we will, to the extent required by law, provide a prospectus supplement that will contain specific information about the terms of that offering. The prospectus supplement may also add to, update or change information contained in this prospectus and, accordingly, to the extent there are inconsistencies between any prospectus supplement, this prospectus and any documents incorporated by reference, the document with the most recent date will control.

The prospectus supplement to be attached to the front of this prospectus may describe, as applicable: the terms of the securities offered; the initial price to the public; the price paid for the securities; net proceeds; and the other specific terms related to the offering of the securities. This prospectus may not be used by us to consummate sales of our securities, unless it is accompanied by a prospectus supplement.

You should only rely on the information contained in, or incorporated by reference into, this prospectus and any prospectus supplement or issuer free writing prospectus relating to a particular offering. We have not authorized any dealer or other person to give any information or make any representations in connection with this offering other than those contained or incorporated by reference in this prospectus, any accompanying prospectus supplement and any related issuer free writing prospectus in connection with the offering described herein and therein, and, if given or made, such information or representations must not be relied upon as having been authorized by us. Neither this prospectus nor any prospectus supplement nor any related issuer free writing prospectus shall constitute an offer to sell or a solicitation of an offer to buy offered securities in any jurisdiction in which it is unlawful for such person to make such an offering or solicitation. This prospectus does not contain all of the information included in the registration statement. For a more complete understanding of the offering of the securities, you should refer to the registration statement, including its exhibits.

You should carefully read this entire prospectus, the applicable prospectus supplement and any related issuer free writing prospectus, as well as the documents incorporated by reference into this prospectus or any prospectus supplement or any related issuer free writing prospectus, before making an investment decision. Neither the delivery of this prospectus or any prospectus supplement or any issuer free writing prospectus nor any sale made hereunder shall under any circumstances imply that the information contained or incorporated by reference herein or in any prospectus supplement or issuer free writing prospectus is correct as of any date subsequent to the date hereof or of such prospectus supplement or issuer free writing prospectus, as applicable. You should assume that the information appearing in this prospectus, any prospectus supplement or any document incorporated by reference is accurate only as of the date of the applicable documents, regardless of the time of delivery of this prospectus or any sale of securities. Our business, financial condition, results of operations and prospects may have changed since that date.

PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus and does not contain all of the information that you should consider in making your investment decision. Before deciding to invest in our securities, you should read this entire prospectus carefully, including the sections of this prospectus entitled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our financial statements and related notes contained elsewhere in this prospectus. Unless the context otherwise requires, references in this prospectus to the “Company” “Soleno Therapeutics,” “we,” “us”, and “our” refer to Soleno Therapeutics, Inc.

Overview

Soleno Therapeutics is focused on the development and commercialization of novel therapeutics for the treatment of rare diseases. Our lead candidate, referred to as DCCR, a once-daily oral tablet for the treatment of Prader-Willi Syndrome, or PWS, a complex metabolic/neurobehavioral disorder, is currently being evaluated in a Phase III clinical development program.

On March 7, 2017, we completed our merger, or the Merger, with Essentialis, Inc., a Delaware corporation, or Essentialis. After the Merger, our primary focus has been the development and commercialization of novel therapeutics for the treatment of rare diseases. Essentialis was a privately-held, clinical-stage biotechnology company focused on the development of breakthrough medicines for the treatment of rare diseases where there is increased mortality and risk of cardiovascular and endocrine complications. Essentialis had tested Diazoxide Choline Controlled Release, or DCCR, tablets as a treatment for PWS. DCCR has orphan designation for the treatment of PWS in the United States, or U.S., as well as in the European Union, or E.U.

Subsequent to the Merger with Essentialis described above, we determined to divest, sell or dispose of our business efforts focused on the development and commercialization of our Serenz and CoSense technologies. Our current research and development efforts are primarily focused on advancing our lead candidate, DCCR tablets for the treatment of PWS, through late-stage clinical development.

Diazoxide Choline Controlled-Release Tablets

DCCR tablets consist of the active ingredient diazoxide choline, a choline salt of diazoxide, which is a benzothiadiazine. Once solubilized from the formulation, diazoxide choline is rapidly converted to diazoxide prior to absorption. Diazoxide acts by stimulating ion flux through ATP-sensitive K⁺ channels (KATP). Diazoxide appears to act on signs and symptoms of PWS in a variety of ways. Agonizing the KATP channel in the hypothalamus has the potential to address the hallmark symptom of PWS – hyperphagia – a chronic feeling of insatiable hunger. Other central effects of DCCR may improve various behavioral abnormalities associated with PWS. In addition, suppression of insulin secretion by agonizing the K-ATP channel in the beta cells of the pancreas may lead to improvement of several metabolic abnormalities

In the U.S., diazoxide was first approved in 1973 as an intravenous formulation, for the emergency treatment of malignant hypertension. In 1976, immediate-release oral formulations including Proglycem® Oral Suspension and Capsules, or Proglycem, were approved and there has been nearly 40 years of use of the 2-3 times a day, orally-administered, drug product in the approved indications. In addition, there are also extensive data on short term and chronic use of Proglycem in children with congenital hyperinsulinism, or CHI, and in adults with insulinoma. Insulinoma patients tend to be older, with 50% of them over 70 years old. Published data have reported that the average duration of use of Proglycem in certain CHI and insulinoma patients is 5 years and 7 years, respectively.

DCCR tablets were formulated with the goals of improving the safety and bioavailability of orally-administered diazoxide and reducing the frequency of daily dosing required by current diazoxide formulations. Diazoxide choline is formulated into an extended-release tablet (DCCR) that lowers peak plasma concentration compared to diazoxide oral suspension and allows for the gradual release of diazoxide choline from DCCR, making it suitable for once-a-day dosing. The gradual release and absorption of diazoxide achieved using DCCR results in consistent intraday circulating drug levels. Once it enters circulation, diazoxide becomes extensively protein bound, however only the unbound drug is active and readily enters tissues. Thus, the continuous absorption of diazoxide from DCCR may result in higher levels of unbound diazoxide for a given administered dose. Formulation into a once-a-day tablet with the choline salt allows for release of Diazoxide throughout the day reducing intraday variability in circulating drug levels than would otherwise be the case if the patient were to take the alternative oral suspension formulation multiple times a day. Avoiding significant swings in circulating drug levels also has the potential to reduce adverse events which are often associated with transiently high circulating drug levels that often follow rapid absorption from immediate release product formulations

Prader-Willi Syndrome

PWS is a rare, complex neurobehavioral/metabolic disorder which is due to the absence of normally active paternally expressed genes from the chromosome 15q11-q13 region. PWS is an imprinted condition with 70-75% of the cases due to a de novo deletion in the paternally inherited chromosome 15q11-q13 region, 20-30% from maternal uniparental disomy 15, or UPD, where the affected individual inherited 2 copies of chromosome from their mother and no copy from their father, and the remaining 2-5% from either microdeletions or epimutations of the imprinting center (i.e., imprinting defects; IDs). The Committee on Genetics of the American Academy of Pediatrics states PWS affects both genders equally and occurs in people from all geographic regions; its estimated incidence is 1 in 15,000 live births. The mortality rate among PWS patients is 3% a year across all ages and 7% in those over 30 years of age. The mean age of death reported from a 40-year mortality study in the U.S. was 29.5 ± 15 years (range: 2 months—67 years).

In addition to hyperphagia, typical behavioral disturbances associated with PWS include skin picking, difficulty with change in routine, obsessive and compulsive behaviors and mood fluctuations. The majority of older adolescent and adult PWS patients display some degree of aggressive or threatening behaviors including being verbally aggressive, seeking to intimidate others, being physically aggressive including attacking others, destroying property, throwing temper tantrums and directing rage or anger at others.

PWS is typically thought of as a genetic obesity. However, many PWS patients today may not be obese because of increasing awareness among families and caregivers leading to significant control of food and its intake. However, patients remain hyperphagic and will typically have a higher body fat and lower lean body mass content. They are prone to cardiometabolic issues such as abnormal lipid profiles, diabetes and hypertension. Other complications in PWS patients include greater risk for autistic symptomatology, psychosis, sleep disorders, distress, food stealing, withdrawal, sulking, nail-biting, hoarding and overeating, and more pronounced attention-deficit hyperactivity disorder symptoms, insistence on sameness, and their association with maladaptive conduct problems. Individuals with PWS show age-related increases in internalizing problems such as anxiety, sadness and a feeling of low self-esteem. Males are at greater risk for aggressive behavior, depression and dependent personality disorder and overall severity of psychopathology than females. Cognitively, most individuals with PWS function in the mild intellectually disability range with a mean IQ in the 60s to low 70s. The combination of food-related preoccupations and numerous maladaptive behaviors make it difficult for individuals with PWS to perform to their IQ potential.

Unmet Medical Needs in PWS

The target indication for DCCR is the treatment of PWS. Currently, the only approved treatment related to PWS is growth hormone which addresses the short stature associated with PWS, but has no effect on hyperphagia. A global patient survey conducted by the Foundation for Prader-Willi Research (n=779), found that 96.5% of respondents rated reducing hunger and 91.2% rated improving behavior around food as very important or most important symptom to be relieved by a new treatment—<https://www.fpwr.org/pws-patient-voices>. Physical function and body composition symptoms for which a high percentage of respondents indicated were very important or most important included: 92.9% indicated improving metabolic health (reduces fat / increases muscle) and 81.3% indicated the related symptom of improving activity and stamina. The behavioral and cognitive symptoms rated by respondents as very or most important were: 85.2% indicated reduction of obsessive/compulsive behavior, 84.6% indicated improvements to intellect/development, and 83.2% indicated reduction of temper outburst severity and frequency. Therefore, there is a clear unmet need in the treatment of PWS to reduce hyperphagia and improve behaviors around food, and to reduce other behavioral and cognitive impacts of this complex disease. In addition, improving metabolic health is also an important unmet need.

Clinical Trial of DCCR for PWS

A Phase II clinical trial has been conducted to evaluate the safety and preliminary efficacy of DCCR in the treatment of PWS subjects. This study, PC025, was a single-center, randomized withdrawal study and enrolled 13 overweight and obese subjects with genetically-confirmed PWS who were between the ages of 11 and 21. The first phase of the study was open-label during which subjects were initiated on a DCCR dose that was escalated every 14 days at the discretion of the investigator. Any subject who showed any increase in resting energy expenditure and/or a reduction in hyperphagia from baseline at certain study visits would be designated a responder, whereas all others would be designated non-responders. This 10-week open-label treatment phase was followed by randomized double-blind, placebo-controlled, withdrawal phase.

Responders were randomized in a 1:1 ratio either to continue on active treatment at the dose they were treated with, or to the placebo equivalent of that dose for an additional 4 weeks. Of the 13 subjects who enrolled, 11 completed the open-label phase and all were designated as responders; the remaining two subjects had discontinued prematurely.

Key efficacy results included a statistically significant reduction in hyperphagia from baseline to the end of the open-label treatment phase. In addition, greater improvement in hyperphagia from baseline was observed in those subjects with moderate to severe hyperphagia who received higher DCCR doses. There was a significant improvement in the number of subjects reporting one or more aggressive and destructive behaviors. During the open-label treatment phase, a mean decrease in body fat mass and increases in lean body mass and lean body mass / fat mass ratio were seen. These changes were associated with a statistically significant reduction in waist circumference, consistent with the loss of visceral fat. Statistically significant reductions from baseline in LDL cholesterol and non-HDL cholesterol were observed. The change in triglycerides, while marked, did not reach statistical significance.

A Phase III clinical trial has been conducted to evaluate the efficacy and safety of DCCR in patients with genetically-confirmed PWS. This study, DESTINY PWS, was a multi-center, randomized, double-blind, placebo-controlled study of 127 children and adults with PWS. Subjects who completed the 15-week DESTINY PWS study were allowed to enroll in a long-term, safety extension study (C602). On

each of March 14, 2019, and October 1, 2019 the Data Safety Monitoring Board (DSMB) recommended the continuation of our Phase III DESTINY PWS trial without any changes. The DSMB is a group of independent experts monitoring the safety of the DESTINY PWS study. The DSMB reviews safety information and can make recommendations to either continue the study without modification, modify the study or terminate the study due to safety concerns. In July 2018, the U.S. Food and Drug Administration, or FDA, designated the development program for investigation of DCCR for the treatment of PWS to be a Fast Track development program. Prior to this, diazoxide choline received orphan designation for the treatment of PWS in the U.S. and in the E.U.

On June 8, 2020, we issued a press release announcing the top-line results from our Phase III Trial of DCCR for the treatment of PWS. The study did not meet its primary endpoint of change from baseline in hyperphagia.

On December 11, 2020, we issued a press release announcing that we received minutes from the FDA in connection with a meeting we had with the FDA on November 12, 2020. As stated in the minutes, the purpose of the meeting was to discuss the efficacy data obtained from the our Phase III clinical trial of DCCR (C601), additional data to be obtained from our long-term extension study of patients treated on C601 (C602) and proposed next steps for developing DCCR as a treatment for PWS. The meeting minutes confirmed the discussion with the FDA regarding the analyses of data from completed and ongoing studies with DCCR, together with external, natural history studies to potentially support a NDA for DCCR for the treatment of PWS. We announced that we intend to submit formal plans for these analyses, which the FDA has stated it is committed to reviewing.

Corporate information

We were incorporated in Delaware in August of 1999. Our principal executive offices are located at 203 Redwood Shores Pkwy, Suite 500, Redwood City, CA 94065, and our telephone number is (650) 213-8444. Our website address is www.soleno.life. The information contained on our website is not incorporated by reference into this prospectus, and you should not consider any information contained on, or that can be accessed through, our website as part of this prospectus, or in deciding whether to purchase our securities.

Description of the Securities We May Offer

The descriptions of the securities contained in this prospectus, together with the applicable prospectus supplements, summarize the material terms and provisions of the various types of securities that we may offer. We will describe in the applicable prospectus supplement relating to any securities the particular amounts, prices and other terms of the securities offered by that prospectus supplement. If we so indicate in the applicable prospectus supplement, the terms of the securities may differ from the terms we have summarized below. We will also include in the prospectus supplement information, where applicable, about material U.S. federal income tax considerations relating to the securities, and the securities exchange, if any, on which the securities will be listed.

In this prospectus, we refer to the Common Stock and warrants, or any combination of Common Stock and warrants, to be sold by us in a primary offering collectively as “securities.” The total dollar amount of all securities that we may issue under this prospectus will not exceed \$100,000,000.

This prospectus may not be used by us to consummate a sale of securities unless it is accompanied by a prospectus supplement.

RISK FACTORS

An investment in our securities involves a high degree of risk. The prospectus supplement applicable to each offering of our securities will contain a discussion of the risks applicable to an investment in our securities. Prior to making a decision about investing in our securities, you should carefully consider the specific factors discussed under the heading “Risk Factors” in the applicable prospectus supplement, together with all of the other information contained or incorporated by reference in the prospectus supplement or appearing or incorporated by reference in this prospectus. You should also consider the risks, uncertainties and assumptions discussed under Item 1A, “Risk Factors,” in our Annual Report on Form 10-K for the fiscal year ended December 31, 2019 and any updates described in our Quarterly Reports on Form 10-Q, all of which are incorporated herein by reference, and may be amended, supplemented or superseded from time to time by other reports we file with the SEC in the future and any prospectus supplement related to a particular offering. The risks and uncertainties we have described are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also affect our operations. The occurrence of any of these known or unknown risks might cause you to lose all or part of your investment in the offered securities.

FORWARD-LOOKING STATEMENTS

This prospectus, each prospectus supplement and the information incorporated by reference in this prospectus and each prospectus supplement contain certain statements that constitute “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended (the “Securities Act”), Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and the Private Securities Litigation Reform Act of 1995. These forward-looking statements include, but are not limited to, statements about our plans, objectives, representations and contentions and are not historical facts and typically are identified by use of terms such as “anticipate,” “could,” “expect,” “believe,” “goal,” “plan,” “intend,” “estimate,” “may,” “seek,” “potential,” “predict,” “project,” “continue,” “should,” “would,” “will,” and similar expressions and variations thereof. Those statements appear in this prospectus, any accompanying prospectus supplement and the documents incorporated herein and therein by reference, particularly in the sections entitled “Prospectus Summary,” “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Business,” and include statements regarding the intent, belief or current expectations of the Company and management that are subject to known and unknown risks, uncertainties and assumptions and other factors that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to those discussed in the section titled “Risk Factors” set forth above.

You should be aware that this prospectus, any prospectus supplement and the information incorporated by reference in this prospectus and any prospectus supplement also contain forward-looking statements that are based on management’s current expectations and beliefs, including estimates and projections about our company, industry, financial condition, results of operations and other matters. These statements are not guarantees of future performance and are subject to numerous risks, uncertainties, and assumptions that are difficult to predict.

Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, you should not rely upon forward-looking statements as predictions of future events. The events and circumstances reflected in the forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Except as required by applicable law, including the securities laws of the United States and the rules and regulations of the SEC, we do not plan to publicly update or revise any forward-looking statements contained herein after we distribute this prospectus, whether as a result of any new information, future events or otherwise.

USE OF PROCEEDS

Unless otherwise indicated in the prospectus supplement, we will use the net proceeds from the sale of securities offered by this prospectus for general corporate purposes, which may include working capital, capital expenditures, other corporate expenses and acquisitions of complementary products, product candidates, technologies or businesses. However, we currently have no present agreements or commitments for any such acquisitions. The timing and amount of our actual expenditures will be based on many factors, including cash flows from operations and the anticipated growth of our business. As a result, unless otherwise indicated in the prospectus supplement, our management will have broad discretion to allocate the net proceeds of the offerings. Pending their ultimate use, we intend to invest the net proceeds in short-term, investment-grade, interest-bearing instruments.

DESCRIPTION OF CAPITAL STOCK

The following description of our Common Stock, together with the additional information we include in any applicable prospectus supplements, summarizes the material terms and provisions of the Common Stock that we may offer under this prospectus. It may not contain all the information that is important to you. For the complete terms of our Common Stock, please refer to our amended and restated certificate of incorporation (the "Certificate of Incorporation") and bylaws, as may be amended from time to time, and which are incorporated by reference into the registration statement which includes this prospectus. The Delaware General Corporation Law (the "DGCL") may also affect the terms of these securities. While the terms we have summarized below will apply generally to any future Common Stock that we may offer, we will describe the particular terms of the Common Stock in more detail in the applicable prospectus supplement. If we so indicate in a prospectus supplement, the terms of any security we offer under that prospectus supplement may differ from the terms we describe below.

General

Our authorized capital stock consists of 260,000,000 shares, all with a par value of \$0.001 per share, 250,000,000 of which are designated as Common Stock and 10,000,000 of which are designated Convertible Preferred Stock.

The following description of our capital stock and certain provisions of our amended and restated certificate of incorporation and amended and restated bylaws are summaries and are qualified by reference to our amended and restated certificate of incorporation and our amended and restated bylaws.

Common Stock

Holders of Common Stock are entitled to one vote per share on matters on which our stockholders vote. There are no cumulative voting rights. Subject to any preferential dividend rights of any outstanding shares of preferred stock, holders of Common Stock are entitled to receive dividends, if declared by our board of directors, out of funds that we may legally use to pay dividends. If we liquidate or dissolve, holders of Common Stock are entitled to share ratably in our assets once our debts and any liquidation preference owed to any then-outstanding preferred stockholders are paid. Our certificate of incorporation does not provide the Common Stock with any redemption, conversion or preemptive rights.

Convertible Preferred Stock

We are authorized to issue 10,000,000 shares of our Convertible Preferred Stock. Our board of directors has the authority, without further action by our stockholders, to issue these shares of Convertible Preferred Stock in one or more series, to establish from time to time the number of shares to be included in each such series, to fix the rights, preferences and privileges of the shares of each wholly unissued series and any qualifications, limitations or restrictions thereon, and to increase or decrease the number of shares of any such series, but not below the number of shares of such series then outstanding. Our board of directors may authorize the issuance of Convertible Preferred Stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of our Common Stock. The purpose of authorizing our board of directors to issue Convertible Preferred Stock and determine its rights and preferences is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of Convertible Preferred Stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in control of us and may adversely affect the market price of our Common Stock and the voting and other rights of the holders of our Common Stock. It is not possible to state the actual effect of the issuance of any shares of Convertible Preferred Stock on the rights of holders of Common Stock until the board of directors determines the specific rights attached to that Convertible Preferred Stock.

Anti-takeover provisions

Amended and Restated Certificate of Incorporation and Bylaws

Our amended and restated certificate of incorporation provides for our board of directors to be 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. Because our stockholders do not have cumulative voting rights, our stockholders holding a majority of the voting power of our shares of Common Stock outstanding will be able to elect all of our directors. The directors may be removed by the stockholders only for cause upon the vote of holders of a majority of the shares then entitled to vote at an election of directors. Furthermore, the authorized number of directors may be changed only by resolution of our board of directors, and vacancies and newly created directorships on our board of directors may, except as otherwise required by law or determined by our board, only be filled by a majority vote of the directors then serving on our board of directors, even though less than a quorum. Our amended and restated certificate of incorporation and amended and restated bylaws provide that all stockholder actions must be effected at a duly called meeting of stockholders and not by a consent in writing. A special meeting of stockholders may be called only by a majority of our whole board of directors, the chair of our board of directors, our chief executive officer or our president. Our amended and restated bylaws also provide that stockholders seeking to present proposals before a meeting of stockholders to nominate candidates for election as directors at a meeting of stockholders must provide timely advance notice in writing, and specify requirements as to the form and content of a stockholder's notice.

Our amended and restated certificate of incorporation further provides that the affirmative vote of holders of at least 66 2/3% of the voting power of all of the then outstanding shares of voting stock, voting as a single class, will be required to amend certain provisions of our certificate of incorporation, including provisions relating to the structure of our board of directors, the size of our board of directors, removal of directors, special meetings of stockholders, actions by written consent and cumulative voting. The affirmative vote of holders of at least 66 2/3% of the voting power of all of the then outstanding shares of voting stock, voting as a single class, will be required to amend or repeal our bylaws, although our bylaws may be amended by a simple majority vote of our board of directors; provided that any bylaw amendment adopted by our stockholders that specifies the votes necessary for the election of directors will not be further amended or repealed by our board of directors.

The foregoing provisions make it more difficult for our existing stockholders to replace our board of directors as well as for another party to obtain control of our company by replacing our board of directors. Since our board of directors has the power to retain and discharge our officers, these provisions could also make it more difficult for existing stockholders or another party to effect a change in management. In addition, the authorization of undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change the control of our company.

These provisions are intended to enhance the likelihood of continued stability in the composition of our board of directors and its policies and to discourage certain types of transactions that may involve an actual or threatened acquisition of our company. These provisions are also designed to reduce our vulnerability to an unsolicited acquisition proposal and to discourage certain tactics that may be used in proxy rights. However, such provisions could have the effect of discouraging others from making tender offers for our shares and may have the effect of deterring hostile takeovers or delaying changes in control of our company or our management. As a consequence, these provisions also may inhibit fluctuations in the market price of our stock that could result from actual or rumored takeover attempts.

Section 203 of the Delaware General Corporation Law

We are subject to Section 203 of the Delaware General Corporation Law, or Section 203, which prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years after the date that such stockholder became an interested stockholder, with the following exceptions:

- before such date, our board of directors approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- upon closing of the transaction that 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 began, excluding for purposes of determining the voting stock outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares owned by: (i) persons who are directors and also officers; and (ii) 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
- on or after such date, the business combination is approved by our board of directors and authorized at an annual or special meeting of the stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder.

In general, Section 203 defines business combination to include the following:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition of ten percent (10%) or more of the assets of the corporation involving the interested stockholder;
- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock or any class or series of the corporation beneficially owned by the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loss, advances, guarantees, pledges or other financial benefits by or through the corporation.

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In general, Section 203 defines an “interested stockholder” as an entity or person who, together with the person’s affiliates and associates, beneficially owns, or within three years prior to the time of determination of interested stockholder status did own, 15% or more of the outstanding voting stock of the corporation.

Limitation on Liability and Indemnification Matters

Our amended and restated certificate of incorporation and amended and restated bylaws provide that we will indemnify our directors and officers, and may indemnify our employees and other agents, to the fullest extent permitted by the Delaware General Corporation Law, which prohibits our amended and restated certificate of incorporation from limiting the liability of our directors for the following:

- 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; or
- any transaction from which the director derived an improper personal benefit.

If Delaware law is amended to authorize corporate action further eliminating or limiting the personal liability of a director, then the liability of our directors will be eliminated or limited to the fullest extent permitted by Delaware law, as so amended. Our amended and restated certificate of incorporation does not eliminate a director’s duty of care and in appropriate circumstances, equitable remedies, such as injunctive or other forms of non-monetary relief, remain available under Delaware law. This provision also does not affect a director’s responsibilities under any other laws, such as the federal securities laws or other state or federal laws. Under our amended and restated bylaws, we will also be empowered to purchase insurance on behalf of any person whom we are required or permitted to indemnify.

In addition to the indemnification required in our amended and restated certificate of incorporation and amended and restated bylaws, we have entered into indemnification agreements with each of our current directors and officers. These agreements provide indemnification for certain expenses and liabilities incurred in connection with any action, suit, proceeding, or alternative dispute resolution mechanism, or hearing, inquiry, or investigation that may lead to the foregoing, to which they are a party, or are threatened to be made a party, by reason of the fact that they are or were a director, officer, employee, agent, or fiduciary of our company, or any of our subsidiaries, by reason of any action or inaction by them while serving as an officer, director, agent, or fiduciary, or by reason of the fact that they were serving at our request as a director, officer, employee, agent, or fiduciary of another entity. In the case of an action or proceeding by, or in the right of, our company or any of our subsidiaries, no indemnification will be provided for any claim where a court determines that the indemnified party is prohibited from receiving indemnification. We believe that these bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers. We also maintain directors’ and officers’ liability insurance.

The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage stockholders from bringing a lawsuit against directors for breach of their fiduciary duties. They may also reduce the likelihood of derivative litigation against directors and officers, even though an action, if successful, might benefit us and our stockholders. A

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stockholder's investment may be harmed to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions. Insofar as we may provide indemnification for liabilities arising under the Securities Act to our directors, officers, and controlling persons pursuant to the foregoing provisions, or otherwise, we have been advised that, in the opinion of the Securities Exchange and Commission, such indemnification is against public policy as expressed in the Securities Act, and is, therefore, unenforceable. There is no pending litigation or proceeding naming any of our directors or officers as to which indemnification is being sought, nor are we aware of any pending or threatened litigation that may result in claims for indemnification by any director or officer.

Transfer agent and registrar

The transfer agent and registrar for our Common Stock is American Stock Transfer & Trust Company, LLC.

DESCRIPTION OF WARRANTS

General

We may issue warrants for the purchase of our Common Stock. Warrants may be issued independently or together with our Common Stock and may be attached to or separate from any offered securities. Each series of warrants will be issued under a separate warrant agreement to be entered into between us and one or more banks or trust companies, as warrant agent, reflecting the particular terms and provisions of a series of offered warrants. The warrant agent will act solely as our agent in connection with the warrants. The warrant agent will not have any obligation or relationship of agency or trust for or with any holders or beneficial owners of warrants.

The following briefly summarizes the material provisions of the warrant agreements and the warrants. This summary of certain provisions of the warrants is not complete. For the terms of a particular series of warrants, you should refer to the prospectus supplement for that series of warrants and the warrant agreement for that particular series, which description may modify or replace the general terms described in this section. If there are differences between the prospectus supplement and this prospectus, the prospectus supplement will control. Thus, the statements made in this section may not apply to your warrant. You can obtain a copy of any form of warrant agreement when it has been filed with the SEC or by following the directions outlined in “Where You Can Find More Information” and “Incorporation of Certain Documents by Reference” or by contacting the applicable warrant agent.

Warrants

The prospectus supplement relating to a particular series of warrants to purchase our Common Stock will describe the terms of the warrants, including the following:

- the title of the warrants;
- the offering price for the warrants, if any;
- the aggregate number of warrants;
- the designation and terms of the Common Stock that may be purchased upon exercise of the warrants;
- if applicable, the designation and terms of the securities with which the warrants are issued and the number of warrants issued with each security;
- if applicable, the date from and after which the warrants and any securities issued with the warrants will be separately transferable;
- the number of shares of Common Stock that may be purchased upon exercise of a warrant and the exercise price for the warrants;
- whether the exercise price may be paid in cash, by the exchange of warrants or other securities or both, and the method of exercising the warrants;

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- whether the warrants will be settled by delivery of the underlying securities or other property or in cash;
- the dates on which the right to exercise the warrants shall commence and expire;
- whether and under what circumstances we may cancel the warrants prior to their expiration date, in which case the holders will be entitled to receive only the applicable cancellation amount, which may be either a fixed amount or an amount that varies during the term of the warrants in accordance with a schedule or formula;
- if applicable, the minimum or maximum amount of the warrants that may be exercised at any one time;
- the currency or currency units in which the offering price, if any, and the exercise price are payable;
- the identities of the warrant agent, any depositaries and any paying, transfer, calculation or other agents for the warrants;
- any securities exchange or quotation system on which the warrants or any securities deliverable upon exercise of the warrants may be listed;
- whether the warrants are to be sold separately or with other securities, and if the warrants are to be sold with the securities of another company or other companies, certain information regarding such company or companies;
- if applicable, a discussion of material U.S. federal income tax considerations;
- the anti-dilution provisions of the warrants, if any;
- the redemption or call provisions, if any, applicable to the warrants;
- any provisions with respect to the holder's right to require us to repurchase the warrants upon a change in control or similar event; and
- any additional terms of the warrants, including procedures, and limitations relating to the exchange, exercise and settlement of the warrants.

Holders of equity warrants will not be entitled:

- to vote, consent or receive dividends;
- receive notice as stockholders with respect to any meeting of stockholders for the election of our directors or any other matter; or
- exercise any rights as stockholders of us.

Exercise of Warrants

Each warrant will entitle the holder to purchase the securities that we specify in the applicable prospectus supplement at the exercise price that we describe in the applicable prospectus supplement. Unless we otherwise specify in the applicable prospectus supplement, holders of the warrants may exercise the warrants at any time up to the specified time on the expiration date that we set forth in the applicable prospectus supplement. After the close of business on the expiration date, unexercised warrants will become void.

Unless we otherwise specify in the applicable prospectus supplement, holders of the warrants may exercise the warrants by delivering the warrant certificate representing the warrants to be exercised together with specified information, and paying the required amount to the warrant agent in immediately available funds, as provided in the applicable prospectus supplement. We will set forth on the reverse side of the warrant certificate and in the applicable prospectus supplement the information that the holder of the warrant will be required to deliver to the warrant agent in connection with the exercise of the warrant.

Upon receipt of the required payment and the warrant certificate properly completed and duly executed at the corporate trust office of the warrant agent or any other office indicated in the applicable prospectus supplement, we will issue and deliver the securities purchasable upon such exercise. If fewer than all of the warrants represented by the warrant certificate are exercised, then we will issue a new warrant certificate for the remaining amount of warrants. If we so indicate in the applicable prospectus supplement, holders of the warrants may surrender securities as all or part of the exercise price for the warrants.

No Limit on Issuance of Warrants

The warrant agreements will not limit the number of warrants or other securities that we may issue, except for the limitation of the number of shares authorized underlying such warrants.

Modifications

We and the relevant warrant agent may, without the consent of the holders, amend each warrant agreement and the terms of each issue of warrants, for the purpose of curing any ambiguity or of correcting or supplementing any defective or inconsistent provision, or in any other manner that we may deem necessary or desirable and that will not adversely affect the interests of the holders of the outstanding unexercised warrants in any material respect.

We and the relevant warrant agent also may, with the consent of the holders of at least a majority in number of the outstanding unexercised warrants affected, modify or amend the warrant agreement and the terms of the warrants. No such modification or amendment may, without the consent of each holder of an affected warrant:

- reduce the amount receivable upon exercise, cancellation or expiration;
- shorten the period of time during which the warrants may be exercised;
- otherwise materially and adversely affect the exercise rights of the beneficial owners of the warrants; or

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- reduce the percentage of outstanding warrants whose holders must consent to modification or amendment of the applicable warrant agreement or the terms of the warrants.

Merger and Similar Transactions Permitted; No Restrictive Covenants or Events of Default

The warrant agreements will not restrict our ability to merge or consolidate with, or sell our assets to, another firm or to engage in any other transactions. If at any time there is a merger or consolidation involving us or a sale or other disposition of all or substantially all of our assets, the successor or assuming company will be substituted for us, with the same effect as if it had been named in the warrant agreement and in the warrants. We will be relieved of any further obligation under the warrant agreement or warrants, and, in the event of any such merger, consolidation, sale or other disposition, we as the predecessor corporation may at any time thereafter be dissolved, wound up or liquidated.

The warrant agreements will not include any restrictions on our ability to put liens on our assets, including our interests in our subsidiaries, nor will they provide for any events of default or remedies upon the occurrence of any events of default

Warrant Agreements Will Not Be Qualified under Trust Indenture Act

No warrant agreement will be qualified as an indenture, and no warrant agent will be required to qualify as a trustee, under the Trust Indenture Act. Therefore, holders of warrants issued under a warrant agreement will not have the protection of the Trust Indenture Act with respect to their warrants.

Governing Law

Unless we provide otherwise in the applicable prospectus supplement, the warrants and warrant agreements, and any claim, controversy or dispute arising or related to the warrants or the warrant agreements, will be governed by and constructed in accordance with the laws of the State of Delaware.

PLAN OF DISTRIBUTION

We may sell the securities from time to time pursuant to underwritten public offerings, negotiated transactions, block trades or a combination of these methods. We may sell the securities to or through underwriters or dealers, through agents, or directly to one or more purchasers. We may distribute securities from time to time in one or more transactions:

- at a fixed price or prices, which may be changed;
- at market prices prevailing at the time of sale;
- at prices related to such prevailing market prices;
- at negotiated prices; or
- a combination of these pricing methods.

We may also sell equity securities covered by this registration statement in an “at the market offering” as defined in Rule 415(a)(4) under the Securities Act. Such offering may be made into an existing trading market for such securities in transactions at other than a fixed price on or through the facilities of NASDAQ or any other securities exchange or quotation or trading service on which such securities may be listed, quoted or traded at the time of sale.

Such at-the-market offerings, if any, may be conducted by underwriters acting as principal or agent.

A prospectus supplement or supplements (and any related free writing prospectus that we may authorize to be provided to you) will describe the terms of the offering of the securities, including, to the extent applicable:

- the name or names of any underwriters, dealers or agents, if any;
- the purchase price of the securities and the proceeds we will receive from the sale;
- any over-allotment options under which underwriters may purchase additional securities from us;
- any agency fees or underwriting discounts and other items constituting agents’ or underwriters’ compensation;
- any initial price to the public;
- any discounts or concessions allowed or reallocated or paid to dealers; and
- any securities exchange or market on which the securities may be listed.

If underwriters are used in the sale, they will acquire the securities for their own account and may resell the securities from time to time in one or more transactions at a fixed public offering price or at varying prices determined at the time of sale. The obligations of the underwriters to purchase the securities will be subject to the conditions set forth in the applicable underwriting agreement. We may offer the securities to the

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public through underwriting syndicates represented by managing underwriters or by underwriters without a syndicate. Subject to certain conditions, the underwriters will be obligated to purchase all of the securities offered by the prospectus supplement. In connection with the sale of the securities, we, or the purchasers of securities for whom the underwriter may act as agent, may compensate the underwriter in the form of underwriting discounts or commissions. The underwriter may sell the securities to or through dealers, and those dealers may receive compensation in the form of discounts, concessions or commissions from the underwriters and/or commissions from the purchasers for which they may act as agent. Any initial price to the public and any discounts or concessions allowed or reallocated or paid to dealers may change from time to time. We may use underwriters with whom we have a material relationship. We will describe in the prospectus supplement, naming the underwriter, the nature of any such relationship.

Any compensation paid to underwriters, dealers or agents in connection with the offering of the securities, and any discounts, concessions or commissions allowed by underwriters to participating dealers will be provided in the applicable prospectus supplement. Underwriters, dealers and agents participating in the distribution of the securities may be deemed to be underwriters within the meaning of the Securities Act, and any discounts and commissions received by them and any profit realized by them on resale of the securities may be deemed to be underwriting discounts and commissions.

We may enter into derivative transactions with third parties, or sell securities not covered by this prospectus to third parties in privately negotiated transactions. If the applicable prospectus supplement so indicates, in connection with those derivatives, the third parties may sell securities covered by this prospectus and the applicable prospectus supplement, including in short sale transactions. If so, the third party may use securities pledged by us or borrowed from us or others to settle those sales or to close out any related open borrowings of stock, and may use securities received from us in settlement of those derivatives to close out any related open borrowings of stock. The third party in such sale transactions will be an underwriter and, if not identified in this prospectus, will be named in the applicable prospectus supplement (or a post-effective amendment). In addition, we may otherwise loan or pledge securities to a financial institution or other third party that in turn may sell the securities short using this prospectus and an applicable prospectus supplement. Such financial institution or other third party may transfer its economic short position to investors in our securities or in connection with a concurrent offering of other securities.

We may sell securities directly or through agents we designate from time to time. We will name any agent involved in the offering and sale of securities, and we will describe any commissions we will pay the agent in the prospectus supplement. Unless the prospectus supplement states otherwise, our agent will act on a best-efforts basis for the period of its appointment.

We may authorize agents or underwriters to solicit offers by certain types of institutional investors to purchase securities from us at the public offering price set forth in the prospectus supplement pursuant to delayed delivery contracts providing for payment and delivery on a specified date in the future. We will describe the conditions to these contracts and the commissions we must pay for solicitation of these contracts in the prospectus supplement.

We may provide agents, dealers and underwriters with indemnification against civil liabilities related to this offering, including liabilities under the Securities Act, or contribution with respect to payments that the agents or underwriters may make with respect to these liabilities and to reimburse those persons for certain expenses. Agents and underwriters may engage in transactions with, or perform services for, us in the ordinary course of business for which they receive compensation.

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All securities we offer, other than our Common Stock, will be new issues of securities with no established trading market. Any underwriters to whom securities offered by this prospectus are sold by us for public offering and sale may make a market in the securities offered by this prospectus, but the underwriters will not be obligated to do so and may discontinue any market making at any time without notice. No assurance can be given as to the liquidity of the trading market for any securities offered by this prospectus.

The securities may or may not be listed on a national securities exchange. To facilitate the offering of securities, any underwriter may engage in over-allotment, stabilizing transactions, short covering transactions and penalty bids. Over-allotment involves sales in excess of the offering size, which create a short position. Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum. Short covering transactions involve purchases of the securities in the open market after the distribution is completed to cover short positions. Penalty bids permit the underwriters to reclaim a selling concession from a dealer when the securities originally sold by the dealer are purchased in a stabilizing or covering transaction to cover short positions. Those activities may cause the price of the securities to be higher than it would otherwise be. If commenced, the underwriters may discontinue any of the activities at any time. These transactions may be effected on any exchange or over-the-counter market or otherwise.

Any underwriters who are qualified market makers on NASDAQ may engage in passive market making transactions in the securities on NASDAQ in accordance with Rule 103 of Regulation M, during the business day prior to the pricing of the offering, before the commencement of offers or sales of the securities. Passive market makers must comply with applicable volume and price limitations and must be identified as passive market makers. In general, a passive market maker must display its bid at a price not in excess of the highest independent bid for such security; if all independent bids are lowered below the passive market maker's bid, however, the passive market maker's bid must then be lowered when certain purchase limits are exceeded. Passive market making may stabilize the market price of the securities at a level above that which might otherwise prevail in the open market and, if commenced, may be discontinued at any time.

The specific terms of any lock-up provisions in respect of any given offering will be described in the applicable prospectus supplement.

We will bear all costs, expenses and fees in connection with the registration of the securities as well as the expense of all commissions and discounts, if any, attributable to the sales of any of our securities by us.

To the extent required, this prospectus may be amended or supplemented from time to time to describe a specific plan of distribution.

LEGAL MATTERS

Wilson Sonsini Goodrich & Rosati, Professional Corporation, Palo Alto, CA, will pass upon the validity of the shares of Common Stock offered hereby. Certain members of, and investment partnerships comprised of members of, and persons associated with, Wilson Sonsini Goodrich & Rosati, Professional Corporation, own an interest representing less than 0.5% of our Common Stock.

EXPERTS

Marcum LLP, an independently registered public accounting firm has audited our financial statements included in our Annual Report on Form 10-k for the year ended December 31, 2019, as set forth in their report which includes an explanatory paragraph as to the Company's ability to continue as a going concern, dated March 4, 2020, which is incorporated by reference in this prospectus and elsewhere in the registration statement. We have included our financial statements in the prospectus and elsewhere in the registration statement in reliance on the report of Marcum LLP, given their authority as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We file annual, quarterly current and other reports, proxy statements and other information with the SEC. Our SEC filings are available to the public over the Internet at the SEC's website at <http://www.sec.gov>. Our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, and Current Reports on Form 8-K, including any amendments to those reports, and other information that we file with or furnish to the SEC pursuant to Section 13(a) or 15(d) of the Exchange Act can also be accessed free of charge through the Internet. These filings will be available as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC.

We have filed with the SEC a registration statement under the Securities Act relating to the offering of these securities. The registration statement, including the attached exhibits, contains additional relevant information about us and the securities. This prospectus does not contain all of the information set forth in the registration statement. You can obtain a copy of the registration statement, at prescribed rates, from the SEC at the address listed above. The registration statement and the documents referred to below under "Incorporation of Certain Documents by Reference" are also available on our website, www.soleno.life. We have not incorporated by reference into this prospectus the information on our website, and you should not consider it to be a part of this prospectus.

INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

The SEC allows us to “incorporate by reference” much of the information we file with it, which means that we can disclose important information to you by referring you to other documents we have filed or will file with the SEC. The information incorporated by reference is deemed to be part of this prospectus, and any of our subsequent filings with the SEC will automatically update and supersede this information. This means that you must look at all of the SEC filings that we incorporate by reference to determine if any statements in the prospectus or any document previously incorporated by reference have been modified or superseded. This prospectus incorporates by reference the documents set forth below (excluding any portions of any Current Report on Form 8-K that are not deemed “filed” pursuant to the General Instructions of Form 8-K):

- our Annual Report on [Form 10-K](#) for the fiscal year ended December 31, 2019, filed with the SEC on March 4, 2020, including portions of our proxy statement relating to our 2020 Annual Meeting of Stockholders held on May 18, 2020, to the extent incorporated by reference into such Annual Report on Form 10-K;
- our Quarterly Reports on [Form 10-Q](#) for the quarter ended September 30, 2020, filed with the SEC on [November 10, 2020](#), June 30, 2020, filed with the SEC on [August 10, 2020](#), and March 31, 2020, filed with the SEC on [May 12, 2020](#);
- our proxy statement for our special meeting of stockholders, filed with the SEC on [October 19, 2020](#) and our proxy statement for our annual meeting of the stockholders, filed with the SEC on [April 20, 2020](#);
- our Current Reports on Form 8-K, filed with the SEC on [January 24, 2020](#), [April 20, 2020](#), [April 28, 2020](#), [May 19, 2020](#), [June 26, 2020](#), [October 2, 2020](#) and [November 13, 2020](#); and
- our description of our Common Stock contained in the Registration Statement on [Form 8-A12B](#) filed with the SEC on August 8, 2014, including any subsequent amendments or reports filed for the purpose of updating such description.

We also incorporate by reference all documents we file in the future pursuant to Section 13(a), 13(c), 14 or 15(d) of the Exchange Act after the date of this prospectus and prior to the completion or termination of the offering (including all such documents filed with the SEC after the date of the initial filing of the registration statement that contains this prospectus and prior to effectiveness of the registration statement or after such effectiveness), except in each case the information contained in such document to the extent “furnished” and not “filed.”

We will provide, upon written or oral request, to each person to whom a prospectus is delivered, including any beneficial owner, a copy of any or all of the information that has been incorporated by reference in the prospectus but not delivered with the prospectus. You may request a copy of these filings, at no cost, by writing or calling us at:

Soleno Therapeutics, Inc.
203 Redwood Shores Parkway, Suite 500
Redwood City, CA 94065
Attn: Chief Financial Officer
(650) 213-8444

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You may also access the documents incorporated by reference in this prospectus through our website at www.soleno.life. Except for the specific incorporated documents listed above, no information available on or through our website shall be deemed to be incorporated in this prospectus or the registration statement of which it forms a part.

You should rely only on the information incorporated by reference or provided in this prospectus or any supplement. We have not authorized anyone else to provide you with different information. You should not assume that information in this prospectus or any supplement is accurate as of any date other than the date on the front of these documents.

\$100,000,000

Soleno Therapeutics, Inc.

Common Stock

Warrants



The information in this preliminary prospectus is not complete and may be changed or supplemented. We may not sell the 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, nor is it a solicitation of an offer to buy these securities in any state where the offer or sale of the securities is not permitted.

Part II

Information Not Required in the Prospectus

Item 14. Other Expenses of Issuance and Distribution

The following table sets forth an estimate of the costs and expenses, other than underwriting discounts and commissions, payable by the registrant in connection with the sale of the securities being registered. All of the amounts shown are estimates except the Securities and Exchange Commission (“SEC”) registration fee and the FINRA filing fee.

SEC registration fee	\$10,910
FINRA filing fee	\$15,500
Accounting fees and expenses	*
Legal fees and expenses	*
Printing and engraving	*
Fees and expenses of the transfer agent or trustee	*
Miscellaneous	*
Total	<u>\$26,410</u>

* These fees and expenses depend on the securities offered and the number of issuances, and accordingly cannot be estimated at this time.

Item 15. Indemnification of Directors and Officers

Our directors and officers are indemnified as provided by the Delaware General Corporation Law, our certificate of incorporation, as amended and restated, and our bylaws, as may be amended from time to time. We have been advised that in the opinion of the SEC indemnification for liabilities arising under the Securities Act of 1933, as amended (the “Securities Act”), 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 is asserted by one of our directors, officers, or controlling persons in connection with the securities being registered, we will, unless in the opinion of our legal counsel the matter has been settled by controlling precedent, submit the question of whether such indemnification is against public policy to a court of appropriate jurisdiction. We will then be governed by the court’s decision. We have entered into indemnification agreements with each of our directors and certain of our executive officers. These agreements provide that we will indemnify each of our directors and certain of our executive officers to the fullest extent permitted by law. We intend to enter into indemnification agreements with any new directors and executive officers in the future.

We also maintain a general liability insurance policy which covers certain liabilities of our directors and officers arising out of claims based on acts or omissions in their capacities as directors or officers.

Item 16. Exhibits

A list of exhibits filed herewith is contained in the exhibit index that immediately precedes such exhibits, which exhibit index is incorporated herein by reference.

Item 17. Undertakings

(a) The undersigned registrant hereby undertakes:

- (1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:
 - (i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;
 - (ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the SEC pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20 percent change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and
 - (iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

provided, however, that paragraphs (a)(1)(i), (a)(1)(ii) and (a)(1)(iii) of this section do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the SEC by the registrant pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement

- (2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.
- (3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.
- (4) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser:
 - (i) Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and

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- (ii) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5) or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii) or (x) for the purpose of providing the information required by Section 10(a) of the Securities Act of 1933 shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof. *Provided, however*, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date.
- (5) That, for the purpose of determining liability of the registrant under the Securities Act of 1933 to any purchaser in the initial distribution of the securities, the undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:
 - (i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;
 - (ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;
 - (iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and
 - (iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.
- (b) The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant's annual report pursuant to Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement 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.

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

EXHIBIT INDEX

<u>Exhibit Number</u>	<u>Description of Document</u>
1.1 **	Form of Underwriting Agreement
4.1	Specimen Common Stock Certificate (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form S-1/A, filed with the SEC on August 5, 2014).
4.2 **	Form of Warrant
4.2**	Form of Warrant Agreement
5.1*	Opinion of Wilson Sonsini Goodrich & Rosati, P.C. relating to base prospectus.
23.1*	Consent of Marcum LLP, Independent Registered Public Accounting Firm.
23.2*	Consent of Wilson Sonsini Goodrich & Rosati, P.C. (included in Exhibit 5.1).
24.1*	Power of Attorney (included on signature page to this Registration Statement on Form S-3).

* Filed herewith.

** To be filed by amendment or as an exhibit to a document incorporated by reference or deemed to be incorporated by reference in this registration statement, including a current report on Form 8-K, in connection with the offering of any securities, as appropriate.

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 Redwood City, State of California, on this 14th day of January, 2021.

SOLENO THERAPEUTICS, INC.

By: /s/ Anish Bhatnagar

Anish Bhatnagar

President and Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below, hereby constitutes and appoints Anish Bhatnagar and James Mackaness his or her true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to the registration statement, including post-effective amendments, and registration statements filed pursuant to Rule 462 under the Securities Act of 1933, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, and does hereby grant unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the foregoing, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or their or his or her substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated:

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Anish Bhatnagar</u> Anish Bhatnagar	President, Chief Executive Officer and Director (Principal Executive Officer)	January 14, 2021
<u>/s/ James Mackaness</u> James Mackaness	Chief Financial Officer (Principal Financial and Accounting Officer)	January 14, 2021
<u>/s/ Ernest Mario</u> Ernest Mario	Chairman	January 14, 2021
<u>/s/ Andrew Sinclair</u> Andrew Sinclair	Director	January 14, 2021
<u>/s/ William G. Harris</u> William G. Harris	Director	January 14, 2021
<u>/s/ Gwen Melincoff</u> Gwen Melincoff	Director	January 14, 2021
<u>/s/ Birgitte Volck</u> Birgitte Volck	Director	January 14, 2021

January 14, 2021

Soleno Therapeutics, Inc.
203 Redwood Shores Parkway, Suite 500
Redwood City, California 94065

Re: **Registration Statement on Form S-3**

Ladies and Gentlemen:

At your request, we have examined the Registration Statement on Form S-3 (the "Registration Statement"), filed by Soleno Therapeutics, Inc., a Delaware corporation (the "Company"), with the Securities and Exchange Commission (the "Commission") in connection with the registration pursuant to the Securities Act of 1933, as amended (the "Act"), of the offer and sale of the Securities (as defined below).

The Registration Statement relates to the proposed offer, sale and issuance by the Company, from time to time, pursuant to Rule 415 under the Act, as set forth in the Registration Statement, the prospectus contained therein (the "Prospectus") and the supplements to the prospectus referred to therein (each a "Prospectus Supplement"), of up to an aggregate offering price of \$100,000,000, or the equivalent thereof, of shares of the Company's common stock, \$0.001 par value per share (the "Common Stock") and warrants to purchase Common Stock (the "Warrants," and together with the Common Stock, the "Securities").

The Securities are to be sold from time to time as set forth in the Registration Statement, the Prospectus contained therein and the Prospectus Supplements. The Securities are to be sold pursuant to a purchase, underwriting or similar agreement in substantially the form to be filed under a Current Report on Form 8-K.

We have examined instruments, documents, certificates and records that we have deemed relevant and necessary for the basis of our opinions hereinafter expressed. In such examination, we have assumed: (i) the authenticity of original documents and the genuineness of all signatures; (ii) the conformity to the originals of all documents submitted to us as copies; (iii) the truth, accuracy and completeness of the information, representations and warranties contained in the instruments, documents, certificates and records we have reviewed; (iv) that the Registration Statement, and any amendments thereto (including post-effective amendments), will have become effective under the Act; (v) that a Prospectus Supplement will have been filed with the Commission describing the Securities offered thereby; (vi) that the Securities will be issued and sold in compliance with applicable U.S. federal and state securities laws and in the manner stated in the Registration Statement and the applicable Prospectus Supplement; (vii) that a definitive purchase, underwriting or similar agreement with respect to any Securities offered will have been duly authorized and validly executed and delivered by the Company and the other parties thereto; (viii) that any Securities issuable upon conversion, exchange, redemption or exercise of any Securities being offered will be duly authorized, created and, if appropriate, reserved for issuance upon such conversion, exchange, redemption or exercise; (ix) with respect to shares of Common Stock, that there will be sufficient shares of Common Stock authorized under the Company's organizational documents that are not otherwise reserved for issuance; and (x) the legal capacity of all natural persons. As to any facts material to the opinions expressed herein that were not independently established or verified, we have relied upon oral or written statements and representations of officers and other representatives of the Company.

Based on such examination, we are of the opinion that:

1. With respect to the shares of Common Stock, when both: (a) the Board of Directors of the Company or a duly constituted and acting committee thereof (such Board of Directors or committee being hereinafter referred to as the "Board") has taken all necessary corporate action to approve the issuance and the terms of the offering of the shares of Common Stock and related matters; and (b) the shares of Common Stock have been duly delivered in accordance with the applicable definitive purchase, underwriting or similar agreement approved by the Board, or upon the exercise of Warrants, upon payment of the consideration therefor (not less than the par value of the Common Stock) provided for therein, then the shares of Common Stock will be validly issued, fully paid and nonassessable.
2. With respect to the Warrants, when both: (a) the Board has taken all necessary corporate action to approve the issuance and terms of the Warrants and related matters; and (b) the Warrants have been duly executed and delivered against payment therefor, pursuant to the applicable definitive purchase, underwriting, warrant or similar agreement, as applicable, duly authorized, executed and delivered by the Company and a warrant agent and the certificates for the Warrants have been duly executed and delivered by the Company and such warrant agent, then the Warrants will be validly issued and will constitute valid and binding obligations of the Company, enforceable against the Company in accordance with their terms.

Our opinion that any document is legal, valid and binding is qualified as to:

- (a) limitations imposed by bankruptcy, insolvency, reorganization, arrangement, fraudulent conveyance, moratorium or other laws relating to or affecting the rights of creditors generally;
- (b) rights to indemnification and contribution, which may be limited by applicable law or equitable principles; and
- (c) general principles of equity, including without limitation concepts of materiality, reasonableness, good faith and fair dealing, and the possible unavailability of specific performance or injunctive relief and limitation of rights of acceleration, regardless of whether such enforceability is considered in a proceeding in equity or at law.

We express no opinion as to the laws of any jurisdiction other than the General Corporation Law of the State of Delaware and the federal laws of the United States of America (including the statutory provisions and all applicable judicial decisions interpreting those laws).

* * *

We hereby consent to the filing of this opinion as an exhibit to the above-referenced Registration Statement and to the use of our name wherever it appears in the Registration Statement, the Prospectus, any Prospectus Supplement, and in any amendment or supplement thereto. In giving such consent, we do not believe that we are “experts” within the meaning of such term as used in the Act or the rules and regulations of the Commission issued thereunder with respect to any part of the Registration Statement, including this opinion as an exhibit.

Very truly yours,

/s/ WILSON SONSINI GOODRICH & ROSATI, P.C.

WILSON SONSINI GOODRICH & ROSATI
Professional Corporation

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM'S CONSENT

We consent to the incorporation by reference in this Registration Statement of Soleno Therapeutics, Inc. on Form S-3 of our report, which includes an explanatory paragraph as to the Company's ability to continue as a going concern dated March 4, 2020, with respect to our audits of the consolidated financial statements of Soleno Therapeutics, Inc. as of December 31, 2019 and 2018 and for each of the two years in the period ended December 31, 2019 appearing in the Annual Report on Form 10-K of Soleno Therapeutics, Inc. for the year ended December 31, 2019. We also consent to the reference to our firm under the heading "Experts" in the Prospectus, which is part of this Registration Statement.

/s/ Marcum LLP

Marcum LLP
San Francisco
January 14, 2021