

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

**SUBJECT TO COMPLETION, DATED MARCH 28, 2022**

**PRELIMINARY PROSPECTUS SUPPLEMENT**  
**(To Prospectus dated February 9, 2021)**



**Shares of Common Stock**

**Pre-Funded Warrants to Purchase up to Shares of Common Stock**

**Warrants to Purchase up to Shares of Common Stock**

We are offering \_\_\_\_\_ shares of our common stock, par value \$0.001 per share, and accompanying common warrants to purchase an aggregate of \_\_\_\_\_ shares of our common stock (and the shares of common stock that are issuable from time to time upon exercise of the common warrants). We are also offering pre-funded warrants to purchase up to \_\_\_\_\_ shares of our common stock to certain purchasers whose purchase of shares of common stock would otherwise result in the purchasers, together with their respective affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our issued and outstanding common stock immediately following the consummation of the offering, if these investors so choose. Each pre-funded warrant will be exercisable for one share of our common stock. The purchase price of each pre-funded warrant and accompanying common warrant will be equal to the price at which a share of common stock and accompanying common warrant are sold to the public in this offering, minus \$0.01, and the exercise price of each pre-funded warrant will be \$0.01 per share.

The pre-funded warrants will be immediately exercisable and may be exercised at any time until all of the pre-funded warrants are exercised in full. This offering also relates to the shares of common stock issuable upon exercise of any pre-funded warrants sold in this offering. Each share of common stock and pre-funded warrant is being sold together with a common warrant to purchase one share of our common stock, at an exercise price of \$ \_\_\_\_\_ per share. The common warrants will be exercisable immediately and will expire five years from the date of issuance. The shares of common stock and pre-funded warrants, and the accompanying common warrants, can only be purchased together in this offering but will be issued separately and will be immediately separable upon issuance.

Our common stock is listed on The Nasdaq Capital Market (Nasdaq) under the symbol "SLNO." On March 25, 2022, the last reported sale price of our shares of common stock on Nasdaq was \$0.30 per share.

There is no established public trading market for the pre-funded warrants or common warrants, and we do not expect a market to develop. In addition, we do not intend to apply for a listing of the pre-funded warrants or common warrants on any national securities exchange.

**Investing in our securities involves significant risks. Please read the information contained in or incorporated by reference under the heading "[Risk Factors](#)" beginning on page S-18 of this prospectus supplement, and under similar headings in other documents filed after the date hereof and incorporated by reference into this prospectus supplement and the accompanying prospectus.**

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus supplement or the accompanying prospectus. Any representation to the contrary is a criminal offense.**

	<u>PER SHARE</u>	<u>PER PRE-FUNDED WARRANT</u>	<u>PER COMMON WARRANT</u>	<u>TOTAL</u>
Public offering price	\$	\$	\$	\$
Underwriting discounts and commissions(1)	\$	\$	\$	\$
Proceeds, before expenses, to us	\$	\$	\$	\$

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

Certain of our existing stockholders, who are affiliated with certain of our directors, have indicated an interest in purchasing securities in this offering at the public offering price. However, because their indications of interest are not binding agreements or commitments to purchase, the underwriters may sell more, less or no securities in this offering to any or all of these persons, or any or all of these persons may determine to purchase more, less or no securities in this offering. Except as otherwise set forth in this prospectus supplement, the underwriters will receive the same underwriting discount on any securities purchased by these stockholders as they will on any other securities sold to the public in this offering.

The underwriters expect to deliver the securities against payment on or about March \_\_\_\_\_, 2022.

*Sole Book-Running Manager*

**Oppenheimer & Co.**

The date of this prospectus supplement is March \_\_\_\_\_, 2022

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## ABOUT THIS PROSPECTUS SUPPLEMENT

This document contains two parts. The first part is this prospectus supplement, which describes the specific terms of this offering and also supplements and updates information contained in the accompanying prospectus and the documents incorporated by reference into this prospectus supplement and the accompanying prospectus. The second part is the accompanying prospectus, which provides more general information, some of which may not apply to this offering. If the information contained in this prospectus supplement differs or varies from the information contained in the accompanying prospectus, you should rely on the information set forth in this prospectus supplement.

We have not, and the underwriters have not, authorized anyone to provide you with information or to make any representation other than the information and representations contained or incorporated by reference in this prospectus supplement and the accompanying prospectus and the documents incorporated by reference herein and therein, along with the information contained in any permitted free writing prospectuses we have authorized for use in connection with this offering. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you.

We are offering to sell, and seeking offers to buy, shares of our common stock and accompanying common warrants and/or pre-funded warrants and accompanying common warrants only in jurisdictions where offers and sales are permitted. For investors outside the United States: we have not, and the underwriters have not, done anything that would permit this offering or possession or distribution of this prospectus supplement, the accompanying prospectus and in any free writing prospectus that we have authorized for use in connection with this offering in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus supplement, the accompanying prospectus and any free writing prospectus that we have authorized for use in connection with this offering must inform themselves about, and observe any restrictions relating to, the offering of shares of our common stock and accompanying common warrants and pre-funded warrants and accompanying common warrants and the distribution of this prospectus supplement, the accompanying prospectus and any free writing prospectus that we have authorized for use in connection with this offering outside the United States.

The information contained in this prospectus supplement and the accompanying prospectus is accurate only as of the date of this prospectus supplement or the date of the accompanying prospectus, and the information in the documents incorporated by reference in this prospectus supplement and the accompanying prospectus is accurate only as of the date of those respective documents, regardless of the time of delivery of this prospectus supplement and the accompanying prospectus or of any sale of our shares of our common stock and accompanying common warrants and/or pre-funded warrants and accompanying common warrants. Our business, financial condition, results of operations and prospects may have changed since those dates. It is important for you to read and consider all information contained or incorporated by reference in this prospectus supplement and the accompanying prospectus in making your investment decision. You should read this prospectus supplement, the accompanying prospectus and any free writing prospectus that we have authorized for use in connection with this offering, as well as the documents incorporated by reference herein and therein and the additional information described under “Where You Can Find More Information” in this prospectus supplement and in the accompanying prospectus, before investing in our shares of common stock and accompanying common warrants and/or pre-funded warrants and accompanying common warrants.

Unless otherwise indicated or the context otherwise requires, references in this prospectus supplement and the accompanying prospectus to “Soleno,” the “Company,” “we,” “us” and “our” refer to Soleno Therapeutics, Inc.

## PROSPECTUS SUPPLEMENT SUMMARY

*This summary highlights certain information about us and this offering. Because it is a summary, it does not contain all of the information that you should consider before investing. Before investing in our shares of common stock and accompanying common warrants and/or pre-funded warrants and accompanying common warrants, you should read this entire prospectus supplement and the accompanying prospectus carefully, including the "Risk Factors," and the financial statements and accompanying notes and other information included and incorporated by reference in this prospectus supplement and the accompanying prospectus.*

### Company Overview

We are a clinical-stage biopharmaceutical company focused on the development and commercialization of novel therapeutics for the treatment of rare diseases. Our lead drug candidate, Diazoxide Choline Extended-Release tablets (DCCR), is a potent ATP-sensitive potassium ( $K_{ATP}$ ) channel activator. The  $K_{ATP}$  channel plays a central role in the regulation of a number of physiological processes which may otherwise be dysregulated, contributing to the pathophysiology of several diseases. In the context of the underlying genetic or structural defects in many forms of hyperphagic obesity, including Prader-Willi syndrome (PWS), these pathophysiological processes may cumulatively contribute to increases in appetite and aggressive food seeking, lack of satiety, accumulation of excess body fat and the establishment and perpetuation of the obese state.

DCCR's unique mode of action with targets in tissues such as the brain, pancreas and fat tissue has the potential to broadly impact complex diseases like PWS to reduce appetite, reduce food seeking, improve satiety, improve insulin and leptin resistance and reduce body fat. It appears that many of the problematic behaviors in conditions like PWS may have hyperphagic drive as a root cause and may therefore be improved by addressing hyperphagia. We have a Fast-Track designation for DCCR in PWS and orphan drug designation for the drug candidate in the United States (U.S.) and the European Union (E.U.).

DCCR has been evaluated in a Phase 3 study (C601 or DESTINY PWS), a 13-week randomized, double-blind placebo-controlled study, which completed enrollment in January 2020, with 127 randomized participants at 29 sites in the U.S. and the United Kingdom (U.K.). Participants who complete treatment in DESTINY PWS and sought continued treatment with DCCR were eligible to receive DCCR in a long-term open-label safety extension study (C602). Top-line results from DESTINY PWS were announced in June 2020. Although the trial did not meet its primary endpoint of change from baseline in hyperphagia, significant improvements were observed in two of three key secondary endpoints. Please review the section below regarding Recent Developments for the current status of our Phase 3 clinical trial.

Our current focus is the development of DCCR for PWS, which has received support from PWS patient advocacy groups and the wider PWS community as a result of patients' and caregivers experiences with DCCR. In April of 2021, the Foundation for Prader-Willi Research and the Prader-Willi Syndrome Association jointly initiated and submitted a petition to the U.S. Food and Drug Administration (FDA) requesting that the FDA apply regulatory flexibility with respect to its review of DCCR. That petition garnered 26,640 signatures.

We estimate that the commercial opportunity for DCCR in the U.S. is greater than \$1 billion per year. Other syndromes that may be similarly addressed include SH2B1 deficient obesity, MC4R deficiency, Alström syndrome, and KSR2 deficient obesity. Another type of disease where DCCR may be efficacious is where hypoglycemia is a significant problem. Examples include hyperinsulinemic hypoglycemia and certain Glycogen Storage Diseases. We have orphan drug designation for the treatment of Glycogen Storage Disease Type 1a in the U.S.

### **Diazoxide Choline Controlled-Release (DCCR) 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  $K_{ATP}$  channels and appears to act on signs and symptoms of PWS in a variety of ways. Activating the  $K_{ATP}$  channel in NPY/AgRP neurons in the hypothalamus may reduce secretion of neuropeptide Y (NPY), Agouti-related peptide (AgRP) and likely gamma-aminobutyric acid (GABA) contributing to a reduction in hyperphagia. Activating the  $K_{ATP}$  channel in the dorsal motor nucleus of vagus has the potential to potentiate the effects of leptin, insulin and  $\alpha$ -melanocortin stimulating hormone to reduce hyperinsulinemia and impact appetite and satiety. Activating the  $K_{ATP}$  in pancreatic  $\beta$ -cells can reduce the secretion of insulin, and further reduce the accumulation of excess body fat and the progression to insulin resistance. Activating the  $K_{ATP}$  channel in adipocytes has the potential to decrease de-novo triglyceride synthesis and increase  $\beta$ -oxidation of fat, reducing fat mass.

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<sup>®</sup> 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 ultra-rare indications related to hyperinsulinism. Both the capsule and IV formulations have been withdrawn from the U.S. market for reasons other than safety. There is 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 dosing required by current diazoxide formulations. Diazoxide choline is formulated into an extended-release tablet that provides lower 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 reducing the potential adverse events often associated with transiently high circulating drug levels, and the ability to provide efficacy at lower diazoxide-equivalent doses.

#### *Prader-Willi Syndrome (PWS)*

PWS is a rare, complex neurobehavioral/metabolic disorder caused by the absence of normally active paternally expressed genes from the chromosome 15q11-q13 region. PWS is an imprinted condition with 60-65% of the cases due to a de novo deletion in the paternally inherited chromosome 15 11-q13 region, 30-35% 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  $29.5 \pm 15$  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, anxiety 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 access to food and its intake. However, patients remain hyperphagic and will typically have a higher body fat and lower lean body mass content compared to similarly obese individuals. They are prone to cardiometabolic issues such as abnormal lipid profiles, diabetes and hypertension associated with obesity once it is established. 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. Cognitively, most individuals with PWS function in the mild intellectual 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. Some older adolescents and many adults reach a stage at which they can no longer be effectively managed in the home and therefore transition to institutional care.

#### *Unmet Medical Needs in PWS*

The target indication for DCCR is the treatment of PWS. Currently, the only approved treatment for 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 a very important or the most important symptom to be relieved by a new treatment - <https://www.fpw.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 an important unmet need.

#### *Clinical Trials of DCCR for PWS*

A Phase 2 clinical trial was conducted at UC Irvine 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.

As described above, a Phase 3 clinical trial, DESTINY PWS, was subsequently conducted to evaluate the efficacy and safety of DCCR in patients with genetically-confirmed PWS. Top-line results were reported in June 2020. Although the trial did not meet its primary endpoint of change from baseline in hyperphagia, significant improvements were observed in two of three key secondary endpoints.

**C601 Primary and Key Secondary Endpoints**

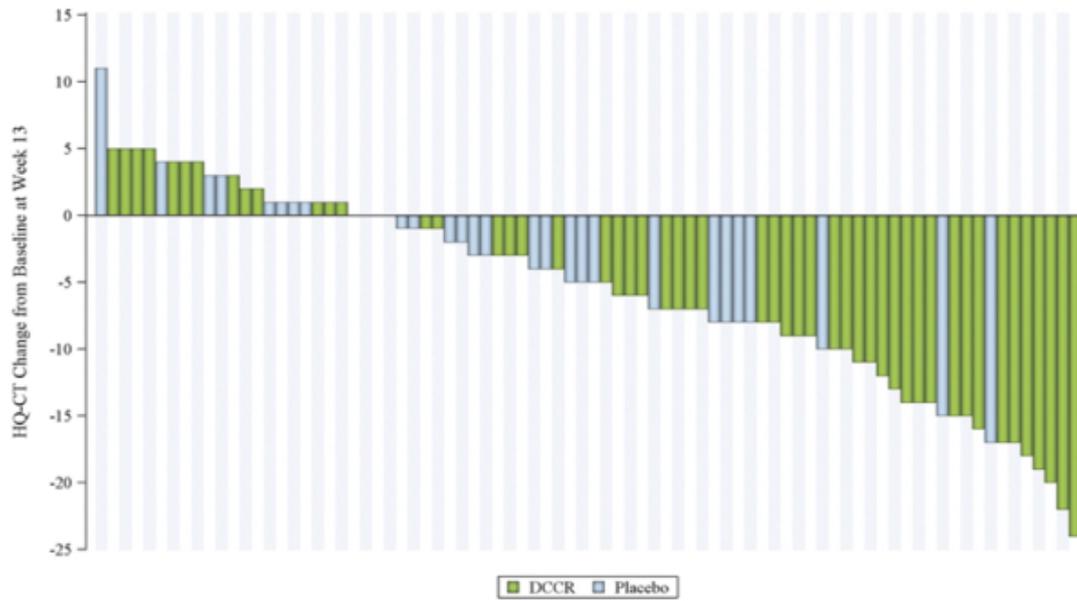
<b>Primary Endpoint</b>	<b>DCCR (N = 82)</b>	<b>Placebo (N = 42)</b>
Mean Change from Baseline in Hyperphagia at Visit 7	-5.94 (0.879)	-4.27 (1.145)
LS Mean Difference [DCCR-Placebo] (SE)	-1.67 (1.294)	
p-value	0.1983	
<b>Key Secondary Endpoints</b>		
Clinical Global Impression of Improvement at Visit 7 (CG-I)	0.029	
Mean Change From Baseline in Body Fat Mass (DXA)	0.025	
Caregiver Global Impression of Change at Visit 7 (Caregiver GI-C)	0.409	

In February 2021, we announced analysis limited to data collected before the onset of the COVID-19 pandemic. The analysis of the data through March 1, 2020 showed statistical significance in the primary, all key secondary and several other efficacy endpoints.

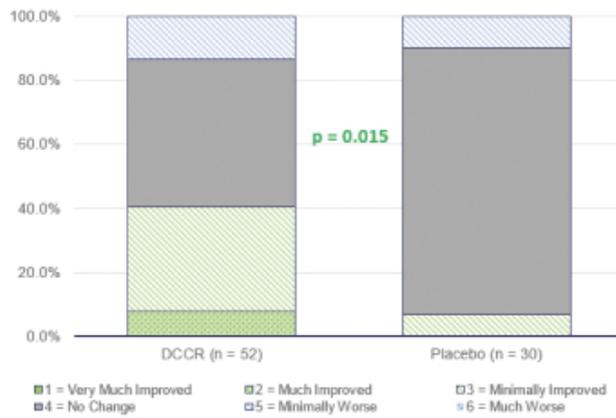
**C601 Primary and Key Secondary Endpoints**

<b>Primary Endpoint</b>	<b>All Data</b>		<b>Data through March 1, 2020</b>	
	<b>DCCR (N = 82)</b>	<b>Placebo (N = 42)</b>	<b>DCCR (N = 80)</b>	<b>Placebo (N = 40)</b>
Mean Change from Baseline in Hyperphagia at Visit 7	-5.94 (0.88)	-4.27 (1.15)	-6.64 (1.00)	-3.51 (1.28)
LS Mean Difference [DCCR-Placebo] (SE)	-1.67(1.29)		-3.13 (1.48)	
p-value	0.198		<b>0.037</b>	
<b>Key Secondary Endpoints</b>				
Clinical Global Impression of Improvement at Visit 7 (CG-I)	<b>0.03</b>		<b>0.015</b>	
Mean Change From Baseline in Body Fat Mass (DXA) at Visit 7	<b>0.03</b>		<b>0.004</b>	
Caregiver Global Impression of Change at Visit 7 (Caregiver GI-C)	0.41		<b>0.031</b>	

**HQ-CT Changes from Baseline Waterfall Plot through March 1, 2020**



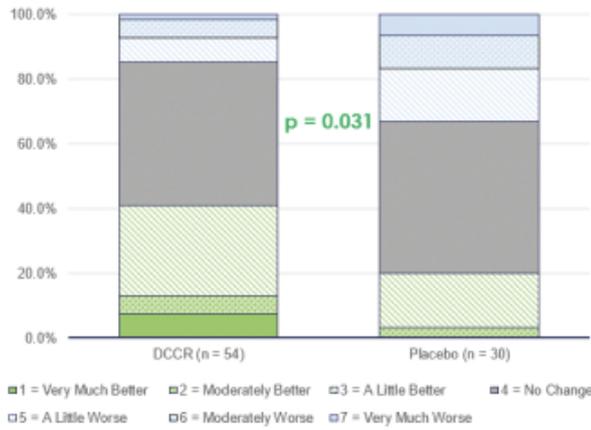
**C601 Key Secondary Endpoint: CGH through March 1, 2020**



CGI-I Rating	DCCR (n = 52)	Placebo (n = 30)
Improved	40.4%	6.7%
No Change	46.2%	83.3%
Worse	13.5%	10.0%

p-value using CMH; all observed values through March 1, 2020  
Using imputation for missing data p = 0.037

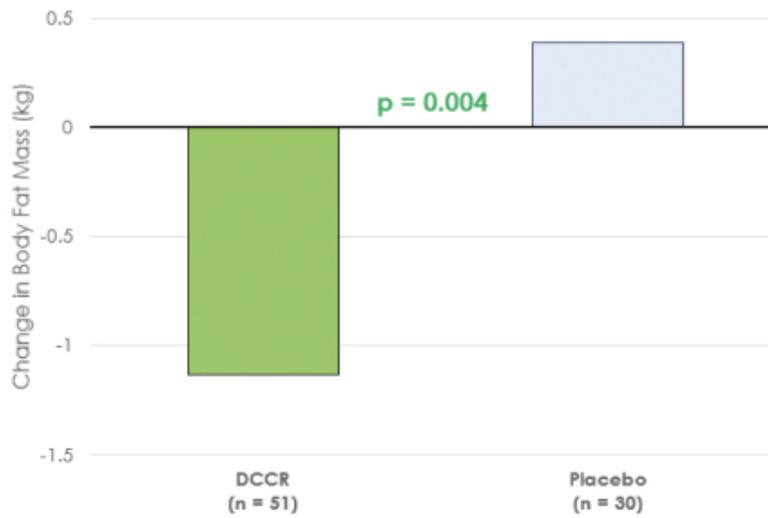
**C601 Key Secondary Endpoint: Caregiver GI-C through March 1, 2020**



Caregiver GI-C Rating	DCCR (n = 54)	Placebo (n = 30)
Better	40.8%	20.0%
No Change	44.4%	46.7%
Worse	14.9%	33.4%

p-value using CMH; all observed values through March 1, 2020  
 Using imputation for missing data  $p = 0.066$

**C601 Key Secondary Endpoint: Body Fat Mass through March 1, 2020**



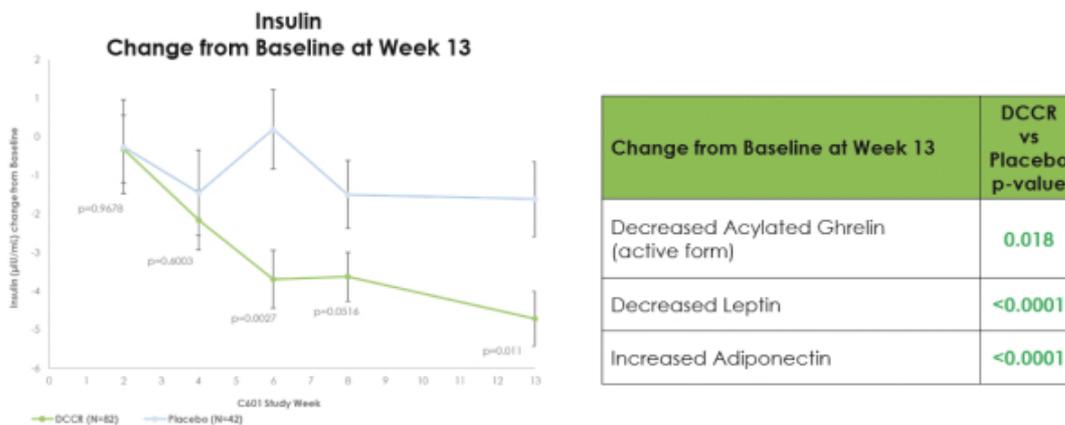
Observed values through March 1, 2020  
 Using imputation for missing data  $p = 0.005$

**C601 Behavioral Endpoints through March 1, 2020**

PWSP Domain	p-value DCCR vs Placebo
Aggressive Behaviors	0.048
Anxiety	0.018
Rigidity, Irritability	0.003
Compulsivity	0.008
Depression	0.185
Disordered Thinking	0.011
<b>DBC-2</b>	
Total Score	0.009
Communication Disturbance	0.003
Social Relating	0.008

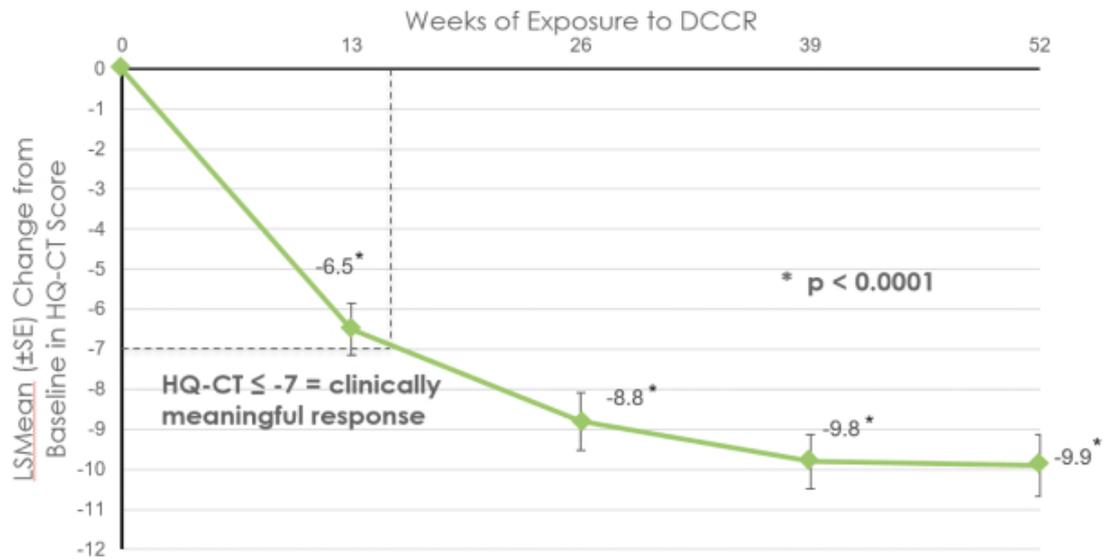
Observed values through March 1, 2020

**C601 Mean Changes from Baseline in Key Endocrine and Hormonal Parameters**

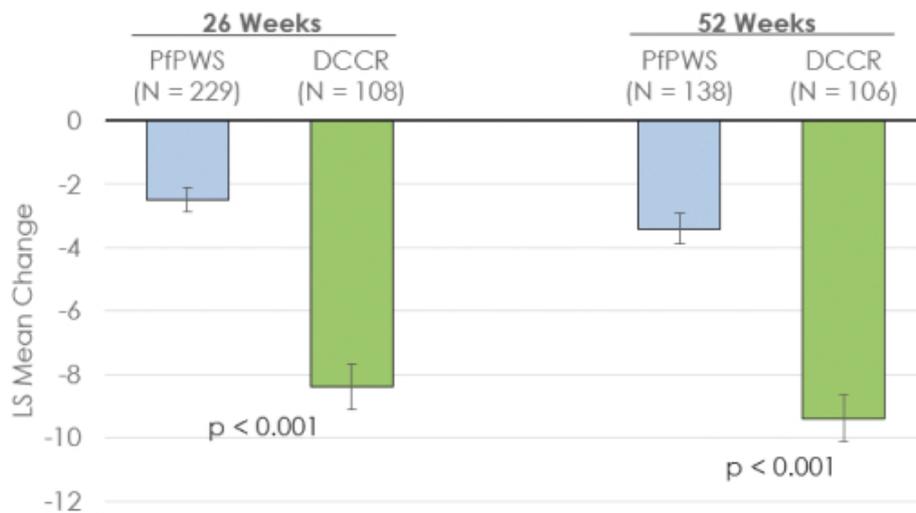


Subjects who completed the DESTINY PWS Phase 3 clinical trial were allowed to enroll in C602. In September 2021, we announced top-line results from the analysis of one-year data from C602 showing statistically significant reduction in hyperphagia and all other PWS behavioral parameters and statistically significant improvements compared to the natural history of PWS from the PATH for PWS Study (PfPWS) over a one year treatment period. PfPWS is an ongoing study sponsored by the Foundation for Prader Willi Research (FPWR) evaluating the natural history of subjects with PWS in more than 700 families.

**DCCR Hyperphagia Change from Baseline**



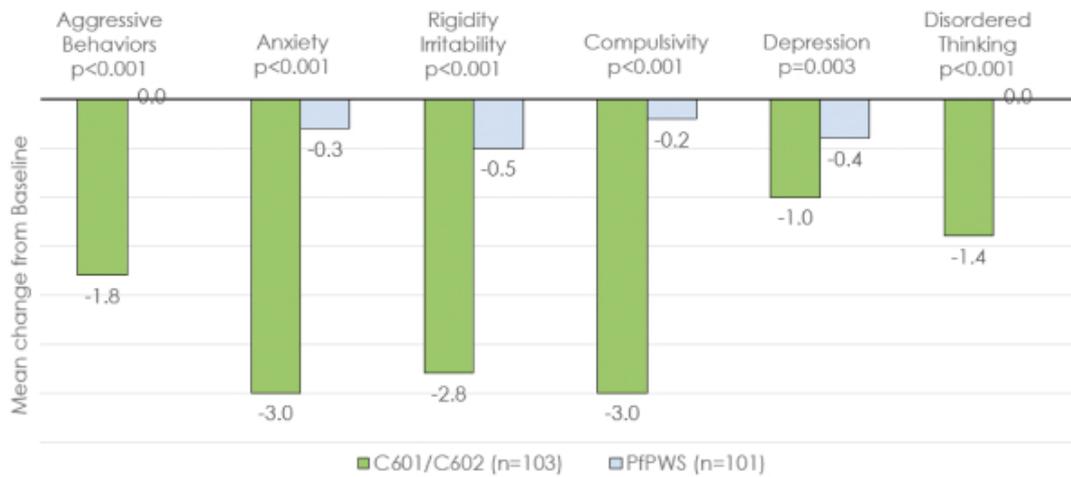
**Change in Hyperphagia with DCCR Compared to PfPWS**



**PWS Profile Behavioral Change Results after One Year of DCCR**

Domain	P-value
Aggressive Behaviors	<0.0001
Aggressive Destructive subfactor	< 0.0001
Anxiety	<0.0001
Compulsivity	<0.0001
Depression	<0.0001
Disordered Thinking	<0.0001
Rigidity Irritability	<0.0001

**Comparison to PFPWS – Change in Behaviors from Baseline at Week 52**



**Endocrine and Hormonal Parameters After One-Year of DCCR**

Parameter	p-value
Decreased Leptin (pg/mL)	<0.0001
Increased Adiponectin (ng/mL)	<0.0001
Decreased Fasting Insulin (μIU/mL)	0.0004
Decreased HOMA-IR	0.0033

*Safety of DCCR in the Treatment of PWS*

In the DESTINY-PWS clinical trial (C601), treatment emergent adverse events (TEAEs) occurred in 83.3% of DCCR treated subjects and 73.8% of placebo treated subjects. The most common TEAEs in both groups included hypertrichosis, hirsutism, upper respiratory tract infections, peripheral edema, headache and hyperglycemia. Hypertrichosis, peripheral edema, and hyperglycemia occurring more frequently in the DCCR group, headache occurred more frequently in the placebo group, and hirsutism and upper respiratory tract infections occurring with almost equal frequency in the two groups.

The safety profile of DCCR in C601 was generally consistent with the known safety profile of diazoxide and prior experience with DCCR. Most events were Grade 1 in severity with no Grade 4 or higher events. There were no serious unexpected adverse events (SUSARs) related to DCCR in clinical study C601.

*Regulatory Status of DCCR for the Treatment of PWS*

Diazoxide choline is being developed in the U.S. under a current Investigational New Drug Application (IND) and is designated as an Orphan Drug for the treatment of PWS in the U.S. and Europe and granted Fast Track designation in the U.S.. If certain criteria are met, DCCR may be eligible for “Accelerated Approval” and “Priority Review” and also “Rolling Review”, which would allow us to submit to the FDA sections of our NDA as they are finished instead of waiting for all sections to be completed before submitting the marketing application. Please review the section below regarding Recent Developments for the current status of our Phase 3 clinical trial.

*Market opportunity*

An estimated 300,000 to 400,000 individuals worldwide have PWS with a birth incidence ranging from 1:15,000 to 1:25,000. In addition, according to an abstract published in the Journal of Endocrine Society, a 2020 review of medical claims provided by IQVIA Health Plan and CMS Medicare fee-for-service claim data, demonstrated a U.S. diagnosed PWS prevalence of approximately 9,000 patients in the United States in 2018. The numbers of identified PWS patients is growing at a rate that is higher than the rate of general population because of improved rates of diagnosis. DCCR may be the first effective treatment for hyperphagia in PWS patients to reach the market both in the U.S. and Europe and may therefore be likely to be used in a large proportion of patients. The Company estimates the commercial opportunity in the U.S. to be greater than \$1 billion per year.

### *Sales and Marketing*

Newly diagnosed PWS patients are typically treated by a multi-disciplinary team led by a pediatric endocrinologist. Many patients receive care at larger clinics devoted to PWS in university-associated hospitals or at children's hospitals. This concentration of care may allow us to market DCCR without a partner by assembling a small, dedicated salesforce to target the limited number of major PWS treatment centers in the U.S. We believe similar dynamics exist in Europe. In contrast, we will likely need to identify a marketing partner for DCCR in Japan, and the rest of the world. The final decision on sales and marketing strategy will be made at a later date.

### *Pricing*

We have not conducted a formal pricing analysis of DCCR in PWS, although analogue orphan drug products that are on the market in the U.S. are priced between \$100,000 to \$500,000 per patient per year. We anticipate that pricing at launch may be influenced by the product label negotiated with the FDA, pharmacoeconomic data developed to support pricing and the potential for greater sales under negotiated government contracts.

### *Competition*

Currently, the only approved products for PWS are Genotropin® (somatropin), and Omnitrope® (somatropin) which are approved only for growth failure due to PWS. There are no approved products to address PWS-associated hyperphagia and behaviors, or for any other abnormalities associated with the disease. However, to our knowledge, there are a number of therapeutic products at various stages of clinical development for the treatment of PWS, including for hyperphagia, by Levo Therapeutics, Inc., Saniona AB, Inversago, and Consynance.

### **Risk Factors**

Our business is subject to substantial risk. Please carefully consider the section titled "Risk Factors" beginning on page S-18 of this prospectus supplement, as well as risk factors referenced in the accompanying prospectus and in our Annual Report on Form 10-K for the year ended December 31, 2020 and our Quarterly Report on Form 10-Q for the three months ended September 30, 2021, for a discussion of the factors you should carefully consider before deciding to purchase securities that may be offered by this prospectus supplement and the accompanying prospectus. These risks include, but are not limited to:

- immediate and substantial dilution in the book value of purchasers' investments in the Company;
- our broad discretion in how we use the net proceeds of this offering;
- dilution of your ownership and restrictions imposed on our business as a result of additional capital raises;
- risks related to holding the pre-funded warrants and common warrants, including the lack of a public market for the pre-funded warrants and common warrants and the speculative nature of such securities;
- we have not paid dividends in the past and do not expect to pay dividends in the future;
- sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall;
- fluctuation in the price of our common stock;
- our lack of approved products, making assessment of our future viability difficult;
- our dependency on the success of DCCR, our sole therapeutic product candidate;

- our need for additional funds to support our operations, which funding may not be available to us on acceptable terms, or at all;
- our limited product revenue and commercialization history, our history of incurring significant losses since our inception, and our anticipation that we will continue to incur substantial losses for the foreseeable future;
- the significant fluctuation of our operating results, which makes our future operating results difficult to predict;
- our engagement in strategic transactions that could impact our liquidity, increase our expenses and present significant distractions to our management;
- our ability to enter into strategic transactions on a timely basis or on acceptable terms, which may impact our development and commercialization plans;
- if we are unable to execute our sales, marketing, distribution, training and support strategies for our products, and are unable to gain acceptance in the market, we may be unable to generate sufficient revenue to sustain our business;
- the performance of our products;
- clinical studies of our planned products may fail to demonstrate safety and effectiveness, or otherwise produce positive results, to the satisfaction of the FDA or similar regulatory authorities outside the U.S.;
- failure to obtain regulatory approval for DCCR or other potential product candidates;
- the expense and lengthiness of clinical drug development, and the possibility that such clinical drug development may not yield favorable results;
- even if planned products receive regulatory approval, these products may fail to achieve the degree of market acceptance by physicians, patients, caregivers, healthcare payors and others in the medical community necessary for commercial success;
- we may attempt to form partnerships with respect to our products, but we may not be able to do so;
- our product candidates may cause serious adverse side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial desirability of an approved label or result in significant negative consequences following any marketing approval;
- competition, which may result in others discovering, developing or commercializing products before we do, or more successfully than we do;
- our patent rights may prove to be an inadequate barrier to competition;
- product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products;
- risks related to the loss of key members of our executive management team and the scarcity of experienced professionals in our industry;
- business, regulatory, political, operational, financial and economic risks associated with doing business outside of the U.S.;
- any future distribution or commercialization agreements we may enter into for our products may place the development of these products outside our control, may require us to relinquish important rights, or may otherwise be on terms unfavorable to us;
- difficulties in managing our growth;
- reliance on third parties to conduct components of our clinical studies;

- risks related to intellectual property rights, including the initiation of legal proceedings by third parties alleging that we are infringing on their intellectual property rights, our ability to obtain and maintain effective intellectual property rights for our technologies and planned products and the protection and enforcement of our trade secrets and intellectual property rights;
- healthcare reform measures could hinder or prevent our planned products' commercial success;
- failure to comply with healthcare regulations;
- risks related to the ownership of our securities;
- breaches into our computer systems and data security;
- risks related to the coronavirus pandemics and other public health epidemics, pandemics, outbreaks or other force majeure events such as the ongoing hostilities between Russia and Ukraine; and
- risks related to the administration of a public company.

Additional risks and uncertainties not presently known to us may also impair our business operations. You should be able to bear a complete loss of your investment.

### **Intellectual Property**

Our patent portfolio consists of issued U.S. patents and pending U.S. applications. Our issued U.S. patents expire in 2025 to 2035. We also have one or more issued patents in Europe, Canada, Japan, China, India, Israel, Hong Kong, Australia, Malaysia, Mexico, New Zealand, Singapore, Indonesia, Korea, and Eurasia. We are prosecuting numerous patent applications in major pharmaceutical markets around the world. The issued patents and pending patent applications include protection of compositions, methods of manufacturing, pharmaceutical formulations, and methods of treating aspects of PWS and Smith-Magenis syndrome (SMS).

### **Recent Developments**

In February 2021, we announced analysis limited to data collected before the onset of the COVID-19 pandemic. The analysis of the data through March 1, 2020 showed statistical significance in the primary, all key secondary and several other efficacy endpoints. In March 2021, the FDA informed us that an additional clinical trial would be necessary to support a New Drug Approval (NDA) submission. In July 2021, we announced that we had received official meeting minutes from a Type B meeting with the FDA on June 11, 2021. Included in the meeting was the "patient voice" represented by the PWS advocacy organizations, as well as the family of a DCCR trial participant. The FDA continued to assert that an additional clinical trial is necessary for the submission of an NDA. However, the FDA strongly encouraged us to submit the available data and clinical study reports for our C601 and C602 studies as well as a comparison to natural history data to allow it to assess if these studies may provide adequate evidence of safety and efficacy to support the submission of an NDA. In September 2021, we announced top-line results from the interim one year data from C602 showing statistically significant reduction in hyperphagia and all other PWS behavioral parameters and statistically significant improvements compared to natural history of PWS from PfpWS over a one year treatment period. We submitted the data in the fourth quarter 2021 and in January 2022, we announced we had received official meeting minutes from a Type C meeting with the FDA held on December 21, 2021. The purpose of the meeting was to discuss the adequacy of the submitted data and possible ways to generate additional controlled clinical data. The FDA recommended that additional controlled data be included in the NDA submission, and indicated they were receptive to a study design involving participants currently enrolled in Study C602, the Company's ongoing open-label extension study to generate the data necessary to support an NDA. In March 2022, the Company submitted a study proposal involving Study C602 participants.

On March 9, 2022, the Company announced that Running for Research - Prader-Willi Syndrome (RFR), an organization committed to raising private donations in support of advancing the science around PWS, will fund an investigator-sponsored clinical study to evaluate DCCR in patients with early phase PWS. The study is expected to be a multi-center trial conducted at four institutions in the U.S. The goal of this study is to evaluate the effects of DCCR in pre-hyperphagic individuals with PWS based on various behavioral and metabolic parameters and to assess if DCCR has potential to prevent progression to hyperphagia and late-phase PWS.

**Financial Update**

As of December 31, 2021, the Company had a total of 79.9 million shares of common stock and 7.2 million shares of potentially dilutive securities outstanding for a total of 87.1 million shares of common stock and dilutive potential shares of common stock outstanding.

We have not commenced commercialization of DCCR, our current sole novel therapeutic product, and accordingly, through December 31, 2021, have generated no revenue from operations. We had a net loss of \$30.9 million during the year ended December 31, 2021 and an accumulated deficit of \$213.4 million as of December 31, 2021 as a result of having incurred losses since our inception. We had \$21.3 million in cash and cash equivalents and \$14.4 million of working capital as of December 31, 2021, used \$27.8 million of cash in operating activities during the year ended December 31, 2021 and expect to continue incurring losses for the foreseeable future. These matters raise substantial doubt about our ability to continue as a going concern.

**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](http://www.soleno.life). The information contained on our website is not incorporated by reference into this prospectus supplement, and you should not consider any information contained on, or that can be accessed through, our website as part of this prospectus supplement, or in deciding whether to purchase our securities.



We intend to use the net proceeds from this offering to fund our current research and development efforts primarily focused on advancing our lead candidate, DCCR tablets for the treatment of PWS, and to provide for general corporate purposes, which may include working capital, capital expenditures, other clinical trials, other corporate expenses and acquisitions of complementary products, technologies or businesses. However, we do not have agreements or commitments for any specific acquisitions at this time.

Risk factors

See “Risk Factors” for a discussion of factors you should carefully consider before deciding to invest in our common stock.

Nasdaq Capital Market symbol

“SLNO”. We do not intend to list the pre-funded warrants or common warrants on any securities exchange or nationally recognized trading system.

The number of shares of common stock to be outstanding immediately after this offering is based on 79,806,487 shares of common stock outstanding as of September 30, 2021 and excludes:

- 6,084,923 shares of common stock issuable upon exercise of stock options outstanding as of September 30, 2021 under our equity incentive plans, with a weighted-average exercise price of \$3.11 per share;
- 435,750 shares of common stock issuable upon the vesting of restricted stock units as of September 30, 2021 under our equity incentive plans;
- 1,661,751 shares of common stock issuable upon exercise of stock options granted after September 30, 2021 under our equity incentive plans, with a weighted-average exercise price of \$0.36 per share;
- 198,703 shares of common stock issuable upon vesting of restricted stock units granted after September 30, 2021;
- 632,187 shares of common stock issuable upon exercise of outstanding warrants, with a weighted average exercise price of \$6.49 per share, as of March 28, 2022;
- 2,805,045 shares of common stock available for future issuance under our 2014 Equity Incentive Plan and 1,285,000 shares of common stock available for future issuance under our 2021 Inducement Equity Incentive Plan, each as of March 28, 2022; and
- shares of common stock issuable upon exercise of the pre-funded warrants and common warrants issued in this offering.

To the extent that any outstanding options, warrants, and convertible securities are exercised or converted, there may be further dilution to new investors. In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

Certain of our existing stockholders, who are affiliated with certain of our directors, have indicated an interest in purchasing shares of our securities in this offering at the public offering price. However, because their indications of interest are not binding agreements or commitments to purchase, the underwriters may sell more, less or no securities in this offering to any or all of these persons, or any or all of these persons may determine to purchase more, less or no securities in this offering. Except as otherwise set forth in this prospectus supplement, the underwriters will receive the same underwriting discount on any securities purchased by these stockholders as they will on any other securities sold to the public in this offering.

## RISK FACTORS

*Investing in our securities involves a high degree of risk. Before making an investment decision, you should carefully consider the risks described below, any amendment or update thereto reflected in our subsequent filings with the Securities and Exchange Commission, or SEC, and all of the other information in this prospectus supplement, including our financial statements and related notes incorporated by reference in this prospectus supplement. If any of these risks are realized, our business, financial condition, results of operations and prospects could be materially and adversely affected. In that event, the trading price of our common stock could decline and you could lose part or all of your investment. Additional risks and uncertainties that are not yet identified or that we think are immaterial may also materially harm our business, operating results and financial condition and could result in a complete loss of your investment.*

### **Risks related to this offering**

*Purchasers in this offering will experience immediate and substantial dilution in the book value of their investment.*

Purchasers of our common stock in this offering will experience immediate dilution in the net tangible book value of the common stock purchased in this offering because the price per share of common stock in this offering is substantially higher than the net tangible book value per share of our common stock outstanding immediately after this offering. Our net tangible book value as of September 30, 2021 was approximately \$7.1 million, or \$0.09 per share of our common stock. If you purchase shares of common stock in this offering, you will suffer immediate and substantial dilution of \$ per share with respect to the net tangible book value of the common stock. See “Dilution” in this prospectus supplement for a detailed discussion of the dilution you will incur if you purchase shares in this offering.

*We will have broad discretion in how we use the net proceeds of this offering. We may not use these proceeds effectively, which could affect our results of operations and cause our stock price to decline.*

Although we currently intend to use the net proceeds from this offering in the manner described in the section entitled “Use of Proceeds” in this prospectus supplement, we will have considerable discretion in the application of the net proceeds of this offering. We may use the net proceeds for purposes that do not yield a significant return or any return at all for our stockholders. In addition, pending their use, we may invest the net proceeds from this offering in a manner that does not produce income or that loses value. If we do not invest or apply the net proceeds from this offering in ways that enhance stockholder value, we may fail to achieve expected financial results, which could cause our stock price to decline.

*If we raise additional capital through the sale of shares of our common stock, convertible securities or debt in the future, your ownership in us could be diluted and restrictions could be imposed on our business.*

In addition to this offering, we may issue shares of our common stock or securities convertible into our common stock to raise additional capital in the future. To the extent we issue such securities, our stockholders may experience substantial dilution and the trading price of our common stock could decline. If we obtain funds through a credit facility or through the issuance of debt or preferred securities, such debt or preferred securities could have rights senior to your rights as a common stockholder, which could impair the value of our common stock.

*We have not paid dividends in the past and do not expect to pay dividends in the future, and, as a result, any return on investment may be limited to the value of our stock.*

We have never paid dividends and do not anticipate paying dividends in the foreseeable future. The payment of dividends will depend on our earnings, capital requirements, financial condition, prospects and other factors our board of directors may deem relevant. If we do not pay dividends, our stock may be less valuable because a return on your investment will only occur if our stock price appreciates and you sell our common stock thereafter.

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*Sales of a substantial number of shares of our common stock in the public market or the exercise of our pre-funded warrants or common warrants could cause our stock price to fall.*

Sales of a substantial number of shares of our common stock in the public market, the perception that these sales might occur or the exercise of pre-funded warrants or common warrants could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that sales may have on the prevailing market price of our common stock. In addition, the sale of substantial amounts of our common stock could adversely impact its trading price. As of December 31, 2021, we had 79,864,310 shares of common stock outstanding, plus 6,125,549 outstanding options and 435,750 restricted stock units to purchase shares of our common stock and 632,187 outstanding warrants to purchase shares of our common stock. 1,226,105 and 1,425,000 additional shares of common stock were available for future issuance under our 2014 Equity Incentive Plan and 2020 Inducement Equity Incentive Plan, as of December 31, 2021, respectively. The sale or the availability for sale of a large number of shares of our common stock in the public market could cause the price of our common stock to decline.

We, along with our directors and executive officers, have agreed that for a period of 90 days after the date of this prospectus supplement, subject to specified exceptions, we or they will not offer, sell, contract to sell, pledge or otherwise dispose of, directly or indirectly, any shares of our common stock or securities convertible into or exchangeable or exercisable for any shares of our common stock.

*There is no public market for the pre-funded warrants or common warrants being offered in this offering.*

There is no established public trading market for the pre-funded warrants or common warrants being offered in this offering, and we do not expect a market to develop. In addition, we do not intend to apply to list the pre-funded warrants or common warrants on any national securities exchange or other nationally recognized trading system, including Nasdaq. Without an active market, the liquidity of the pre-funded warrants or common warrants will be limited.

*Holders of our pre-funded warrants or common warrants will have no rights as a common stockholder until they acquire our common stock.*

Until you acquire shares of our common stock upon exercise of the pre-funded warrants or common warrants, you will have no rights with respect to shares of our common stock issuable upon exercise of the pre-funded warrants or common warrants. Upon exercise of your warrants, you will be entitled to exercise the rights of a common stockholder only as to matters for which the record date occurs after the exercise date.

*The pre-funded warrants and common warrants are speculative in nature.*

The pre-funded warrants or common warrants offered hereby do not confer any rights of common stock ownership on their holders, such as voting rights or the right to receive dividends, but rather merely represent the right to acquire shares of common stock at a fixed price. Specifically, commencing on the date of issuance, holders of the pre-funded warrants or common warrants may acquire the common stock issuable upon exercise of such warrants at an exercise price of \$        per share. Moreover, following this offering, the market value of the pre-funded warrants or common warrants is uncertain and there can be no assurance that the market value of the pre-funded warrants or common warrants will equal or exceed their public offering price. There can be no assurance that the market price of the common stock will ever equal or exceed the exercise price of the pre-funded warrants or common warrants and consequently, whether it will ever be profitable for holders of the pre-funded warrants or common warrants to exercise such warrants.

*If the price of our common stock fluctuates significantly, your investment could lose value.*

Our common stock is traded on Nasdaq, under the symbol “SLNO,” and, to date, has traded on a limited basis. We cannot assure you that an active public market will continue for our common stock. If an active public market for our common stock does not continue, the trading price and liquidity of our common stock will be materially and adversely affected. If there is a thin trading market or “float” for our stock, the market price for our common stock may fluctuate significantly more than the stock market as a whole. Without a large float, our common stock would be less liquid than the stock of companies with broader public ownership and, as a result,

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the trading prices of our common stock may be more volatile. In addition, in the absence of an active public trading market, investors may be unable to liquidate their investment in us. Furthermore, the stock market is subject to significant price and volume fluctuations, and the price of our common stock could fluctuate widely in response to several factors, including, but not limited to:

- our quarterly or annual operating results;
- additions or departures of key or qualified personnel;
- failure to adequately protect our intellectual property;
- costs associated with defending claims, including intellectual property infringement claims and related judgments or settlements;
- changes in governmental or other regulations affecting our business; and
- our compliance with governmental or other regulations affecting our business.

The stock market has experienced extreme price and volume fluctuations in recent years that have significantly affected the quoted prices of the securities of many companies, including companies in our industry. The changes may not be possible to predict and often appear to occur without regard to specific operating performance. The price of our common stock could fluctuate based upon factors that have little or nothing to do with our company and these fluctuations could materially reduce our stock price.

*If securities or industry analysts do not publish research or reports about our business, or if they issue adverse or misleading opinions regarding our stock, our stock price and trading volume could decline.*

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. If any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our target studies and operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

### **Risks related to our financial condition and capital requirements**

*We are a clinical-stage company with no approved products, which makes assessment of our future viability difficult.*

We are primarily a clinical-stage company, with a relatively limited operating history and with no approved therapeutic products or revenues from the sale of therapeutic products. As a result, there is limited information for investors to use when assessing our future viability as a company focused primarily on therapeutic products and our potential to successfully develop product candidates, conduct clinical trials, manufacture our products on a commercial scale, obtain regulatory approval and profitably commercialize any approved products.

*We are dependent upon the success of DCCR, our sole therapeutic product candidate.*

We invest a significant portion of our efforts and financial resources in the development of DCCR for the treatment of PWS, a rare complex genetic neurobehavioral/metabolic disease. Our ability to generate product revenues, which may not occur for the foreseeable future, if ever, will depend heavily on the successful development, regulatory approval, and commercialization of DCCR.

Any delay or impediment in our ability to obtain regulatory approval to commercialize in any region, or, if approved, obtain coverage and adequate reimbursement from third-parties, including government payors, for DCCR, may cause us to be unable to generate the revenues necessary to continue our research and development

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pipeline activities, thereby adversely affecting our business and our prospects for future growth. Further, the success of DCCR will depend on a number of factors, including the following:

- obtain a sufficiently broad label that would not unduly restrict patient access;
- receipt of marketing approvals for DCCR in the U.S. and E.U.;
- building an infrastructure capable of supporting product sales, marketing, and distribution of DCCR in territories where we pursue commercialization directly;
- establishing commercial manufacturing arrangements with third party manufacturers;
- establishing commercial distribution agreements with third party distributors;
- launching commercial sales of DCCR, if and when approved, whether alone or in collaboration with others;
- acceptance of DCCR, if and when approved, by patients, the medical community, and third-party payers;
- the regulatory approval pathway that we pursue for DCCR in the U.S.;
- effectively competing with other therapies;
- a continued acceptable safety profile of DCCR following approval;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity;
- protecting our rights in our intellectual property portfolio; and
- obtaining a commercially viable price for our products.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize DCCR, which would materially harm our business. We have been in discussions with the FDA regarding the clinical data necessary to support the submission of a new drug application (NDA) seeking approval to market DCCR for the treatment of PWS, after our Phase 3 clinical trial, DESTINY PWS (C601) trial failed to demonstrate statistical significance on the primary efficacy endpoints. As we previously disclosed, the FDA has indicated that based on the data the agency has seen to date, at least an additional clinical trial will be necessary to support our planned NDA. As part of the ongoing discussions with the FDA, we have provided the agency with the clinical study report for the C601 clinical trial and available data from our long-term, open-label extension study (C602) to allow FDA to further assess if those data may provide adequate evidence of safety and efficacy to permit us to submit a 505(b)(2) NDA for the product candidate. We cannot be certain that the FDA will agree that these additional data, once reviewed by FDA, are sufficient for the agency to determine that we have demonstrated substantial evidence that DCCR is safe and effective for the treatment of PWS.

Complying with any additional requests for information from the FDA or designing and conducting a new randomized controlled clinical trial if the agency continues to assert that an additional controlled data is necessary, will be time-consuming, expensive, and delay or prevent our ability to continue to study and develop DCCR, or may result in a change in our regulatory strategy such as pursuing a narrower indication of use. If we are unable to adequately address any previous or further recommendations, concerns, requests, or objections in a manner satisfactory to the FDA, as applicable, in a timely manner, or at all, we could be delayed or prevented from seeking approval of DCCR for any intended use. Moreover, there can be no assurance that any future randomized controlled trial will be successfully enrolled or completed.

*We will need additional funds to support our operations, and such funding may not be available to us on acceptable terms, or at all, which would force us to delay, reduce or suspend our research and development programs and other operations or commercialization efforts. Raising additional capital may subject us to unfavorable terms, cause dilution to our existing stockholders, restrict our operations, or require us to relinquish rights to our planned products and technologies.*

We have not commenced commercialization of DCCR, our current sole novel therapeutic product, and accordingly, through December 31, 2021, have generated no revenue from operations. We had a net loss of

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\$30.9 million during the year ended December 31, 2021 and an accumulated deficit of \$213.4 million at December 31, 2021 as a result of having incurred losses since our inception. We had \$21.3 million in cash and cash equivalents and \$14.4 million of working capital at December 31, 2021, used \$27.8 million of cash in operating activities during the year ended December 31, 2021 and expect to continue incurring losses for the foreseeable future. These matters raise substantial doubt about our ability to continue as a going concern.

We intend to raise additional capital, either through debt or equity financings to achieve our business plan objectives, including ongoing expenses related to resources being deployed to manage participants in our current ongoing clinical trial of DCCR and other activities necessary to support the submission of an NDA to the FDA. Because of the numerous risks and uncertainties associated with our product development and planned commercialization efforts, we are unable to predict the extent of our future losses or when, or if, we will generate meaningful revenue or become profitable, and it is possible we will never achieve these goals. Our ability to obtain additional financing will depend on a number of factors, including, among others, our ability to generate positive data from our clinical studies, our ability to obtain FDA clearance for DCCR, the condition of the capital markets and the other risks described in these risk factors. If any one of these risks are realized, we may not be able to obtain additional funding, in which case, our business could be jeopardized and we may not be able to continue our operations or pursue our strategic plans. If we are forced to scale down, limit or cease operations, our stockholders could lose all of their investment. Even if we are successful at raising capital, there is no assurance that any funds raised will be sufficient to enable us to attain profitable operations or continue as a going concern.

To the extent that we are unsuccessful raising sufficient capital, we may need to curtail or cease our operations and implement a plan to extend payables or reduce overhead until sufficient additional capital is raised to support further operations. There can be no assurance that such a plan will be successful. If adequate funds are not available, we may be required to curtail our operations significantly or to obtain funds on unfavorable terms, through dilutive financings or entering into arrangements with collaborative partners or others that may require us to relinquish rights to certain of our product candidates that we would not otherwise relinquish. If we issue equity or convertible debt securities to raise additional funds, our existing stockholders will experience further dilution, and the new equity or debt securities may have rights, preferences and privileges senior to those of our existing stockholders. If we incur debt, our fixed payment obligations, liabilities and leverage relative to our equity capitalization would increase, which could increase the cost of future capital. Further, the terms of any debt securities we issue or borrowings we incur, if available, could impose significant restrictions on our operations, such as limitations on our ability to incur additional debt or issue additional equity or other operating restrictions that could adversely affect our ability to conduct our business, and any such debt could be secured by any or all of our assets pledged as collateral. Additionally, we may incur substantial costs in pursuing future capital, including investment banking, legal and accounting fees, printing and distribution expenses and other costs.

*We have a limited commercialization history and have incurred significant losses since our inception, and we anticipate that we will continue to incur substantial losses for the foreseeable future. We transitioned to be primarily a research and development company, which, together with our limited operating history, makes it difficult to evaluate our business and assess our future viability.*

We are a developer of therapeutics with a limited commercialization history. Evaluating our performance, viability or future success will be more difficult than if we had a longer operating history or approved products for sale on the market. We continue to incur significant research and development and general and administrative expenses related to our operations. Investment in product development is highly speculative, because it entails substantial upfront capital expenditures and significant risk that any planned product will fail to demonstrate adequate accuracy or clinical utility.

We expect that our future financial results will depend primarily on our success in developing, launching, selling and supporting our products. This will require us to be successful in a range of activities, including clinical trials, manufacturing, marketing and selling our products. We are only in the preliminary stages of some of these activities. We may not succeed in these activities and may never generate revenue that is

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sufficient to be profitable in the future. Even if we are profitable, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to achieve sustained profitability would depress the value of our company and could impair our ability to raise capital, expand our business, diversify our planned products, market our current and planned products, or continue our operations.

*We currently have generated limited product revenue and may never become profitable.*

To date, we have not generated significant revenues to achieve profitability. Our ability to generate significant revenue from product sales and achieve profitability will depend upon our ability, alone or with any future collaborators, to successfully commercialize products that we may develop, in-license or acquire in the future. Our ability to generate revenue from product sales from planned products also depends on a number of additional factors, including our ability to:

- develop a commercial organization capable of sales, marketing and distribution of any products for which we obtain marketing approval in markets where we intend to commercialize independently;
- achieve market acceptance of our current and future products, if any;
- set a commercially viable price for our current and future products, if any;
- establish and maintain supply and manufacturing relationships with reliable third parties, and ensure adequate and legally compliant manufacturing to maintain that supply;
- obtain coverage and adequate reimbursement from third-party payors, including government and private payors;
- find suitable global and U.S. distribution partners to help us market, sell and distribute our products in other markets;
- complete and submit applications to, and obtain regulatory approval from, foreign regulatory authorities;
- complete development activities successfully and on a timely basis;
- establish, maintain and protect our intellectual property rights and avoid third-party patent interference or patent infringement claims; and
- attract, hire and retain qualified personnel.

In addition, because of the numerous risks and uncertainties associated with product development and commercialization, including that our planned products may not advance through development, achieve the endpoints of applicable clinical trials or obtain approval, we are unable to predict the timing or amount of increased expenses, or when or if we will be able to achieve or maintain profitability. In addition, our expenses could increase beyond expectations if we decide, or are required by the FDA or foreign regulatory authorities, to perform studies or clinical trials in addition to those that we currently anticipate.

Even if we are able to generate significant revenue from the sale of any of our products that may be approved or commercialized, we may not become profitable and may need to obtain additional funding to continue operations. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce or shut down our operations.

*Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or below our guidance.*

Our quarterly and annual operating results may fluctuate significantly in the future, which makes it difficult for us to predict our future operating results. From time to time, we may enter into collaboration agreements with other companies that include development funding and significant upfront and milestone payments or royalties, which may become an important source of our revenue. Accordingly, our revenue may depend on development funding and the achievement of development and clinical milestones under any potential future collaboration and license agreements and sales of our products, if approved. These upfront and milestone payments may vary

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significantly from period to period, and any such variance could cause a significant fluctuation in our operating results from one period to the next. In addition, we measure compensation cost for stock-based awards made to employees at the grant date of the award, based on the fair value of the award as determined by our board of directors, and recognize the cost as an expense over the employee's requisite service period. As the variables that we use as a basis for valuing these awards change over time, including our underlying stock price and stock price volatility, the magnitude of the expense that we must recognize may vary significantly. Furthermore, our operating results may fluctuate due to a variety of other factors, many of which are outside of our control and may be difficult to predict, including the following:

- our ability to enroll patients in clinical trials and the timing of enrollment;
- the cost and risk of initiating sales and marketing activities;
- the timing and cost of, and level of investment in, research and development activities relating to our planned products, which will change from time to time;
- the cost of manufacturing our products may vary depending on FDA and other regulatory requirements, the quantity of production and the terms of our agreements with manufacturers;
- expenditures that we will or may incur to acquire or develop additional planned products and technologies;
- the design, timing and outcomes of clinical studies;
- changes in the competitive landscape of our industry, including consolidation among our competitors or potential partners;
- any delays in regulatory review or approval in the U.S. or globally, of any of our planned products;
- the level of demand for our products may fluctuate significantly and be difficult to predict;
- the risk/benefit profile, cost and reimbursement policies with respect to our future products, if approved, and existing and potential future drugs that compete with our planned products;
- competition from existing and potential future offerings that compete with our products;
- our ability to commercialize our products inside and outside of the U.S., either independently or working with third parties;
- our ability to establish and maintain collaborations, licensing or other arrangements;
- our ability to adequately support future growth;
- potential unforeseen business disruptions that increase our costs or expenses;
- future accounting pronouncements or changes in our accounting policies; and
- the changing and volatile global economic environment.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated revenue or earnings guidance we may provide.

*We may engage in strategic transactions that could impact our liquidity, increase our expenses and present significant distractions to our management.*

From time to time we may consider strategic transactions, such as acquisitions, asset purchases and sales, and out-licensing or in-licensing of products, product candidates or technologies. Additional potential transactions

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that we may consider include a variety of different business arrangements, including spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. Any such transaction may require us to incur non-recurring or other charges, may increase our near and long-term expenditures, could not result in perceived benefits that were contemplated upon entering into the transaction, and may pose significant integration challenges or disrupt our management or business, which could adversely affect our operations, solvency and financial results. For example, these transactions may entail numerous operational and financial risks, including:

- exposure to unknown and contingent liabilities;
- disruption of our business and diversion of our management's time and attention in order to develop acquired products, product candidates or technologies;
- incurrence of substantial debt or dilutive issuances of equity securities to pay for acquisitions;
- higher than expected acquisition and integration costs;
- the timing and likelihood of payment of milestones or royalties;
- write-downs of assets or goodwill or impairment charges;
- increased operating expenditures, including additional research, development and sales and marketing expenses;
- increased amortization expenses;
- difficulty and cost in combining the operations and personnel of any acquired businesses with our operations and personnel; and
- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership.

Accordingly, although there can be no assurance that we will undertake or successfully complete any additional transactions of the nature described above or that we will achieve an economic benefit that justifies such transactions, any additional transactions that we do complete could have a material adverse effect on our business, results of operations, financial condition and prospects.

*We may not be able to enter into strategic transactions on a timely basis or on acceptable terms, which may impact our development and commercialization plans.*

We have relied, and expect to continue to rely, on strategic transactions, which include in-licensing, out-licensing, purchases and sales of assets, and other ventures. The terms of any additional strategic transaction that we may enter into may not be favorable to us, and the contracts governing such strategic transaction may be subject to differing interpretations exposing us to potential litigation. We may also be restricted under existing collaboration or licensing arrangements from entering into future agreements on certain terms with potential strategic partners. We may not be able to negotiate additional strategic transactions on a timely basis, on acceptable terms, or at all. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our products or bring them to market and generate product revenue. Furthermore, there is no assurance that any such transaction will be successful or that we will derive an economic benefit as a result.

### **Risks related to the development and commercialization of our products**

*We may not be successful in commercializing our approved products.*

Commercialization of products is subject to a variety of regulations regarding the manner in which potential customers may be engaged, the manner in which products may be lawfully advertised, and the claims that can be made for the benefits of the product, among other things. Our lack of experience with product launches may expose us to a higher than usual level of risk of non-compliance with these regulations, with consequences that may include fines or the removal of our approved products from the marketplace by regulatory authorities.

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*If we are unable to execute our sales and marketing strategy for our products, and are unable to gain acceptance in the market, we may be unable to generate sufficient revenue to sustain our business.*

Although we believe that DCCR and our other planned products represent promising commercial opportunities, our products may never gain significant acceptance in the marketplace and therefore may never generate substantial revenue or profits for us. We will need to establish a market for DCCR globally and build these markets through physician education, awareness programs, and other marketing efforts. Gaining acceptance in medical communities depends on a variety of factors, including clinical data published or reported in reputable contexts and word-of-mouth between physicians. The process of publication in leading medical journals is subject to a peer review process and peer reviewers may not consider the results of our studies sufficiently novel or worthy of publication. Failure to have our studies published in peer-reviewed journals may limit the adoption of our products. Our ability to successfully market our products will depend on numerous factors, including:

- the outcomes of clinical utility studies of such products in collaboration with key thought leaders to demonstrate our products' value in informing important medical decisions such as treatment selection;
- the success of our distribution partners;
- whether healthcare providers believe such tests provide clinical utility;
- whether the medical community accepts that such tests are sufficiently sensitive and specific to be meaningful in-patient care and treatment decisions; and
- whether hospital administrators, health insurers, government health programs and other payers will cover and pay for such tests and, if so, whether they will adequately reimburse us.

We are relying, or will rely, on third parties with whom we are directly engaged with, but who we do not control, to distribute and sell our products. If these distributors are not committed to our products or otherwise run into their own financial or other difficulties, it may result in failure to achieve widespread market acceptance of our products, and would materially harm our business, financial condition and results of operations.

*If we are unable to implement our sales, marketing, distribution, training and support strategies or enter into agreements with third parties to perform these functions in markets outside of the U.S. and E.U., we will not be able to effectively commercialize DCCR and may not reach profitability.*

We do not have a sales or marketing infrastructure and have no experience in the sale, marketing or distribution of therapeutic products. To achieve commercial success for DCCR, if and when we obtain marketing approval, we will need to establish a sales and marketing organization.

In the future, we expect to build a targeted sales, marketing, training and support infrastructure to market DCCR in the U.S. and E.U. and to opportunistically establish collaborations to market, distribute and support DCCR outside of the U.S. and E.U. There are risks involved with establishing our own sales, marketing, distribution, training and support capabilities. For example, recruiting and training sales and marketing personnel is expensive and time consuming and could delay any product launch. If the commercial launch of DCCR is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales, marketing, training and support personnel.

Factors that may inhibit our efforts to commercialize DCCR on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe DCCR or any future products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines;

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- unforeseen costs and expenses associated with creating an independent sales and marketing organization; and
- efforts by our competitors to commercialize products at or about the time when our product candidates would be coming to market.

If we are unable to establish our own sales, marketing, distribution, training and support capabilities and instead enter into arrangements with third parties to perform these services, our product revenues and our profitability, if any, are likely to be lower than if we were to market, sell and distribute DCCR ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell, market and distribute DCCR or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to commercialize DCCR effectively. If we do not establish sales, marketing, distribution, training and support capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing DCCR and achieving profitability, and our business would be harmed.

*If physicians decide not to order our products in significant numbers, we may be unable to generate sufficient revenue to sustain our business.*

To generate demand for our current and planned products, we will need to educate physicians and other health care professionals on the clinical utility, benefits and value of the tests we provide through published papers, presentations at scientific conferences, educational programs and one-on-one education sessions by members of our sales force. In addition, we will need support of hospital administrators that the clinical and economic utility of our products justifies payment for the device and consumables at adequate pricing levels. We need to hire additional commercial, scientific, technical and other personnel to support this process.

*If our products do not continue to perform as expected, our operating results, reputation and business will suffer.*

Our success depends on the market's confidence that our products can provide reliable, high-quality results or treatments. We believe that our customers are likely to be particularly sensitive to any test defects and errors in our products, and prior products made by other companies for the same diagnostic purpose have failed in the marketplace, in part as a result of poor accuracy. As a result, the failure of our current and planned products to perform as expected would significantly impair our reputation and the clinical usefulness of such tests. Reduced sales might result, and we may also be subject to legal claims arising from any defects or errors.

*If clinical studies of any of our planned products fail to demonstrate safety and effectiveness to the satisfaction of the FDA or similar regulatory authorities outside the U.S. or do not otherwise produce positive results, we may incur additional costs, experience delays in completing or ultimately fail in completing the development and commercialization of our planned products.*

Before obtaining regulatory approval for the sale of any planned product we must conduct extensive clinical studies to demonstrate the safety and effectiveness of our planned products in humans. Clinical studies are expensive, difficult to design and implement, can take many years to complete and are uncertain as to outcome. A failure of one or more of our clinical studies could occur at any stage of testing.

Numerous unforeseen events during, or as a result of, clinical studies could occur, which would delay or prevent our ability to receive regulatory approval or commercialize any of our planned products, including the following:

- clinical studies may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical studies or abandon product development programs;
- the number of patients required for clinical studies may be larger than we anticipate, enrollment in these clinical studies may be insufficient or slower than we anticipate, or patients may drop out of these clinical studies at a higher rate than we anticipate;

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- the cost of clinical studies or the manufacturing of our planned products may be greater than we anticipate; including due to inflationary pressures outside of our control;
- third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we might have to suspend or terminate clinical studies of our planned products for various reasons, including a finding that our planned products have unanticipated serious side effects or other unexpected characteristics or that the patients are being exposed to unacceptable health risks;
- regulators may not approve our proposed clinical development plans;
- regulators or independent institutional review boards (IRBs), may not authorize us or our investigators to commence a clinical study or conduct a clinical study at a prospective study site;
- regulators or IRBs may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements; and
- the supply or quality of our planned products or other materials necessary to conduct clinical studies of our planned products may be insufficient or inadequate.

If we or any future collaboration partners are required to conduct additional clinical trials or other testing of any planned products beyond those that we contemplate, if those clinical studies or other testing cannot be successfully completed, if the results of these studies or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for our planned products;
- not obtain marketing approval at all;
- obtain approval for indications that are not as broad as intended;
- have the product removed from the market after obtaining marketing approval;
- be subject to additional post-marketing testing requirements; or
- be subject to restrictions on how the product is distributed or used.

Our product development costs will also increase if we experience delays in testing or approvals. We do not know whether any clinical studies will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant clinical study delays also could shorten any periods during which we may have the exclusive right to commercialize our planned products or allow our competitors to bring products to market before we do, which would impair our ability to commercialize our planned products and harm our business and results of operations.

*If we fail to obtain regulatory approval for DCCR in the U.S. and E.U., our business would be harmed.*

We are required to obtain regulatory approval for each indication we are seeking before we can market and sell DCCR in a particular jurisdiction, for such indication. Our ability to obtain regulatory approval of DCCR depends on, among other things, successful completion of clinical trials by demonstrating efficacy with statistical significance and clinical meaning, and safety in humans. The results of our current and future clinical trials may not meet the FDA, the European Medicines Agency (EMA), or other regulatory agencies' requirements to approve DCCR for marketing under any specific indication, and these regulatory agencies may otherwise determine that our third parties' manufacturing processes, validation, and/ or facilities are insufficient to support approval. As such, we may need to conduct more clinical trials than we currently anticipate and upgrade the manufacturing processes and facilities, which may require significant additional time and expense, and may delay or prevent approval. If we fail to obtain regulatory approval in a timely manner, our commercialization of DCCR would be delayed and our business would be harmed.

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*Clinical drug development involves a lengthy and expensive process with an uncertain outcome, results of earlier studies and trials may not be predictive of future trial results, and our clinical trials may fail to adequately demonstrate the safety and efficacy of DCCR or other potential product candidates.*

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. A failure of one or more of our clinical trials can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later stage clinical trials. There is a high failure rate for drugs proceeding through clinical trials, and product candidates in later stages of clinical trials may fail to show the required safety and efficacy despite having progressed through preclinical studies and initial clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier clinical trials, and we cannot be certain that we will not face similar setbacks. Even if our clinical trials are completed, the results may not be sufficient to obtain regulatory approval for our product candidates.

We may experience delays in our clinical trials. We do not know whether future clinical trials, if any, will begin on time, need to be redesigned, enroll an adequate number of patients in a timely manner or be completed on schedule, if at all. Clinical trials can be delayed, suspended or terminated for a variety of reasons, including failure to:

- generate sufficient nonclinical, toxicology, or other in vivo or in vitro data, or clinical safety data to support the initiation or continuation of clinical trials;
- obtain regulatory approval, or feedback on trial design, to commence a trial;
- identify, recruit and train suitable clinical investigators;
- reach agreement on acceptable terms with prospective contract research organizations (CROs), and clinical trial sites;
- obtain and maintain IRB approval at each clinical trial site;
- identify, recruit and enroll suitable patients to participate in a trial;
- have a sufficient number of patients complete a trial and/or return for post-treatment follow-up;
- ensure clinical investigators observe trial protocol or continue to participate in a trial;
- address any patient safety concerns that arise during the course of a trial;
- address any conflicts or compliance with new or existing laws, rule, regulations or guidelines;
- have a sufficient number of clinical trial sites to conduct the trials;
- timely manufacture sufficient quantities of product candidate suitable for use at the stage of clinical development; or
- raise sufficient capital to fund a trial.

Patient enrollment is a significant factor in the timing of clinical trials and is affected by many factors, including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, competing clinical trials and clinicians' and patients' or caregivers' perceptions as to the potential advantages of the drug candidate being studied in relation to other available therapies, including any new drugs or treatments that may be approved for the indications we are investigating or any investigational new drugs or treatment under development for the indications we are investigating.

We could also encounter delays if a clinical trial is suspended or terminated by us, by a data safety monitoring board for such trial or by the FDA or any other regulatory authority, or if the IRBs of the institutions in which such trials are being conducted suspend or terminate the participation of their clinical investigators and sites

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subject to their review. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

If we experience delays in the completion of, or termination of, any clinical trial of our product candidates for any reason, the commercial prospects of our product candidates may be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may significantly harm our business, financial condition and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

*We may be unable to obtain regulatory approval for DCCR or other potential product candidates. The denial or delay of any such approval would delay commercialization and have a material adverse effect on our potential to generate revenue, our business and our results of operations.*

The research, development, testing, manufacturing, labeling, packaging, approval, promotion, advertising, storage, record keeping, marketing, distribution, post-approval monitoring and reporting, and export and import of drug products are subject to extensive regulation by the FDA, and by foreign regulatory authorities in other countries. The legislation and regulations differ from country to country. To gain approval to market our product candidates, we must provide development, manufacturing and clinical data that adequately demonstrates the safety and efficacy of the product for the intended indication. We have not yet obtained regulatory approval to market any of our product candidates in the U.S. or any other country. Our business depends upon obtaining these regulatory approvals. The FDA can delay, limit or deny approval of our product candidates for many reasons, including:

- our inability to satisfactorily demonstrate that the product candidates are safe and effective for the requested indication;
- the FDA's disagreement with our trial protocol or the interpretation of data from preclinical studies or clinical trials;
- the population studied in the clinical trial may not be sufficiently broad or representative to assess safety in the full population for which we seek approval;
- our inability to demonstrate that clinical or other benefits of our product candidates outweigh any safety or other perceived risks;
- the FDA's determination that additional preclinical or clinical trials are required;
- the FDA's non-approval of the formulation, labeling or the specifications of our product candidates;
- the FDA's failure to accept the manufacturing processes or facilities of third-party manufacturers with which we contract; or
- the potential for approval policies or regulations of the FDA to significantly change in a manner rendering our clinical data insufficient for approval.

Even if we eventually complete clinical testing and receive approval of any regulatory filing for our product candidates, the FDA may grant approval contingent on the performance of costly additional post-approval clinical trials. The FDA may also approve our product candidates for a more limited indication or a narrower patient population than we originally requested, and the FDA may not approve the labeling that we believe is necessary or desirable for the successful commercialization of our product candidates. To the extent we seek regulatory approval in foreign countries, we may face challenges similar to those described above with

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regulatory authorities in applicable jurisdictions. Any delay in obtaining, or inability to obtain, applicable regulatory approval for any of our product candidates would delay or prevent commercialization of our product candidates and would materially adversely impact our business, results of operations and prospects.

*Even if any planned products receive regulatory approval, these products may fail to achieve the degree of market acceptance by physicians, patients, caregivers, healthcare payors and others in the medical community necessary for commercial success.*

If any planned products receive regulatory approval from the FDA or other regulatory agencies in jurisdictions in which they are not currently approved, they may nonetheless fail to gain sufficient market acceptance by physicians, hospital administrators, patients, healthcare payors and others in the medical community. The degree of market acceptance of our planned products, if approved for commercial sale, will depend on a number of factors, including the following:

- the prevalence and severity of any side effects;
- their effectiveness and potential advantages compared to alternative treatments;
- the price we charge for our planned products;
- the willingness of physicians to change their current treatment practices;
- convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength or effectiveness of marketing and distribution support or partners; and
- the availability of third-party coverage or reimbursement.

*If the market opportunity for DCCR is smaller than we believe it is, then our revenues may be adversely affected, and our business may suffer.*

PWS is a rare disease, and as such, our projections of both the number of people who have this disease, as well as the subset of people with PWS who have the potential to benefit from treatment with our product candidate, are based on estimates.

Currently, most reported estimates of the prevalence of PWS are based on studies of small subsets of the population of specific geographic areas, which are then extrapolated to estimate the prevalence of the diseases in the broader world population. In addition, as new studies are performed the estimated prevalence of these diseases may change. There can be no assurance that the prevalence of PWS in the study populations, particularly in these newer studies, accurately reflects the prevalence of this disease in the broader world population. If our estimates of the prevalence of PWS, or of the number of patients who may benefit from treatment with our product candidates prove to be incorrect, the market opportunities for our product candidate may be smaller than we believe it is, our prospects for generating revenue may be adversely affected and our business may suffer.

*DCCR is currently under development and we have no sales and distribution personnel, and limited marketing capabilities at the present time to commercialize DCCR, if we receive regulatory approval. If we are unable to develop a sales and marketing and distribution capability on our own or through collaborations or other marketing partners, we will not be successful in commercializing our products, or other planned products.*

There are risks involved with both establishing our own sales and marketing capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time-consuming, and could delay any product launch. If the commercial launch of a planned product for which we recruit a sales force and establish marketing capabilities is delayed, or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

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To achieve commercial success for any approved product, we must either develop a sales and marketing infrastructure or outsource these functions to third parties. We also may not be successful entering into arrangements with third parties to sell and market our planned products or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively and could damage our reputation. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our planned products.

*We may attempt to form partnerships with respect to our products, but we may not be able to do so, which may cause us to alter our development and commercialization plans and may cause us to terminate any such programs.*

We may form strategic alliances, create joint ventures or collaborations, or enter into licensing agreements with third parties that we believe will more effectively provide resources to develop and commercialize our programs.

If we attempt to seek appropriate strategic partners, we may face significant competition, and the negotiation process to secure favorable terms is time-consuming and complex. We may not be successful in our efforts to establish such a strategic partnership for any future products and programs on terms that are acceptable to us, or at all.

Any delays in identifying suitable collaborators and entering into agreements to develop or commercialize our future products could negatively impact the development or commercialization of our future products, particularly in geographic regions like the E.U., where we do not currently have development and commercialization infrastructure. Absent a partner or collaborator, we would need to undertake development or commercialization activities at our own expense. If we elect to fund and undertake development and commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we are unable to do so, we may not be able to develop our future products or bring them to market, and our business may be materially and adversely affected.

*Our product candidates may cause serious adverse side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial desirability of an approved label or result in significant negative consequences following any marketing approval.*

The risk of failure of clinical development is high. It is impossible to predict when or if any planned product candidates will prove safe enough to receive regulatory approval. Undesirable side effects caused by any of our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials or could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authority. Additionally, if any of our planned products receives additional marketing approvals, and we or others later identify undesirable side effects caused by such product, a number of potentially significant negative consequences could result, including:

- we may be forced to recall such product and suspend the marketing of such product;
- regulatory authorities may withdraw their approvals of such product;
- regulatory authorities may require additional warnings on the label that could diminish the usage or otherwise limit the commercial success of such products;
- the FDA or other regulatory bodies may issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings about such product;
- the FDA may require the establishment or modification of Risk Evaluation Mitigation Strategies or a comparable foreign regulatory authority may require the establishment or modification of a similar strategy that may, for instance, restrict distribution of our products and impose burdensome implementation requirements on us;

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- we may be required to change the way the product is administered or conduct additional clinical trials;
- we could be sued and held liable for harm caused to subjects or patients;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular planned product, if approved.

*We face competition, which may result in others discovering, developing or commercializing products before we do, or more successfully than we do.*

Alternatives exist for our product candidates and we will likely face competition with respect to any planned products that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies, medical device companies, and biotechnology companies worldwide. These companies may reduce prices for their competing drugs in an effort to gain or retain market share and undermine the value our products might otherwise be able to offer to payers. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization. Many of these competitors are attempting to develop therapeutics for our target indications.

Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified technical and management personnel, establishing clinical study sites and patient registration for clinical studies, as well as in acquiring technologies complementary to, or necessary for, our programs.

There has recently been increased activity in the development of drugs to treat PWS. We are aware of seven other current or proposed clinical trials evaluating PWS therapies.

*Our patent rights may prove to be an inadequate barrier to competition.*

We are the sole owner of patents and patent applications in the U.S. with claims covering the compounds underlying our primary product candidate, DCCR. Foreign counterparts of these patents and applications have been issued in the E.U., Japan, China, Canada, Australia, India and Hong Kong. However, the lifespan of any one patent is limited, and each of these patents will ultimately expire and we cannot be sure that pending applications will be granted, or that we will discover new inventions which we can successfully patent. Moreover, any of our granted patents may be held invalid by a court of competent jurisdiction, and any of these patents may also be construed narrowly by a court of competent jurisdiction in such a way that it is held to not directly cover DCCR. Furthermore, even if our patents are held to be valid and broadly interpreted, third parties may find legitimate ways to compete with DCCR by inventing around our patent. Finally, the process of obtaining new patents is lengthy and expensive, as is the process for enforcing patent rights against an alleged infringer. Any such litigation could take years, cost large sums of money and pose a significant distraction to management. Indeed, certain jurisdictions outside of the U.S. and E.U., where we hope to initially commercialize DCCR have a history of inconsistent, relatively lax or ineffective enforcement of patent rights. In such jurisdictions, even a valid patent may have limited value. Our failure to effectively prosecute our patents would have a harmful impact on our ability to commercialize DCCR in these jurisdictions.

*Even if we are able to engage partners in commercializing our products, they may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, thereby harming our business.*

The regulations that govern marketing approvals, pricing and reimbursement for new products vary widely from country to country. Some countries require approval of the sale price of a product before it can be

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marketed. In many countries, the pricing review period begins after marketing approval is granted. In some foreign markets, pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain regulatory approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product and negatively impact the revenue we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more planned products, even if our planned products obtain regulatory approval.

Our ability to commercialize our products successfully also will depend in part on the extent to which reimbursement for these products and related treatments becomes available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payers, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and these third-party payers have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. We cannot be sure that reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Reimbursement may impact the demand for, or the price of, any product for which we obtain marketing approval. Obtaining reimbursement for our products may be particularly difficult because of the higher prices often associated with products administered under the supervision of a physician. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any planned product that we successfully develop.

In the U.S., eligibility for reimbursement does not imply that any product will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim payments for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Payment rates may vary according to the use of the product and the clinical setting in which it is used, may be based on payments allowed for lower cost products that are already reimbursed and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or private payers and by any future relaxation of laws that presently restrict imports of products from countries where they may be sold at lower prices than in the U.S. Third-party payers often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies.

Our inability to promptly obtain coverage and profitable payment rates from both government funded and private payers for new products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition. In some foreign countries, including major markets in the E.U. and Japan, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take nine to twelve months or longer after the receipt of regulatory marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product to other available therapies. Our business could be materially harmed if reimbursement of our products, if any, is unavailable or limited in scope or amount or if pricing is set at unsatisfactory levels.

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

We face an inherent risk of product liability exposure related to the sale of our products. The marketing, sale and use of our products could lead to the filing of product liability claims against us if someone alleges that our tests failed to perform as designed. We may also be subject to liability for a misunderstanding of, or inappropriate reliance upon, the information we provide. If we cannot successfully defend ourselves against claims that our products caused injuries, we may incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any planned products that we may develop;

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- injury to our reputation and significant negative media attention;
- withdrawal of patients from clinical studies or cancellation of studies;
- significant costs to defend the related litigation and distraction to our management team;
- substantial monetary awards to patients;
- loss of revenue; and
- the inability to commercialize any products that we may develop.

We currently hold \$8.0 million in product liability insurance coverage, which may not be adequate to cover all liabilities that we may incur. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

*The loss of key members of our executive management team could adversely affect our business.*

Our success in implementing our business strategy depends largely on the skills, experience and performance of key members of our executive management team and others in key management positions, including Dr. Anish Bhatnagar, our Chief Executive Officer, James Mackaness, our Chief Financial Officer, Neil M. Cowen, our Senior Vice President of Drug Development, Kristen Yen, our Vice President of Clinical Operations, and Patricia Hirano our Vice President of Regulatory Affairs. The collective efforts of each of these persons, and others working with them as a team, are critical to us as we continue to develop our technologies, tests and research and development and sales programs. As a result of the difficulty in locating qualified new management, the loss or incapacity of existing members of our executive management team could adversely affect our operations. If we were to lose one or more of these key employees, we could experience difficulties in finding qualified successors, competing effectively, developing our technologies and implementing our business strategy. Our officers all have employment agreements; however, the existence of an employment agreement does not guarantee retention of members of our executive management team and we may not be able to retain those individuals for the duration of or beyond the end of their respective terms. We do not currently maintain “key person” life insurance on any of our employees.

In addition, we rely on collaborators, consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our collaborators, consultants and advisors are generally employed by employers other than us and may have commitments under agreements with other entities that may limit their availability to us.

*There is a scarcity of experienced professionals in our industry. If we are not able to retain and recruit personnel with the requisite technical skills, we may be unable to successfully execute our business strategy.*

The specialized nature of our industry results in an inherent scarcity of experienced personnel in the field. Our future success depends upon our ability to attract and retain highly skilled personnel, including scientific, technical, commercial, business, regulatory and administrative personnel, necessary to support our anticipated growth, develop our business and perform certain contractual obligations. Given the scarcity of professionals with the scientific knowledge that we require and the competition for qualified personnel among biotechnology businesses, we may not succeed in attracting or retaining the personnel we require to continue and grow our operations.

*We may acquire other businesses or form joint ventures or make investments in other companies or technologies that could harm our operating results, dilute our stockholders' ownership, increase our debt or cause us to incur significant expense.*

As part of our business strategy, we may pursue acquisitions or licenses of assets or acquisitions of businesses. We also may pursue strategic alliances and joint ventures that leverage our core technology and industry experience to expand our product offerings or sales and distribution resources. Our company has limited experience with acquiring other companies, acquiring or licensing assets or forming strategic alliances and joint

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ventures. We may not be able to find suitable partners or acquisition candidates, and we may not be able to complete such transactions on favorable terms, if at all. If we make any acquisitions, we may not be able to integrate these acquisitions successfully into our existing business, and we could assume unknown or contingent liabilities. Any future acquisitions also could result in significant write-offs or the incurrence of debt and contingent liabilities, any of which could have a material adverse effect on our financial condition, results of operations and cash flows. Integration of an acquired company also may disrupt ongoing operations and require management resources that would otherwise focus on developing our existing business. We may experience losses related to investments in other companies, which could have a material negative effect on our results of operations.

We may not identify or complete these transactions in a timely manner, on a cost-effective basis, or at all, and we may not realize the anticipated benefits of any acquisition, license, strategic alliance or joint venture. To finance such a transaction, we may choose to issue shares of our common stock as consideration, which would dilute the ownership of our stockholders. If the price of our common stock is low or volatile, we may not be able to acquire other companies or fund a joint venture project using our stock as consideration. Alternatively, it may be necessary for us to raise additional funds for acquisitions through public or private financings. Additional funds may not be available on terms that are favorable to us, or at all.

*International expansion of our business will expose us to business, regulatory, political, operational, financial and economic risks associated with doing business outside of the U.S.*

Our business strategy contemplates international expansion, including partnering with distributors, and introducing our current products and other planned products outside the U.S. Doing business internationally involves a number of risks, including:

- multiple, conflicting and changing laws and regulations such as tax laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses;
- potential failure by us or our distributors to obtain regulatory approvals for the sale or use of our current products and our planned future products in various countries;
- difficulties in managing foreign operations;
- complexities associated with managing government payer systems, multiple payer-reimbursement regimes or self-pay systems;
- logistics and regulations associated with shipping products, including infrastructure conditions and transportation delays;
- limits on our ability to penetrate international markets if our distributors do not execute successfully;
- financial risks, such as longer payment cycles, difficulty enforcing contracts and collecting accounts receivable, and exposure to foreign currency exchange rate fluctuations;
- reduced protection for intellectual property rights, or lack of them in certain jurisdictions, forcing more reliance on our trade secrets, if available;
- natural disasters, political and economic instability, including wars, terrorism and political unrest, including the outbreak of hostilities in the Ukraine, outbreak of disease, boycotts, curtailment of trade and other business restrictions; and
- failure to comply with the Foreign Corrupt Practices Act, including its books and records provisions and its anti-bribery provisions, by maintaining accurate information and control over sales activities and distributors' activities.

Any of these risks, if encountered, could significantly harm our future international expansion and operations and, consequently, have a material adverse effect on our financial condition, results of operations and cash flows.

## Risks related to the operation of our business

*Any future distribution or commercialization agreements we may enter into for our products may place the development of these products outside our control, may require us to relinquish important rights, or may otherwise be on terms unfavorable to us.*

We may enter into additional distribution or commercialization agreements with third parties with respect to our products. Our likely collaborators for any distribution, marketing, licensing or other collaboration arrangements include large and mid-size companies, regional and national companies, and distribution or group purchasing organizations. We will have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our products. Our ability to generate revenue from these arrangements will depend in part on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements.

Collaborations involving our products are subject to numerous risks, which may include the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to any such collaborations;
- collaborators may not pursue development and commercialization of our products, or may elect not to continue or renew efforts based on clinical study results, changes in their strategic focus for a variety of reasons, potentially including the acquisition of competitive products, availability of funding, and mergers or acquisitions that divert resources or create competing priorities;
- collaborators may delay clinical studies, provide insufficient funding for a clinical study program, stop a clinical study, abandon a product, repeat or conduct new clinical studies or require a new engineering iteration of a product for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products;
- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to their marketing and distribution;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that causes the delay or termination of the research, development or commercialization of our products or that results in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable products; and
- collaborators may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we would not have the exclusive right to commercialize such intellectual property.

Any termination or disruption of collaborations could result in delays in the development of products, increases in our costs to develop the products or the termination of development of a product.

*We expect to expand our development, regulatory and sales and marketing capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.*

As of December 31, 2021, we had 20 employees and 11 full-time or part-time consultants. Over the next several years, we expect to experience significant growth in the number of our employees and the scope of our

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operations, particularly in the areas of drug development, quality assurance, engineering, product development, regulatory affairs and sales and marketing. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The physical expansion of our operations may lead to significant costs and may divert our management and business development resources. Future growth would impose significant added responsibilities on members of management, including:

- managing our clinical trials effectively, which we anticipate being conducted at numerous clinical sites;
- identifying, recruiting, maintaining, motivating and integrating additional employees with the expertise and experience we will require;
- managing our internal development efforts effectively while complying with our contractual obligations to licensors, licensees, contractors and other third parties;
- managing additional relationships with various strategic partners, suppliers and other third parties;
- improving our managerial, development, operational and finance reporting systems and procedures; and
- expanding our facilities.

Our failure to accomplish any of these tasks could prevent us from successfully growing. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

*Because we intend to commercialize our products outside the U.S., we will be subject to additional risks.*

A variety of risks associated with international operations could materially adversely affect our business, including:

- different regulatory requirements for drug approvals in foreign countries;
- reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the U.S.;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, including the outbreak of hostilities in the Ukraine, or natural disasters including earthquakes, typhoons, floods and fires.

*We rely on third parties to conduct certain components of our clinical studies, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such studies.*

We rely on third parties, such as CROs, investigational product packaging, labeling and distribution, laboratories, medical institutions and clinical investigators and staff, to perform various functions for our clinical trials. Our reliance on these third parties for clinical development activities reduces our control over these activities but does not relieve us of our responsibilities. We remain responsible for ensuring that each of

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our clinical studies is conducted in accordance with the general investigational plan and protocols for the study. Moreover, the FDA requires us and third parties involved in the set-up, conduct, analysis and reporting of the clinical studies to comply with regulations and with standards, commonly referred to as good clinical practices (GCPs), to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of patients in clinical studies are protected. Our clinical investigators are also required to comply with GCPs. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical studies in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, regulatory approvals for our planned products and will not be able to, or may be delayed in our efforts to, successfully commercialize our planned products.

*If we use biological and hazardous materials in a manner that causes injury, we could be liable for damages.*

Our manufacturing processes currently require the controlled use of potentially harmful chemicals. We cannot eliminate the risk of accidental contamination or injury to employees or third parties from the use, storage, handling or disposal of these materials. In the event of contamination or injury, we could be held liable for any resulting damages, and any liability could exceed our resources or any applicable insurance coverage we may have. Additionally, we are subject to, on an ongoing basis, federal, state and local laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. The cost of compliance with these laws and regulations may become significant and could have a material adverse effect on our financial condition, results of operations and cash flows. In the event of an accident or if we otherwise fail to comply with applicable regulations, we could lose our permits or approvals or be held liable for damages or penalized with fines.

### **Risks related to intellectual property**

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

Patent and other intellectual property litigation is prevalent in our sectors. Our commercial success depends upon our ability and the ability of our distributors, contract manufacturers, and suppliers to manufacture, market, and sell our planned products, and to use our proprietary technologies without infringing, misappropriating or otherwise violating the proprietary rights or intellectual property of third parties. We may become party to, or be threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our products and technology. Third parties may assert infringement claims against us based on existing or future intellectual property rights. If we are found to infringe a third-party's intellectual property rights, we could be required to obtain a license from such third-party to continue developing and marketing our products and technology. We may also elect to enter into such a license in order to settle pending or threatened litigation. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us and could require us to pay significant royalties and other fees.

We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, we could be found liable for monetary damages. A finding of infringement could prevent us from commercializing our planned products or force us to cease some of our business operations, which could materially harm our business. Many of our employees were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. These and other claims that we have misappropriated the confidential information or trade secrets of third parties can have a similar negative impact on our business to the infringement claims discussed above.

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Even if we are successful in defending against intellectual property claims, litigation or other legal proceedings relating to such claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of litigation or other intellectual property related proceedings could have a material adverse effect on our ability to compete in the marketplace.

*Our ability to successfully commercialize our technology and products may be materially adversely affected if we are unable to obtain and maintain effective intellectual property rights for our technologies and planned products, or if the scope of the intellectual property protection is not sufficiently broad.*

Our success depends in large part on our ability to obtain and maintain patent and other intellectual property protection in the U.S. and in other countries with respect to our proprietary technology and products.

The patent position of pharmaceutical companies generally is highly uncertain and involves complex legal and factual questions for which legal principles remain unresolved. In recent years patent rights have been the subject of significant litigation. As a result, the issuance, scope, validity, enforceability and commercial value of the patent rights we rely on are highly uncertain. Pending and future patent applications may not result in patents being issued which protect our technology or products or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the U.S. and other countries may diminish the value of the patents we rely on or narrow the scope of our patent protection. The laws of foreign countries may not protect our rights to the same extent as the laws of the U.S. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the U.S. and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we or were the first to file for patent protection of such inventions.

Even if the patent applications we rely on issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner. The issuance of a patent is not conclusive as to its scope, validity or enforceability, and the patents we rely on may be challenged in the courts or patent offices in the U.S. and abroad. Such challenges may result in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop or prevent us from stopping others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Given the amount of time required for the development, testing and regulatory review of new planned products, patents protecting such products might expire before or shortly after such products are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours or otherwise provide us with a competitive advantage.

The scope, validity, enforceability, and commercial value of trademark rights are also uncertain. Pending and future trademark applications may not be successful.

*We may become involved in legal proceedings to protect or enforce our intellectual property rights, which could be expensive, time-consuming, or unsuccessful.*

Competitors may infringe or otherwise violate the patents we rely on, or our other intellectual property rights including trademarks. To counter infringement or unauthorized use, we may be required to file infringement

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claims, which can be expensive and time-consuming. Any claims that we assert against perceived infringers could also provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property rights. In addition, in an infringement proceeding, a court may decide that a patent we are asserting is invalid or unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that the patents we are asserting do not cover the technology in question. An adverse result in any litigation proceeding could put one or more patents at risk of being invalidated or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

Interference or derivation proceedings provoked by third parties or brought by the U.S. Patent and Trademark Office (USPTO), or any foreign patent authority may be necessary to determine the priority of inventions or other matters of inventorship with respect to patents and patent applications. We may become involved in proceedings, including oppositions, interferences, derivation proceedings interparty reviews, patent nullification proceedings, or re-examinations, challenging our patent rights or the patent rights of others, and the outcome of any such proceedings are highly uncertain. An adverse determination in any such proceeding could reduce the scope of, or invalidate, important patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Our business also could be harmed if a prevailing party does not offer us a license on commercially reasonable terms, if any license is offered at all. Litigation or other proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may also become involved in disputes with others regarding the ownership of intellectual property rights. If we are unable to resolve these disputes, we could lose valuable intellectual property rights.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical or management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the market price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. Uncertainties resulting from the initiation and continuation of intellectual property litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

*If we are unable to protect the confidentiality of our trade secrets, the value of our technology could be materially adversely affected, harming our business and competitive position.*

In addition to our patented technology and products, we rely upon confidential proprietary information, including trade secrets, unpatented know-how, technology and other proprietary information, to develop and maintain our competitive position. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in the market. We seek to protect our confidential proprietary information, in part, by confidentiality agreements with our employees and our collaborators and consultants. We also have agreements with our employees and selected consultants that obligate them to assign their inventions to us. These agreements are designed to protect our proprietary information; however, we cannot be certain that our trade secrets and other confidential information will not be disclosed or that competitors will not otherwise gain access to our trade secrets, or that technology relevant to our business will not be independently developed by a person that is not a party to such an agreement. Furthermore, if the employees, consultants or collaborators that are parties to these agreements breach or violate the terms of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets through such breaches or violations. Further, our trade secrets could be disclosed, misappropriated or otherwise become known or be independently discovered by our competitors. In addition, intellectual property laws in foreign countries may not protect trade secrets and confidential information to the same extent as the laws of the U.S. If we are unable to prevent disclosure of the intellectual property related to our technologies to

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third parties, we may not be able to establish or maintain a competitive advantage in our market, which would harm our ability to protect our rights and have a material adverse effect on our business.

The ongoing conflict in Ukraine and related sanctions could significantly devalue our Russian, Belarusian, and Eurasian patents and/or patent applications. Recent Russian decrees may also significantly limit our ability to enforce Russian patents. We cannot predict when or how this situation will change.

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

Filing, prosecuting and defending patents and trademarks on all of our planned products throughout the world would be prohibitively expensive to us. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but where enforcement is not as strong as in the U.S. These products may compete with our products in jurisdictions where we do not have any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

*Intellectual property rights do not necessarily address all potential threats to our competitive advantage.*

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

- others may be able to make products that are similar to our current and planned products, but that are not covered by claims in our patents;
- the original filers of our patents that we developed or purchased might not have been the first to make the inventions covered by the claims contained in such patents;
- we might not have been the first to file patent applications covering an invention;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- pending patent applications may not lead to issued patents;
- issued patents may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop or in-license additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

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

*Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.*

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents or applications will be due to be paid by us to the USPTO and various governmental patent agencies outside of the

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U.S. in several stages over the lifetime of the patents or applications. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to use our technologies and this circumstance would have a material adverse effect on our business.

*Changes in U.S. patent law or the patent law of other countries or jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.*

The U.S. has enacted and implemented wide-ranging patent reform legislation. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we have licensed or that we might obtain in the future. Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have licensed or that we may obtain in the future.

*If we do not obtain a patent term extension in the U.S. under the Hatch-Waxman Act and in foreign countries under similar legislation, thereby potentially extending the term of our marketing exclusivity for our planned products, our business may be materially harmed.*

Depending upon the timing, duration and specifics of FDA marketing approval of our products, if any, one or more of the U.S. patents covering any such approved product(s) or the use thereof may be eligible for up to five years of patent term restoration under the Hatch-Waxman Act. The Hatch-Waxman Act allows a maximum of one patent to be extended per FDA approved product. Patent term extension also may be available in certain foreign countries upon regulatory approval of our planned products. Nevertheless, we may not be granted patent term extension either in the U.S. or in any foreign country because of, for example, our failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the term of extension, as well as the scope of patent protection during any such extension, afforded by the governmental authority could be less than we request.

If we are unable to obtain patent term extension or restoration, or the term of any such extension is less than requested, the period during which we will have the right to exclusively market our product will be shortened and our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced, possibly materially.

### **Risks related to government regulation**

*The regulatory approval process is expensive, time consuming and uncertain, and may prevent us from obtaining approvals for our planned products.*

The research, testing, manufacturing, labeling, approval, selling, import, export, marketing and distribution of our products are subject to extensive regulation by the FDA in the U.S. and other regulatory authorities in other countries, which regulations differ from country to country. We are not permitted to market our planned products in the U.S. until we received the requisite approval or clearance from the FDA. We have not submitted an application or received marketing approval for any planned products. Obtaining approvals from the FDA can be a lengthy, expensive and uncertain process. In addition, failure to comply with FDA and other applicable

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U.S. and foreign regulatory requirements may subject us to administrative or judicially imposed sanctions, including the following:

- warning letters;
- civil or criminal penalties and fines;
- injunctions;
- suspension or withdrawal of regulatory approval;
- suspension of any ongoing clinical studies;
- voluntary or mandatory product recalls and publicity requirements;
- refusal to accept or approve applications for marketing approval of new drugs or biologics or supplements to approved applications filed by us;
- restrictions on operations, including costly new manufacturing requirements; or
- seizure or detention of our products or import bans.

Prior to receiving approval to commercialize any of our planned products in the U.S. or abroad, we may be required to demonstrate with substantial evidence from well-controlled clinical studies, and to the satisfaction of the FDA and other regulatory authorities abroad, that such planned products are safe and effective for their intended uses. Results from preclinical studies and clinical studies can be interpreted in different ways. Even if we believe the preclinical or clinical data for our planned products are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. Administering any of our planned products to humans may produce undesirable side effects, which could interrupt, delay or cause suspension of clinical studies of our planned products and result in the FDA or other regulatory authorities denying approval of our planned products for any or all targeted indications.

Regulatory approval from the FDA is not guaranteed, and the approval process is expensive and may take several years. The FDA also has substantial discretion in the approval process. Despite the time and expense exerted, failure can occur at any stage, and we could encounter problems that cause us to abandon or repeat clinical studies or perform additional preclinical studies and clinical studies. The number of preclinical studies and clinical studies that will be required for FDA approval varies depending on the planned product, the disease or condition that the planned product is designed to address and the regulations applicable to any particular planned product. The FDA can delay, limit or deny approval of a planned product for many reasons, including, but not limited to, the following:

- a planned product may not be deemed safe or effective;
- FDA officials may not find the data from preclinical studies and clinical studies sufficient;
- the FDA might not approve our or our third-party manufacturer's processes or facilities; or
- the FDA may change its approval policies or adopt new regulations.

If any planned products fail to demonstrate safety and effectiveness in clinical studies or do not gain regulatory approval, our business and results of operations will be materially and adversely harmed.

The research, development, conduct of clinical trials, manufacturing, labeling, approval, selling, import, export, marketing and distribution of pharmaceutical and biologic products also are subject to extensive regulation by the FDA in the U.S. and other regulatory authorities in other countries, which regulations differ from country to country.

### *Nonclinical Testing*

Before a drug candidate can be tested in humans, it must be studied in laboratory experiments and in animals to generate data to support the drug candidate's potential benefits and safety. Additional nonclinical testing may be required during the clinical development process such as reproductive toxicology and juvenile toxicology studies. Carcinogenicity studies in two species are generally required for products intended for long-term use.

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### *Investigational New Drug Exemption Application (IND)*

The results of initial nonclinical tests, together with manufacturing information, analytical data and a proposed clinical trial protocol and other information, are submitted as part of an IND to the FDA. If FDA does not identify significant issues during the initial 30-day IND review, the drug candidate can then be studied in human clinical trials to determine if the drug candidate is safe and effective. Each clinical trial protocol and/or amendment, new nonclinical data, and/or new or revised manufacturing information must be submitted to the IND, and the FDA has 30 days to complete its review of each submission.

### *Clinical Trials*

These clinical trials involve three separate phases that often overlap, can take many years and are very expensive. These three phases, which are subject to considerable regulation, are as follows:

- Phase 1. The drug candidate is given to a small number of healthy human control subjects or patients suffering from the indicated disease, to test for safety, dose tolerance, pharmacokinetics, metabolism, distribution and excretion.
- Phase 2. The drug candidate is given to a limited patient population to determine the effect of the drug candidate in treating the disease, the best dose of the drug candidate, and the possible side effects and safety risks of the drug candidate. It is not uncommon for a drug candidate that appears promising in Phase 1 clinical trials to fail in the more rigorous Phase 2 clinical trials.
- Phase 3. If a drug candidate appears to be effective and safe in Phase 2 clinical trials, Phase 3 clinical trials are commenced to confirm those results. Phase 3 clinical trials are conducted over a longer term, involve a significantly larger population, are conducted at numerous sites in different geographic regions and are carefully designed to provide reliable and conclusive data regarding the safety and benefits of a drug candidate. It is not uncommon for a drug candidate that appears promising in Phase 2 clinical trials to fail in the more rigorous and extensive Phase 3 clinical trials.

For each clinical trial, an independent IRB or independent ethics committee, covering each site proposing to conduct a clinical trial must review and approve the plan for any clinical trial and informed consent information for subjects before the trial commences at that site and it must monitor the study until completed. The FDA, the IRB, or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk or for failure to comply with the IRB's requirements, or may impose other conditions.

Clinical trials involve the administration of an investigational drug to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. Sponsors of clinical trials generally must register and report, at the NIH-maintained website [ClinicalTrials.gov](http://ClinicalTrials.gov), key parameters of certain clinical trials.

At any point in this process, the development of a drug candidate can be stopped for a number of reasons including safety concerns and lack of treatment benefit. We cannot be certain that any clinical trials that we are currently conducting or any that we conduct in the future will be completed successfully or within any specified time period. We may choose, or FDA may require us, to delay or suspend our clinical trials at any time if it appears that the patients are being exposed to an unacceptable health risk or if the drug candidate does not appear to have sufficient treatment benefit.

### *FDA Approval Process*

When we believe that the data from our clinical trials show an adequate level of safety and efficacy, we submit the application to market the drug for a particular use, normally a New Drug Application (NDA) with FDA. FDA may hold a public hearing where an independent advisory committee of expert advisors asks additional questions and makes recommendations regarding the drug candidate. This committee makes a recommendation

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to FDA that is not binding but is generally followed by FDA. If FDA agrees that the compound has met the required level of safety and efficacy for a particular use, it will allow the drug candidate in the U.S. to be marketed and sold for that use. It is not unusual, however, for FDA to reject an application because it believes that the risks of the drug candidate outweigh the purported benefit or because it does not believe that the data submitted are reliable or conclusive. The FDA may also issue a Complete Response Letter (CRL), to indicate that the review cycle for an application is complete and that the application is not ready for approval. CRLs generally outline the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when the deficiencies have been addressed to the FDA's satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

FDA may also require Phase 4 non-registrational studies to explore scientific questions to further characterize safety and efficacy during commercial use of our drug. FDA may also require us to provide additional data or information, improve our manufacturing processes, procedures or facilities or may require extensive surveillance to monitor the safety or benefits of our product candidates if it determines that our filing does not contain adequate evidence of the safety and benefits of the drug. In addition, even if FDA approves a drug, it could limit the uses of the drug. FDA can withdraw approvals if it does not believe that we are complying with regulatory standards or if problems are uncovered or occur after approval.

In addition to obtaining FDA approval for each drug, we obtain FDA approval of the manufacturing facilities for companies who manufacture our drugs for us. All of these facilities are subject to periodic inspections by FDA. FDA must also approve foreign establishments that manufacture products to be sold in the U.S. and these facilities are subject to periodic regulatory inspection.

Once issued, the FDA may withdraw product approval if ongoing regulatory requirements are not met or if safety problems are identified after the product reaches the market. In addition, the FDA may require post-approval testing, including Phase 4 studies, and surveillance programs to monitor the effect of approved products which have been commercialized, and the FDA has the authority to prevent or limit further marketing of a product based on the results of these post-marketing programs. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved label, and, even if the FDA approves a product, it may limit the approved indications for use for the product or impose other conditions, including labeling or distribution restrictions or other risk-management mechanisms. Further, if there are any modifications to the drug, including changes in indications, labeling, or manufacturing processes or facilities, the sponsor may be required to submit and obtain FDA approval of a new or supplemental NDA, which may require the development of additional data or conduct of additional pre-clinical studies and clinical trials.

*Even if we receive marketing approval for a planned product, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and subject us to penalties if we fail to comply with applicable regulatory requirements.*

Once marketing approval has been obtained, the approved product and its manufacturer are subject to continual review by the FDA or non-U.S. regulatory authorities. Future approvals may contain requirements for potentially costly post-marketing follow-up studies to monitor the safety and effectiveness of the approved product. In addition, we are subject to extensive and ongoing regulatory requirements by the FDA and other regulatory authorities with regard to the labeling, packaging, adverse event reporting, storage, advertising, promotion and recordkeeping for our products.

In addition, we are required to comply with cGMP regulations regarding the manufacture of our drugs, which include requirements related to quality control and quality assurance as well as the corresponding maintenance of records and documentation. Further, regulatory authorities must approve these manufacturing facilities before they can be used to manufacture drug products, and these facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP regulations. If we

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or a third party discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory authority may impose restrictions on that product, the manufacturer or us, including requiring withdrawal of the product from the market or suspension of manufacturing.

Once a pharmaceutical product is approved, a product will be subject to pervasive and continuing regulation by the FDA, EMA, and other health authorities, including, among other things, recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. The drug name will also be subject to review and approval by the FDA and other non-U.S. regulatory authorities.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and generally require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP or QSR and impose reporting and documentation requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP or QSR compliance.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market, though the FDA must provide an application holder with notice and an opportunity for a hearing in order to withdraw its approval of an application. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates the marketing, labeling, advertising and promotion of drug and device products that are placed on the market. While physicians may prescribe drugs and devices for off label uses, manufacturers may only promote for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off label uses, and a company that is found to have improperly promoted off label uses may be subject to significant liability.

Drugs that treat serious or life-threatening diseases and conditions that are not adequately addressed by existing drugs, and for which the development program is designed to address the unmet medical need, may be designated as fast track and/or breakthrough candidates by FDA and may be eligible for accelerated and priority review.

Drugs that are developed for rare diseases can be designated as Orphan Drugs. In the U.S., the disease or condition has an incidence of less than 200,000 persons and in the E.U. the prevalence of the condition must be not more than 5 in 10,000 persons. In the U.S., orphan-designated drugs are granted up to 7-year market exclusivity. In the E.U., products granted orphan designation are subject to reduced fees for protocol assistance, marketing authorization applications, inspections before authorization, applications for changes to marketing authorizations, and annual fees, access to the centralized authorization procedure, and 10 years of market exclusivity.

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Drugs are also subject to extensive regulation outside of the U.S. In the E.U., there is a centralized approval procedure that authorizes marketing of a product in all countries of the E.U. (which includes most major countries in the E.U.). If this centralized approval procedure is not used, approval in one country of the E.U. can be used to obtain approval in another country of the E.U. under one of two simplified application processes: the mutual recognition procedure or the decentralized procedure, both of which rely on the principle of mutual recognition. After receiving regulatory approval through any of the E.U. registration procedures, separate pricing and reimbursement approvals are also required in most countries. The E.U. also has requirements for approval of manufacturing facilities for all products that are approved for sale by the E.U. regulatory authorities.

*Failure to obtain marketing approvals in foreign jurisdictions will prevent us from marketing our products internationally.*

We intend to seek distribution and marketing partners for our current products outside the U.S. and may market planned products in international markets.

We have had limited interactions with foreign regulatory authorities. The approval procedures vary among countries and can involve additional clinical testing, and the time required to obtain approval may differ from that required to obtain FDA approval. Moreover, clinical studies or manufacturing processes conducted in one country may not be accepted by regulatory authorities in other countries. Approval by the FDA does not ensure approval by regulatory authorities in other countries or regions, and approval by one or more foreign regulatory authorities does not ensure approval by regulatory authorities in other foreign countries or by the FDA. However, a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. We may not obtain foreign regulatory approvals on a timely basis, if at all. We may not be able to file for regulatory approvals and even if we file we may not receive necessary approvals to commercialize our products in any market.

*Healthcare reform measures could hinder or prevent our planned products' commercial success.*

In the U.S., there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system in ways that could affect our future revenue and profitability and the future revenue and profitability of our potential customers. Federal and state lawmakers regularly propose and, at times, enact legislation that would result in significant changes to the healthcare system, some of which are intended to contain or reduce the costs of medical products and services. For example, one of the most significant healthcare reform measures in decades, the Patient Protection and Affordable Care Act of 2010 (PPACA), was enacted in 2010. The PPACA contains a number of provisions, including those governing enrollments in federal healthcare programs, reimbursement changes and fraud and abuse measures, all of which will impact existing government healthcare programs and will result in the development of new programs. The PPACA, among other things:

- could result in the imposition of injunctions;
- requires collection of rebates for drugs paid by Medicaid managed care organizations; and
- requires manufacturers to participate in a coverage gap discount program, under which they must agree to offer 50% point-of-sale discounts off negotiated prices of applicable branded drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D.

While the U.S. Supreme Court upheld the constitutionality of most elements of the PPACA in June 2012, other legal challenges are still pending final adjudication in several jurisdictions. The current presidential administration and Congress may continue to attempt broad sweeping changes to the current health care laws. We face uncertainties that might result from modifications or repeal of any of the provisions of the PPACA, including as a result of current and future executive orders and legislative actions. The impact of those changes

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on us and potential effect on the medical industry as a whole is currently unknown. Any changes to the PPACA are likely to have an impact on our results of operations and may have a material adverse effect on our results of operations. We cannot predict what other health care programs and regulations will ultimately be implemented at the federal or state level or the effect of any future legislation or regulation in the U.S. may have on our business.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. For example, the Budget Control Act of 2011, among other things, created the Joint Select Committee on Deficit Reduction to recommend proposals for spending reductions to Congress. The Joint Select Committee did not achieve a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, which triggered the legislation's automatic reduction to several government programs, including aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013. In January 2013, former President Obama signed into law the American Taxpayer Relief Act of 2012 (ATRA), which delayed for another two months the budget cuts mandated by the sequestration provisions of the Budget Control Act of 2011. The ATRA, among other things, also reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. In March 2013, the President signed an executive order implementing sequestration, and in April 2013, the 2% Medicare reductions went into effect. We cannot predict whether any additional legislative changes will affect our business.

There likely will continue to be legislative and regulatory proposals at the federal and state levels directed at containing or lowering the cost of health care. We cannot predict the initiatives that may be adopted in the future or their full impact. The continuing efforts of the government, insurance companies, managed care organizations and other payers of healthcare services to contain or reduce costs of health care may adversely affect:

- our ability to set a price that we believe is fair for our products;
- our ability to generate revenue and achieve or maintain profitability; and
- the availability of capital.

Further, changes in regulatory requirements and guidance may occur and we may need to amend clinical study protocols to reflect these changes. Amendments may require us to resubmit our clinical study protocols IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical study. In light of widely publicized events concerning the safety risk of certain drug products, regulatory authorities, members of Congress, the Governmental Accounting Office, medical professionals and the general public have raised concerns about potential drug safety issues. These events have resulted in the recall and withdrawal of drug products, revisions to drug labeling that further limit use of the drug products and establishment of risk management programs that may, for instance, restrict distribution of drug products or require safety surveillance or patient education. The increased attention to drug safety issues may result in a more cautious approach by the FDA to clinical studies and the drug approval process. Data from clinical studies may receive greater scrutiny with respect to safety, which may make the FDA or other regulatory authorities more likely to terminate or suspend clinical studies before completion or require longer or additional clinical studies that may result in substantial additional expense and a delay or failure in obtaining approval or approval for a more limited indication than originally sought.

Given the serious public health risks of high-profile adverse safety events with certain drug products, the FDA may require, as a condition of approval, costly risk evaluation and mitigation strategies, which may include safety surveillance, restricted distribution and use, patient education, enhanced labeling, special packaging or labeling, expedited reporting of certain adverse events, preapproval of promotional materials and restrictions on direct-to-consumer advertising.

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*If we fail to comply with healthcare regulations, we could face substantial penalties and our business, operations and financial condition could be adversely affected.*

Even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payers, certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. We could be subject to healthcare fraud and abuse and patient privacy regulation by both the federal government and the states in which we conduct our business. The regulations that may affect our ability to operate include, without limitation:

- the federal healthcare program Anti-Kickback Statute, which prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs, such as the Medicare and Medicaid programs;
- indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs, such as the Medicare and Medicaid programs;
- the federal False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, false claims, or knowingly using false statements, to obtain payment from the federal government, and which may apply to entities like us which provide coding and billing advice to customers;
- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- the federal transparency requirements under the Health Care Reform Law requires manufacturers of drugs, devices, biologics and medical supplies to report to the HHS information related to physician payments and other transfers of value and physician ownership and investment interests;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers.

The PPACA, among other things, amends the intent requirement of the Federal Anti-Kickback Statute and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the PPACA provides that the government may assert that a claim including items or services resulting from a violation of the Federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

## Risks related to ownership of our securities

*Our stock price may be volatile, and purchasers of our securities could incur substantial losses.*

Our stock price has been and is likely to continue to be volatile. The stock market in general, and the market for biotechnology and medical device companies in particular, have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. During the period from January 1, 2021, through December 31, 2021, the high and low closing prices of our common stock ranged from \$3.30 to \$0.41. As a result of this volatility, investors may not be able to sell their common stock at or above the purchase price. The market price for our common stock may be influenced by many factors, including the following:

- the results of our clinical trials and our ability to obtain regulatory approval of DCCR in Prader Willi Syndrome, our clinical trials and our ability to obtain regulatory approval for DCCR;
- our ability to successfully commercialize, and realize significant revenues from sales of our products;
- the success of competitive products or technologies;
- the results of other clinical studies of our products or those of our competitors;
- regulatory or legal developments in the U.S. and other countries, especially changes in laws or regulations applicable to our products;
- introductions and announcements of new products by us, our commercialization partners, or our competitors, and the timing of these introductions or announcements;
- actions taken by regulatory agencies with respect to our products, clinical studies, manufacturing process or sales and marketing terms;
- variations in our financial results or those of companies that are perceived to be similar to us;
- the success of our efforts to acquire or in-license additional products or planned products;
- developments concerning our collaborations, including but not limited to those with our sources of manufacturing supply and our commercialization partners;
- developments concerning our ability to bring our manufacturing processes to scale in a cost-effective manner;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- developments or disputes concerning patents or other proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our products;
- our ability or inability to raise additional capital and the terms on which we raise it;
- the recruitment or departure of key personnel;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- actual or anticipated changes in earnings estimates or changes in stock market analyst recommendations regarding our common stock, other comparable companies or our industry generally;
- trading volume of our common stock;
- sales of our common stock by us or our stockholders;
- general economic, industry and market conditions; including those due to inflation; and
- the other risks described in this “Risk Factors” section.

These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance. In the past, following periods of volatility in the market, securities class-action

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litigation has often been instituted against companies. Such litigation, if instituted against us, could result in substantial costs and diversion of management's attention and resources, which could materially and adversely affect our business, financial condition, results of operations and growth prospects.

*Future sales of our common stock, or the perception that future sales may occur, may cause the market price of our common stock to decline, even if our business is doing well.*

Sales of substantial amounts of our common stock in the public market, or the perception that these sales may occur, could materially and adversely affect the price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. All of our shares of common stock are freely tradable, without restriction, in the public market, except for any shares held by our affiliates.

In the future, we may issue additional shares of common stock or other equity or debt securities convertible into common stock in connection with a financing, acquisition, litigation settlement, employee arrangement or otherwise. Any such issuance could result in substantial dilution to our existing stockholders and could cause our stock price to decline.

*Our executive officers, directors and principal stockholders may continue to maintain the ability to control or significantly influence all matters submitted to stockholders for approval and under certain circumstances may have control over key decision making.*

Our executive officers, directors and principal stockholders own a majority of our outstanding common stock. As a result, the foregoing group of stockholders are able to control all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these stockholders will control the election of directors and the approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of voting power could delay or prevent an acquisition of our company on terms that other stockholders may desire.

*Our ability to use our net operating loss carry forwards and certain other tax attributes will be limited.*

Our ability to utilize our federal net operating loss, carryforwards and federal tax credit will be limited under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, (the Code). The limitations apply if an "ownership change," as defined by Section 382, occurs. Generally, an ownership change occurs if the percentage of the value of the stock that is owned by one or more direct or indirect "five percent shareholders" increases by more than 50% over their lowest ownership percentage at any time during the applicable testing period (typically three years). During the year ended December 31, 2016, we experienced an "ownership change", and in the year ended December 31, 2017 our acquisition of Essentialis resulted in an ownership change, of which both changes will limit our ability to utilize our existing and acquired net operating losses and other tax attributes to offset taxable income. In addition, this offering and capital raises in October 2019 and June 2020 may further limit our ability to utilize our net operating losses and other tax attributes to offset taxable income. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards and other tax attributes to offset U.S. federal taxable income will be subject to limitations, which could potentially result in increased future tax liability to us.

*As our warrant holders exercise their warrants into shares of our common stock, our stockholders will be diluted.*

The exercise of some or all of our warrants will result in the issuance of common stock that dilute the ownership interests of existing stockholders. Any sales of the common stock issuable upon exercise of our warrants could adversely affect prevailing market prices of our common stock.

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*If holders of our warrants elect to exercise their warrants and sell material amounts of our common stock in the market, such sales could cause the price of our common stock to decline, and the potential for such downward pressure on the price of our common stock may encourage short selling of our common stock by holders of our warrants or other parties.*

If there is significant downward pressure on the price of our common stock, it may encourage holders of our warrants, or other parties, to sell shares by means of short sales or otherwise. Short sales involve the sale, usually with a future delivery date, of common stock the seller does not own. Covered short sales are sales made in an amount not greater than the number of shares subject to the short seller's right to acquire common stock, such as upon exercise of warrants. A holder of warrants may close out any covered short position by exercising all, or a portion, of its warrants, or by purchasing shares in the open market. In determining the source of shares to close out the covered short position, a holder of warrants will likely consider, among other things, the price of common stock available for purchase in the open market as compared to the exercise price of the warrants. The existence of a significant number of short sales generally causes the price of common stock to decline, in part because it indicates that a number of market participants are taking a position that will be profitable only if the price of the common stock declines.

*Under certain circumstances, we may be required to settle the value of the 2018 PIPE Warrants in cash.*

If, at any time while the 2018 PIPE Warrants (the Warrants), are outstanding, we enter into a "Fundamental Transaction" (as defined in the Warrants), which includes, but is not limited to, a purchase offer, tender offer or exchange offer, a stock or share purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off or other scheme of arrangement), then each registered holder of outstanding Warrants as at any time prior to the consummation of the Fundamental Transaction, may elect and require us to purchase the Warrants held by such person immediately prior to the consummation of such Fundamental Transaction by making a cash payment in an amount equal to the Black Scholes Value of the remaining unexercised portion of such registered holder's Warrants.

*We might not be able to maintain the listing of our securities on The Nasdaq Capital Market.*

We have listed our common stock on Nasdaq. We might not be able to maintain the listing standards of that exchange, which includes requirements that we maintain our shareholders' equity, total value of shares held by unaffiliated shareholders, market capitalization above certain specified levels and minimum bid requirement of \$1.00 per common share. We do not expect to become profitable for some time and there is a risk that our shareholders' equity could fall below the \$2.5 million level required by Nasdaq. If we do not regain compliance with the minimum bid requirement or our shareholders' equity falls below \$2.5 million, it will cause us to fail to conform to Nasdaq listing requirements on an ongoing basis, which in turn could cause our common stock to cease to trade on Nasdaq exchange, and be required to move to the Over the Counter Bulletin Board or the "pink sheets" exchange maintained by OTC Markets Group, Inc. The OTC Bulletin Board and the "pink sheets" are generally considered to be markets that are less efficient, and to provide less liquidity in the shares, than Nasdaq market.

On September 16, 2021, we received a letter from the Listing Qualifications Department of Nasdaq indicating that, based upon the closing bid price of our common stock for the last 30 consecutive business days, we did not meet the minimum bid price of \$1.00 per share required for continued listing on Nasdaq pursuant to Nasdaq Listing Rule 5550(a)(2) (the Minimum Bid Price Requirement). The letter also indicated that we will be provided with a compliance period of 180 calendar days, or until March 15, 2022, in which to regain compliance pursuant to Nasdaq Listing Rule 5810(c)(3)(A).

On March 16, 2022, we received another letter from Nasdaq notifying us that we have been granted an additional 180-day period, or until September 12, 2022, to regain compliance with the Minimum Bid Price Requirement. The new compliance period is an extension of the initial compliance period provided for in Nasdaq's deficiency notice. During this new compliance period, we must comply with all other Nasdaq continued listing standards except for the Minimum Bid Price Requirement.

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If we are unable to regain compliance with the Minimum Bid Price Requirement by September 12, 2022, or if we fail to meet any of the other continued listing requirements, including stockholder equity requirements, our securities may be delisted from Nasdaq, which could reduce the liquidity of our common stock materially and result in a corresponding material reduction in the price of our common stock. In addition, delisting could harm our ability to raise capital through alternative financing sources on terms acceptable to us, or at all, and may result in the potential loss of confidence by investors, employees and business development opportunities. Such a delisting likely would impair your ability to sell or purchase our common stock when you wish to do so. Further, if we were to be delisted from Nasdaq, our common stock may no longer be recognized as a “covered security” and we would be subject to regulation in each state in which we offer our securities. Thus, delisting from Nasdaq could adversely affect our ability to raise additional financing through the public or private sale of equity securities, would significantly impact the ability of investors to trade our securities and would negatively impact the value and liquidity of our common stock.

If we implement a reverse stock split the liquidity of our common stock may be adversely effected.

We may be required to seek approval from our stockholders to effect a reverse stock split of the issued and outstanding shares of our common stock in order to regain compliance with Nasdaq Minimum Bid Price Requirement. However, there can be no assurance that the reverse stock split would be approved by our stockholders. Further, there can be no assurance that the market price per new share of our common stock after the reverse stock split will remain unchanged or increase in proportion to the reduction in the number of old shares of our common stock outstanding before the reverse stock split. The liquidity of the shares of our common stock may be affected adversely by any reverse stock split given the reduced number of shares of our common stock that will be outstanding following the reverse stock split, especially if the market price of our common stock does not increase as a result of the reverse stock split. In addition, the reverse stock split may increase the number of shareholders who own odd lots (less than 100 shares) of our common stock, creating the potential for such shareholders to experience an increase in the cost of selling their shares and greater difficulty effecting such sales.

Following any reverse stock split, the resulting market price of our common stock may not attract new investors and may not satisfy the investing requirements of those investors. Although we believe that a higher market price of our common stock may help generate greater or broader investor interest, there can be no assurance that the reverse stock split will result in a share price that will attract new investors, including institutional investors. In addition, there can be no assurance that the market price of our common stock will satisfy the investing requirements of those investors. As a result, the trading liquidity of our common stock may not necessarily improve.

*Due to the speculative nature of warrants, there is no guarantee that it will ever be profitable for holders of the pre-funded warrants or common warrants to exercise their warrants.*

The warrants we have issued and outstanding do not confer any rights of common stock ownership on their holders, such as voting rights or the right to receive dividends, but rather merely represent the right to acquire shares of common stock at a fixed price for a limited period of time. Holders of the 2018 PIPE Warrants are entitled to purchase one share of our common stock at an exercise price equal to \$2.00 per share prior to the expiration of the five-year term on December 21, 2023.

There can be no assurance that the market price of the common stock will ever equal or exceed the exercise price of the pre-funded warrants or common warrants, and, consequently, whether it will ever be profitable for holders of the pre-funded warrants or common warrants to exercise the warrants.

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

Provisions in our corporate charter and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which

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stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our Board. Because our Board is responsible for appointing the members of our management team, these provisions could in turn affect any attempt by our stockholders to replace current members of our management team. Among others, these provisions include the following:

- our Board is divided into three classes with staggered three-year terms which may delay or prevent a change of our management or a change in control;
- our Board has the right to elect directors to fill a vacancy created by the expansion of our Board or the resignation, death or removal of a director, which will prevent stockholders from being able to fill vacancies on our Board;
- our stockholders are not able to act by written consent or call special stockholders' meetings; as a result, a holder, or holders, controlling a majority of our capital stock cannot take certain actions other than at annual stockholders' meetings or special stockholders' meetings called by our Board, the chairman of our board, the chief executive officer or the president;
- our certificate of incorporation prohibits cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- amendments of our certificate of incorporation and bylaws require the approval of 66 2/3% of our outstanding voting securities;
- our stockholders are required to provide advance notice and additional disclosures in order to nominate individuals for election to our Board or to propose matters that can be acted upon at a stockholders' meeting, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of our company; and
- our Board are able to issue, without stockholder approval, shares of undesignated preferred stock, which makes it possible for our Board to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to acquire us.

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

*Our employment agreements with our executive officers may require us to pay severance benefits to any of those persons who are terminated in connection with a change in control of us, which could harm our financial condition or results.*

Certain of our executive officers are parties to employment agreements that contain change in control and severance provisions providing for aggregate cash payments for severance and other benefits and acceleration of stock options vesting in the event of a termination of employment in connection with a change in control of us. The accelerated vesting of options could result in dilution to our existing stockholders and harm the market price of our common stock. The payment of these severance benefits could harm our financial condition and results. In addition, these potential severance payments may discourage or prevent third parties from seeking a business combination with us.

### **General risks**

*Intrusions into our computer systems could result in compromise of confidential information.*

Any software we develop or use for any of our products may be potentially subject to malfunction or vulnerable to physical break-ins, hackers, improper employee or contractor access, computer viruses, programming errors,

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or similar problems. Any of these might result in confidential medical, business or other information of other persons or of ourselves being revealed to unauthorized persons.

There are a number of state, federal and international laws protecting the privacy and security of health information and personal data, including on electronic medical systems. As part of the American Recovery and Reinvestment Act 2009, or ARRA, Congress amended the privacy and security provisions of the Health Insurance Portability and Accountability Act of 1996, or HIPAA. HIPAA imposes limitations on the use and disclosure of an individual's protected healthcare information by healthcare providers, healthcare clearinghouses, and health insurance plans, collectively referred to as covered entities. The HIPAA amendments also impose compliance obligations and corresponding penalties for non-compliance on individuals and entities that provide services to healthcare providers and other covered entities, collectively referred to as business associates. ARRA also made significant increases in the penalties for improper use or disclosure of an individual's health information under HIPAA and extended enforcement authority to state attorneys general. The amendments also create notification requirements for individuals whose health information has been inappropriately accessed or disclosed: notification requirements to federal regulators and in some cases, notification to local and national media. Notification is not required under HIPAA if the health information that is improperly used or disclosed is deemed secured in accordance with encryption or other standards developed by HHS. Most states have laws requiring notification of affected individuals and state regulators in the event of a breach of personal information, which is a broader class of information than the health information protected by HIPAA. Many state laws impose significant data security requirements, such as encryption or mandatory contractual terms to ensure ongoing protection of personal information. Activities outside of the U.S. implicate local and national data protection standards, impose additional compliance requirements and generate additional risks of enforcement for non-compliance. We may be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws, to protect against security breaches and hackers or to alleviate problems caused by such breaches.

*Public health epidemics, pandemics or outbreaks, including the coronavirus pandemic (COVID-19), could adversely affect our business.*

In December 2019, the novel coronavirus (COVID-19) was identified in Wuhan, China. The virus continues to spread globally, has been declared a pandemic by the World Health Organization and has spread to over 100 countries, including the U.S. The COVID-19 outbreak is significantly affecting our employees, patients, communities and business operations, as well as the U.S. economy and financial markets. The full extent to which the COVID-19 outbreak will impact our business, results of operations, financial condition and cash flows will depend on future developments that are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning COVID-19 and the actions to contain it or treat its impact and the economic impact on local, regional, national and international markets. As the COVID-19 pandemic continues, our results of operations, financial condition and cash flows are likely to be materially adversely affected, particularly if the pandemic persists for a significant amount of time.

COVID-19 or other public health epidemics, pandemics or outbreaks, and the resulting business or economic disruptions resulting therefrom, may adversely impact our business as well as our ability to raise capital. The impact of this pandemic has been and will likely continue to be extensive in many aspects of society, which has resulted in and will likely continue to result in significant disruptions to the global economy, as well as businesses and capital markets around the world.

While we cannot presently predict the scope and severity of any potential business shutdowns or disruptions, if we or any of our business partners, clinical trial sites, manufacturing sites and other third parties with whom we conduct business, were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively impacted. While there was no meaningful impact on the timelines for top-line data for the Phase 3 program, there have been certain changes in the conduct of our clinical trials depending on institution-, state- and country-specific restrictions such as stay at home requirements. The changes are consistent with the FDA's and MHRA's

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guidance regarding the conduct of clinical trials during the COVID-19 public health emergency. However, the changes in the way the trial is being conducted may impact the quality and quantity of the overall data being collected (for example, certain study related procedures which need to be conducted at a clinical trial site may not be performed or be delayed) which may have implications for our future plans.

The foregoing and other continued disruptions to our business as a result of COVID-19 could result in a material adverse effect on our business, results of operations, financial condition and cash flows. Furthermore, the COVID-19 pandemic could heighten the risks in certain of the other risk factors described herein.

*Unfavorable U.S. or global economic conditions as a result of international conflict, or otherwise, could adversely affect our ability to raise capital and our business, results of operations and financial condition.*

While the potential economic impact brought by the hostilities in the Ukraine are difficult to assess or predict, these conditions have resulted in, and may continue to result in, extreme volatility and disruptions in the capital and credit markets, reducing our ability to raise additional capital through equity, equity-linked or debt financings, which could negatively impact our short-term and long-term liquidity and our ability to operate in accordance with our operating plan, or at all. Additionally, our results of operations could be adversely affected by general conditions in the global economy and financial markets. A severe or prolonged economic downturn could result in a variety of risks to our business, including weakened demand for our products and services our ability to raise additional capital when needed on favorable terms, if at all. A weak or declining economy could strain our customers' budgets or cause delays in their payments to us. Additionally, inflation and surging oil and gas prices could increase our costs of production. Any of the foregoing could harm our business, and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our ability to raise capital, business, results of operations and financial condition.

*We have incurred and will continue to incur significant increased costs as a result of operating as a public company, and our management has devoted and will be required to continue to devote substantial time to new compliance initiatives.*

We have incurred and will continue to incur significant legal, accounting and other expenses as a public company. We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, the other rules and regulations of the SEC, and the rules and regulations of Nasdaq. The expenses of being a public company are material, and compliance with the various reporting and other requirements applicable to public companies requires considerable time and attention of management. For example, the Sarbanes-Oxley Act and the rules of the SEC and national securities exchanges have imposed various requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls. Our management and other personnel need to devote a substantial amount of time to these compliance initiatives. These rules and regulations will continue to increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, these rules and regulations may make it difficult and expensive for us to obtain adequate director and officer liability insurance, and we may be required to accept reduced policy limits on coverage or incur substantial costs to maintain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified personnel to serve on our board of directors, on the committees of our board of directors committees, or as executive officers.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal control over financial reporting and disclosure controls and procedures. In particular, we must perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act (Section 404). We currently do not have an internal audit group, and we will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge.

If we are not able to comply with the requirements of Section 404 in a timely manner the market price of our stock could decline and we could be subject to sanctions or investigations by Nasdaq, the SEC or other

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regulatory authorities, which would require additional financial and management resources. Our ability to successfully implement our business plan and comply with Section 404 requires us to be able to prepare timely and accurate financial statements. We expect that we will need to continue to improve existing, and implement new operational and financial systems, procedures and controls to manage our business effectively. Any delay in the implementation of, or disruption in the transition to, new or enhanced systems, procedures or controls, may cause our operations to suffer and we may be unable to conclude that our internal control over financial reporting is effective. This, in turn, could have an adverse impact on trading prices for our common stock, and could adversely affect our ability to access the capital markets.

## FORWARD-LOOKING STATEMENTS

This prospectus supplement, the accompanying prospectus and the information incorporated by reference herein and therein contain certain statements that constitute “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Exchange Act.

The words “believe,” “may,” “will,” “potentially,” “estimate,” “continue,” “anticipate,” “intend,” “could,” “would,” “project,” “plan,” “goal,” “expect” and the negative and plural forms of these words and similar expressions are intended to identify forward-looking statements, but are not the exclusive means of identifying such statements. Those statements appear in this prospectus supplement, the accompanying prospectus and the documents incorporated herein and therein by reference, particularly in the sections titled “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.

This prospectus supplement, the accompanying prospectus and the information incorporated by reference herein and therein also contain statements that are based on the current expectations of our company and management. You are cautioned that any such forward-looking statements are not guarantees of future performance and involve risks and uncertainties, and that actual results may differ materially from those projected in the forward-looking statements as a result of various factors. This prospectus supplement, the accompanying prospectus and the information incorporated by reference herein and therein may also contain estimates and other statistical data made by independent parties and by us relating to market size and growth and other data about our industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. In addition, projections, assumptions and estimates of our future performance and the future performance of the markets in which we operate are necessarily subject to a high degree of uncertainty and risk.

In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this prospectus supplement, and although we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted a thorough inquiry into, or review of, all potentially available relevant information.

Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, you should not unduly 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 supplement, whether as a result of any new information, future events or otherwise.

## USE OF PROCEEDS

We estimate that the net proceeds from this offering will be approximately \$ \_\_\_\_\_ million, excluding any proceeds that may be received upon the exercise of the pre-funded warrants and common warrants, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

We intend to use the net proceeds from this offering to fund our current research and development efforts primarily focused on advancing our lead candidate, DCCR tablets for the treatment of PWS, and to provide for general corporate purposes, which may include working capital, capital expenditures, other clinical trials, other corporate expenses and acquisitions of complementary products, technologies or businesses. However, we do not have agreements or commitments for any specific acquisitions at this time.

As of the date of this prospectus supplement, we cannot specify all of the particular uses for the net proceeds to be received upon the completion of this offering. Accordingly, our management and board of directors will have broad discretion in the application and specific allocations of the net proceeds, and investors will be relying on the judgment of our management and board of directors regarding the application of the proceeds of this offering.

These expected uses represent our current intentions based upon our present plans and market conditions. The amounts we actually expend in these areas, and the timing thereof, may vary significantly from our current intentions and will depend upon a number of factors, including research and product development efforts, cash generated from future operations and actual expenses to operate our business.

Pending our use of the net proceeds from this offering, we intend to invest the net proceeds in bank deposits, money market funds, and U.S. government securities.

## **DIVIDEND POLICY**

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain any future earnings to invest in our business and do not expect to pay any dividends in the foreseeable future. Any determination to pay dividends in the future will be at the discretion of our board of directors and will depend on our financial condition, operating results, capital requirements and general business conditions and other factors that our board of directors may deem relevant.

## DILUTION

If you purchase our common stock and accompanying common warrants or pre-funded warrants and accompanying common warrants in this offering, your ownership interest will be immediately diluted to the extent of the difference between the public offering price per share of our common stock and the net tangible book value per share of our common stock immediately after this offering. Net tangible book value per share is determined by dividing the number of shares of common stock outstanding as of September 30, 2021 into our total tangible assets less total liabilities.

Our net tangible book value as of September 30, 2021 was approximately \$7.1 million, or \$0.09 per share, based on 79,806,487 shares of our common stock outstanding as of that date.

After giving effect to the sale of shares of common stock and accompanying common warrant by us at the public offering price of \$      per share and accompanying common warrant and the sale of      pre-funded warrants and accompanying common warrant in this offering at an offering price of \$      per pre-funded warrant and accompanying common warrant (which equals the public offering price per share of the common stock less the \$0.01 per share exercise price of the pre-funded warrants) (and excluding shares of common stock issued and any proceeds received upon exercise of the pre-funded warrants, common warrants or any resulting accounting associated with the pre-funded warrants and common warrants) and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us, our as adjusted net tangible book value as of September 30, 2021 would have been \$      million, or \$      per share. This represents an immediate increase in net tangible book value of \$      per share to existing stockholders and immediate dilution of \$      per share to investors in this offering, as illustrated by the following table:

Public offering price per share		\$
Net tangible book value per share as of September 30, 2021	\$ 0.09	
Increase in net tangible book value per share attributable to investors participating in this offering		
As adjusted net tangible book value per share after giving effect to this offering		
Dilution per share to investors in this offering		\$

If holders of pre-funded warrants or common warrants purchased in this offering exercise such pre-funded warrants or common warrants and we receive the aggregate exercise price payable under such pre-funded warrants or common warrants, the as adjusted net tangible book value per share of our common stock as of September 30, 2021 after giving effect to this offering would be \$      per share, and the dilution in such as adjusted net tangible book value per share to investors participating in this offering would be \$      per share.

The number of shares of common stock to be outstanding immediately after this offering is based on 79,806,487 shares outstanding as of September 30, 2021 and excludes:

- 6,084,923 shares of common stock issuable upon exercise of stock options outstanding as of September 30, 2021 under our equity incentive plans, with a weighted-average exercise price of \$3.11 per share;
- 435,750 shares of common stock issuable upon the vesting of restricted stock units as of September 30, 2021 under our equity incentive plans;
- 1,661,751 shares of common stock issuable upon exercise of stock options granted after September 30, 2021 under our equity incentive plans, with a weighted-average exercise price of \$0.36 per share;
- 198,703 shares of common stock issuable upon vesting of restricted stock units granted after September 30, 2021;
- 632,187 shares of common stock issuable upon exercise of outstanding warrants, with a weighted average exercise price of \$6.49 per share, as of March 28, 2022;

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- 2,805,045 shares of common stock available for future issuance under our 2014 Equity Incentive Plan and 1,285,000 shares of common stock available for future issuance under our 2021 Inducement Equity Incentive Plan, each as of March 28, 2022; and
- shares of common stock issuable upon exercise of the pre-funded warrants and common warrants issued in this offering.

To the extent that additional shares are issued pursuant to the foregoing, investors purchasing our common stock in this offering will experience further dilution. In addition, we may offer other securities in other offerings due to market conditions or strategic considerations. To the extent we issue such securities, you may experience further dilution.

## DESCRIPTION OF THE SECURITIES WE ARE OFFERING

### Description of the Capital Stock

A description of the common stock we are offering pursuant to this prospectus supplement is set forth under the heading “Description of Capital Stock,” starting on page 9 of the accompanying prospectus. As of September 30, 2021, we had 79,806,487 shares of common stock outstanding.

### Description of the Pre-Funded Warrants

In this offering, we are offering pre-funded warrants to purchase \_\_\_\_\_ shares of our common stock. The following description is subject in all respects to the provisions contained in the form of pre-funded warrant. You should review a copy of the form of pre-funded warrant, which will be filed as an exhibit to our Current Report on Form 8-K being filed with the SEC in connection with this offering, for a complete description of the terms and conditions of the pre-funded warrants. The pre-funded warrants will be issued as individual warrant agreements with the holders. The pre-funded warrants are exercisable at any time after their original issuance at an exercise price of \$0.001 per share. The pre-funded warrants will be exercisable, at the option of each holder, in whole or in part by delivering to us a duly executed exercise notice and by payment in full in immediately available funds for the number of shares of common stock purchased upon such exercise. As an alternative to payment in immediately available funds, the holder may, in its sole discretion, elect to exercise the pre-funded warrant through a cashless exercise, in which case the holder would receive upon such exercise the net number of shares of common stock determined according to the formula set forth in the pre-funded warrant. No fractional shares of common stock will be issued in connection with the exercise of a pre-funded warrant. In lieu of issuing fractional shares, we will pay the holder an amount in cash equal to such fraction multiplied by the exercise price or rounded up to the next whole share. The exercise price per whole share of our common stock purchasable upon the exercise of the pre-funded warrants is \$0.001 per share of common stock. The exercise price of the pre-funded warrants is subject to adjustment from time to time in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our common stock and also upon any distributions for no consideration of assets, including cash, stock or other property, to all of our stockholders. A holder will not have the right to exercise any portion of the pre-funded warrant if the holder (together with its affiliates) would beneficially own in excess of 4.99% (or, at the election of the purchaser, 9.99%) of the number of shares of our common stock outstanding immediately after giving effect to the exercise. However, any holder may increase or decrease such ownership percentage limit to any other percentage not in excess of 19.99% upon at least 61 days’ prior notice from the holder to us.

We do not plan on applying to list the pre-funded warrants on Nasdaq or any other national securities exchange or any other nationally recognized trading system. Subject to applicable laws, the pre-funded warrants may be offered for sale, sold, transferred or assigned without our consent.

In the event of a fundamental transaction, as defined in the pre-funded warrants and generally including, without limitation, any reclassification of our common stock into other securities, cash or property, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition by any person or group, whether in a tender offer, exchange offer, stock purchase agreement, or other business combination, of more than 50% of the voting power of our capital stock, the holders of the pre-funded warrants will be entitled to receive upon exercise of the pre-funded warrants the same amount and kind of securities, cash or other property that the holders would have received had they exercised the pre-funded warrants immediately prior to such fundamental transaction. Except as otherwise provided in the pre-funded warrants or by virtue of such holder’s ownership of shares of our common stock, the holder of a pre-funded warrant does not have the rights or privileges of a holder of our common stock, including any voting rights, until the holder exercises the prefunded warrant.

### Description of the Common Warrants

The following summary of certain terms and provisions of the common warrants being offered in this offering is not complete and is subject to, and qualified in its entirety by, the provisions of the common warrants.

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Prospective investors should carefully review the terms and provisions of the form of common warrant for a complete description of the terms and conditions of the common warrants.

### ***Duration and Exercise Price***

Each common warrant will have an exercise price of \$ \_\_\_\_\_ per share, will be immediately exercisable, and will expire five years from the date of issuance. The exercise price and number of shares of common stock issuable upon exercise is subject to appropriate adjustments in the event of stock dividends, stock splits, or similar events affecting our common stock and the exercise price. The common warrants will be issued separately from the shares of common stock or pre-funded warrants being sold in this offering.

### ***Cashless Exercise***

If, at the time a holder exercises its common warrants, a registration statement registering the issuance of the shares of common stock underlying the common warrants under the Securities Act is not then effective or available for the issuance of such shares, then in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder will be permitted to receive upon such exercise (either in whole or in part) the net number of shares of common stock determined according to a formula set forth in the common warrants.

### ***Exercisability***

The common warrants will be exercisable, at the option of each holder, in whole or in part, by delivering to us a duly executed exercise notice and payment in full for the number of shares of our common stock purchased upon such exercise (except in the case of a cashless exercise as discussed above). A holder (together with its affiliates) may not exercise any portion of a common warrant to the extent that the holder would own more than 4.99% of the outstanding common stock immediately after exercise, except that upon at least 61 days' prior notice from the holder to us, the holder may increase the amount of ownership of outstanding stock after exercising the holder's common warrants up to 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the common warrants. Purchasers in this offering may also elect prior to the issuance of common warrants to have the initial exercise limitation set at 9.99% of our outstanding common stock.

### ***Fractional Shares***

No fractional shares of common stock will be issued upon the exercise of the common warrants. Rather, the number of shares of common stock to be issued will be rounded down to the nearest whole number.

### ***Transferability***

Subject to applicable laws, a common warrant may be transferred at the option of the holder upon surrender of the warrant to us together with the appropriate instruments of transfer.

### ***Exchange Listing***

We do not intend to list the common warrants on any securities exchange or nationally recognized trading system. The common stock issuable upon exercise of the common warrants is currently listed on the Nasdaq.

### ***Right as a Stockholder***

Except as otherwise provided in the common warrants or by virtue of such holder's ownership of shares of our common stock, the holders of the common warrants do not have the rights or privileges of holders of our common stock, including any voting rights, until they exercise their common warrants.

***Fundamental Transaction***

In the event of a fundamental transaction, as described in the common warrants and generally including any reorganization, recapitalization or reclassification of our common stock, the sale, transfer, or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of at least 50% of our outstanding common stock, or any person or group becoming the beneficial owner of at least 50% of the voting power represented by our outstanding common stock, the holders of the common warrants will be entitled to receive upon exercise of the common warrants the kind and amount of securities, cash, or other property that the holders would have received had they exercised the common warrants immediately prior to such fundamental transaction. In addition, in the event of a change of control, as described in the common warrants, that is approved by the Company's board of directors, the holders of the common warrants have the right to require us or a successor entity to redeem the common warrants for cash in the amount of the Black-Scholes value of the unexercised portion of the common warrants on the date of the consummation of the change of control. In the event of a change of control that is not approved by the Company's board of directors, the holders of the common warrants shall only be entitled to receive from the Company or any successor entity, as of the date of consummation of the change of control the same type or form of consideration (and in the same proportion), at the Black Scholes Value of the unexercised portion of the common warrant, that is being offered and paid to the holders of common stock of the Company in connection with the change of control, whether that consideration be in the form of cash, stock, or any combination thereof, or whether the holders of common stock are given the choice to receive from among alternative forms of consideration in connection with the change of control.

## **MATERIAL U.S. FEDERAL INCOME TAX CONSIDERATIONS FOR NON-U.S. HOLDERS OF OUR COMMON STOCK, PRE-FUNDED WARRANTS AND COMMON WARRANTS**

The following discussion describes the material U.S. federal income tax consequences of the acquisition, ownership and disposition of our common stock, pre-funded warrants and warrants acquired in this Offering. This discussion is based on the current provisions of the Internal Revenue Code of 1986, as amended, or the Code, existing and proposed U.S. Treasury regulations promulgated thereunder, and administrative rulings and court decisions in effect as of the date hereof, all of which are subject to change at any time, possibly with retroactive effect. No ruling has been or will be sought from the Internal Revenue Service, or IRS, with respect to the matters discussed below, and there can be no assurance the IRS will not take a contrary position regarding the tax consequences of the acquisition, ownership or disposition of our common stock, pre-funded warrants and warrants, or that any such contrary position would not be sustained by a court.

We assume in this discussion that the shares of our common stock, pre-funded warrants and warrants will be held as capital assets (generally, property held for investment). This discussion does not address all aspects of U.S. federal income taxes, does not discuss the potential application of the Medicare contribution tax on net investment income or the alternative minimum tax and does not deal with state or local taxes, U.S. federal gift and estate tax laws, except as specifically provided below with respect to non-U.S. holders, or any non-U.S. tax consequences that may be relevant to holders in light of their particular circumstances. This discussion also does not address the special tax rules applicable to particular holders, such as

- financial institutions;
- brokers or dealers in securities or currencies or traders in securities that elect to use a mark-to-market method of accounting for their securities holdings;
- tax-exempt organizations;
- pension plans;
- regulated investment companies, real estate investment trusts;
- owners that hold our common stock or warrants as part of a straddle, hedge, conversion transaction, synthetic security or other integrated investment;
- insurance companies;
- persons that own, or are deemed to own, more than 5% of our capital stock and/or pre-funded warrants (except to the extent specifically set forth below);
- entities or arrangements treated as partnerships for U.S. federal income tax purposes and other pass-through entities (and partners or other investors therein);
- controlled foreign corporations, passive foreign investment companies, or corporations that accumulate earnings to avoid U.S. federal income tax;
- persons subject to special tax accounting rules as a result of any item of gross income with respect to our common stock, pre-funded warrants or warrants being taken into account in an applicable financial statement;
- persons deemed to sell our common stock, pre-funded warrants or warrants under the constructive sale provisions of the Code; and
- certain U.S. expatriates and certain former citizens or long-term residents of the United States.

In addition, this discussion does not address the tax treatment of partnerships or other pass-through entities or persons who hold our common stock, pre-funded warrants or warrants through partnerships or other entities which are pass-through entities for U.S. federal income tax purposes. A partner in a partnership or other pass-through entity that will hold our common stock, pre-funded warrants or warrants should consult his, her or its own tax advisor regarding the tax consequences of the ownership and disposition of our common stock, pre-funded warrants or warrants through a partnership or other pass-through entity, as applicable.

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This discussion of U.S. federal income tax considerations is for general information purposes only and is not tax advice. Prospective investors should consult their own tax advisors regarding the U.S. federal, state, local and non-U.S. income and other tax considerations of acquiring, holding and disposing of our common stock, pre-funded warrants and warrants.

For the purposes of this discussion, a “U.S. Holder” means a beneficial owner of our common stock, pre-funded warrants or warrants that is, (or other entity classified as a partnership for U.S. federal income tax purposes:

(a) an individual who is a citizen or resident of the United States, (b) a corporation (or other entity taxable as a corporation for U.S. federal income tax purposes), created or organized in or under the laws of the United States, any state thereof or the District of Columbia, (c) an estate the income of which is subject to U.S. federal income taxation regardless of its source, or (d) a trust if it (1) is subject to the primary supervision of a court within the United States and one or more U.S. persons (within the meaning of Section 7701(a)(30) of the Code) have the authority to control all substantial decisions of the trust or (2) has a valid election in effect under applicable U.S. Treasury regulations to be treated as a U.S. person. A “Non-U.S. Holder” is, for U.S. federal income tax purposes, a beneficial owner of common stock, pre-funded warrants or warrants that is not a U.S. Holder or an entity or arrangement treated as a partnership for U.S. federal income tax purposes.

### **General Treatment of Pre-Funded Warrants**

Although the law in this area is not completely settled, the pre-funded warrants are generally expected to be treated as shares of our common stock for U.S. federal income tax purposes and a holder of pre-funded warrants should generally be taxed in the same manner as a holder of common stock as described below, and not as a holder of a warrant as described below. Accordingly, no gain or loss should be recognized upon the exercise of a pre-funded warrant and, upon exercise, the holding period of a pre-funded warrant should carry over to the common shares received. Similarly, the tax basis of a pre-funded warrant should carry over to the common share received upon exercise, increased by the exercise price (if applicable). Holders should discuss with their tax advisor the consequences of the acquisition, ownership and disposition of the pre-funded warrants, as well as the exercise of, certain adjustments to, and any payments in respect of the pre-funded warrants (including potential alternative characterizations). The balance of this discussion generally assumes that the characterization described above is respected for U.S. federal income tax purposes.

### **Allocation of Purchase Price**

For U.S. federal income tax purposes, the shares of common stock and warrants or pre-funded warrants and warrants acquired in this Offering will be treated as an “investment unit” consisting of one share of common stock and a warrant to acquire one share of our common stock or one pre-funded warrant and a warrant to acquire one share of our common stock. The purchase price for each investment unit will be allocated between these two components in proportion to their relative fair market values at the time the unit is purchased by the holder. This allocation of the purchase price for each unit will establish the holder’s initial tax basis for U.S. federal income tax purposes in the share of common stock or pre-funded warrant and the warrant included in each unit. The separation of the share of common stock or pre-funded warrant and the warrant included in each unit should not be a taxable event for U.S. federal income tax purposes. Each holder should consult his, her or its own tax advisor regarding the allocation of the purchase price for a unit.

### **Tax Considerations Applicable to U.S. Holders**

#### *Exercise and Expiration of Warrants*

In general, a U.S. Holder will not recognize gain or loss for U.S. federal income tax purposes upon exercise of a warrant. The U.S. Holder will take a tax basis in the shares acquired on the exercise of a warrant equal to the exercise price of the warrant, increased by the U.S. Holder’s adjusted tax basis in the warrant exercised (as determined pursuant to the rules discussed above). The U.S. Holder’s holding period in the shares of our common stock acquired on exercise of the warrant will begin on the date of exercise of the warrant, and will not include any period for which the U.S. Holder held the warrant.

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In certain limited circumstances, a U.S. Holder may be permitted to undertake a cashless exercise of warrants into our common stock. The U.S. federal income tax treatment of a cashless exercise of warrants into our common stock is unclear, and the tax consequences of a cashless exercise could differ from the consequences upon the exercise of a warrant described in the preceding paragraph. U.S. Holders should consult their own tax advisors regarding the U.S. federal income tax consequences of a cashless exercise of warrants.

The lapse or expiration of a warrant will be treated as if the U.S. Holder sold or exchanged the warrant and recognized a capital loss equal to the U.S. Holder's tax basis in the warrant. The deductibility of capital losses is subject to limitations.

### **Certain Adjustments to and Distributions on Warrants**

Under Section 305 of the Code, an adjustment to the number of shares of common stock issued on the exercise of the warrants or an adjustment to the exercise price of the warrants may be treated as a constructive distribution to a U.S. Holder of the warrants if, and to the extent that, such adjustment has the effect of increasing such U.S. Holder's proportionate interest in our "earnings and profits" or assets, depending on the circumstances of such adjustment (for example, if such adjustment is to compensate for a distribution of cash or other property to our shareholders). An adjustment made pursuant to a bona fide reasonable adjustment formula that has the effect of preventing dilution should generally not be considered to result in a constructive distribution. Any such constructive distribution would be taxable whether or not there is an actual distribution of cash or other property to the holders of warrants. In certain circumstances, if we were to make a distribution in cash or other property with respect to our common stock after the issuance of the warrants, then we may make a corresponding distribution to the holders of the warrants. The taxation of a distribution received with respect to a warrant is unclear. It is possible such a distribution would be treated as a distribution (or constructive distribution), although other treatments are possible. For more information regarding the U.S. federal income tax considerations related to distributions, see the discussion below regarding "—Distributions." U.S. Holders should consult their tax advisors regarding the proper treatment of any adjustments to the warrants and any distributions with respect to the warrants.

### ***Distributions***

As discussed above, we currently intend to retain any future earnings to invest in our business and do not expect to pay any dividends in the foreseeable future. In the event that we do make distributions on our common stock to a U.S. Holder, those distributions generally will constitute dividends for U.S. tax purposes to the extent paid out of our current or accumulated earnings and profits (as determined under U.S. federal income tax principles). Distributions in excess of our current and accumulated earnings and profits will constitute a return of capital that is applied against and reduces, but not below zero, a U.S. Holder's adjusted tax basis in our common stock. Any remaining excess will be treated as gain realized on the sale or exchange of our common stock as described below under the section titled "—Disposition of Our Common Stock or Warrants." Under current law, if certain requirements are met, a preferential U.S. federal income tax rate will apply to any dividends paid to the beneficial owner of our common stock who is an individual U.S. Holder and meets certain holding period requirements.

Distributions constituting dividends for U.S. federal income tax purposes that are made to U.S. Holders that are corporate shareholders may qualify for the dividends received deduction, or DRD, which is generally available to corporate shareholders. No assurance can be given that we will have sufficient earnings and profits (as determined for U.S. federal income tax purposes) to cause any distributions to be eligible for a DRD. In addition, a DRD is available only if certain holding periods and other taxable income requirements are satisfied.

The taxation of a distribution received with respect to a pre-funded warrant is unclear. It is possible such a distribution would be treated as a distribution as described in this section, although other treatments may also be possible. Holders should consult their tax advisors regarding the proper treatment of any payments in respect of the pre-funded warrants.

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### ***Disposition of Our Common Stock or Warrants***

Upon a sale or other taxable disposition of our common stock or warrants, a U.S. Holder generally will recognize capital gain or loss in an amount equal to the difference between the amount realized and the U.S. Holder's adjusted tax basis in the common stock or warrants. Capital gain or loss will constitute long-term capital gain or loss if the U.S. Holder's holding period for the common stock or warrants exceeds one year. The deductibility of capital losses is subject to certain limitations. U.S. Holders who recognize losses with respect to a disposition of our common stock or warrants should consult their own tax advisors regarding the tax treatment of such losses.

### ***Information Reporting and Backup Withholding***

Information reporting requirements generally will apply to payments of dividends (including constructive dividends) on the common stock and warrants and to the proceeds of a sale or other disposition of common stock and warrants paid by us to a U.S. Holder unless such U.S. Holder is an exempt recipient, such as a corporation. Backup withholding will apply to those payments if the U.S. Holder fails to provide the holder's taxpayer identification number, or certification of exempt status, or if the holder otherwise fails to comply with applicable requirements to establish an exemption.

Backup withholding is not an additional tax. Rather, any amounts withheld under the backup withholding rules will be allowed as a refund or a credit against the U.S. Holder's U.S. federal income tax liability provided the required information is timely furnished to the IRS. U.S. Holders should consult their own tax advisors regarding their qualification for exemption from information reporting and backup withholding and the procedure for obtaining such exemption.

### **Tax Considerations Applicable to Non-U.S. Holders**

#### ***Exercise and Expiration of Warrants***

In general, a Non-U.S. Holder will not recognize gain or loss for U.S. federal income tax purposes upon the exercise of warrants into shares of common stock. The U.S. federal income tax treatment of a cashless exercise of warrants into our common stock is unclear. A Non-U.S. Holder should consult his, her, or its own tax advisor regarding the U.S. federal income tax consequences of a cashless exercise of warrants.

The expiration of a warrant will be treated as if the Non-U.S. Holder sold or exchanged the warrant and recognized a capital loss equal to the Non-U.S. Holder's tax basis in the warrant. However, a Non-U.S. Holder will not be able to utilize a loss recognized upon expiration of a warrant against the Non-U.S. Holder's U.S. federal income tax liability unless the loss is effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (and, if an income tax treaty applies, is attributable to a permanent establishment or fixed base in the United States) or is treated as a U.S.-source loss and the Non-U.S. Holder is present 183 days or more in the taxable year of disposition and certain other conditions are met.

#### ***Certain Adjustments to and Distributions on Warrants***

As described under "—U.S. Holders—Certain Adjustments to and Distributions on Warrants," an adjustment to the warrants could result in a constructive distribution to a Non-U.S. Holder, which would be treated as described under "—Distributions" below, and the tax treatment of distributions on the warrants is unclear. Any resulting withholding tax attributable to deemed dividends would be collected from other amounts payable or distributable to the Non-U.S. Holder. Non-U.S. Holders should consult their tax advisors regarding the proper treatment of any adjustments to and distributions on the warrants.

#### ***Distributions***

As discussed above, we currently intend to retain any future earnings to invest in our business and do not expect to pay any dividends in the foreseeable future. In the event that we do make distributions on our common stock

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to a Non-U.S. Holder, those distributions generally will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as described in “—U.S. Holders – Distributions.”

Any distribution (including constructive distributions) on our common stock that is treated as a dividend paid to a Non-U.S. Holder that is not effectively connected with the holder’s conduct of a trade or business in the United States will generally be subject to withholding tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and the Non-U.S. Holder’s country of residence. To obtain a reduced rate, of withholding under a treaty, a Non-U.S. Holder generally will be required to provide the applicable withholding agent with a properly executed IRS Form W-8BEN, IRS Form W-8BEN-E or other appropriate form, certifying the Non-U.S. Holder’s entitlement to benefits under that treaty. Such form must be provided prior to the payment of dividends and must be updated periodically. If a Non-U.S. Holder holds stock through a financial institution or other agent acting on the holder’s behalf, the holder will be required to provide appropriate documentation to such agent. The holder’s agent may then be required to provide certification to the applicable withholding agent, either directly or through other intermediaries. If you are eligible for a reduced rate of U.S. withholding tax under an income tax treaty, you should consult with your own tax advisor to determine if you are able to obtain a refund or credit of any excess amounts withheld by timely filing an appropriate claim for a refund with the IRS.

We generally are not required to withhold tax on dividends paid (or constructive dividends deemed paid) to a Non-U.S. Holder that are effectively connected with the holder’s conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, are attributable to a permanent establishment or fixed base that the holder maintains in the United States) if a properly executed IRS Form W-8ECI, stating that the dividends are so connected, is furnished to us (or, if stock is held through a financial institution or other agent, to the applicable withholding agent). In general, such effectively connected dividends will be subject to U.S. federal income tax on a net income basis at the regular graduated rates applicable to U.S. persons. A corporate Non-U.S. Holder receiving effectively connected dividends may also be subject to an additional “branch profits tax,” which is imposed, under certain circumstances, at a rate of 30% (or such lower rate as may be specified by an applicable treaty) on the corporate Non-U.S. Holder’s effectively connected earnings and profits, subject to certain adjustments.

The taxation of a distribution received with respect to a pre-funded warrant is unclear. It is possible such a distribution would be treated as a distribution as described in this section, although other treatments may also be possible. Non-U.S. Holders should consult their own tax advisors regarding the proper treatment of any payments in respect of the pre-funded warrants.

See also the sections below titled “—Backup Withholding and Information Reporting” and “—Foreign Accounts” for additional withholding rules that may apply to dividends paid to certain foreign financial institutions or non-financial foreign entities.

### ***Disposition of Our Common Stock or Warrants***

Subject to the discussions below under the sections titled “—Backup Withholding and Information Reporting” and “—Foreign Accounts” a Non-U.S. Holder generally will not be subject to U.S. federal income or withholding tax with respect to gain realized on a sale or other disposition of our common stock or warrants unless:

- the gain is effectively connected with the Non-U.S. Holder’s conduct of a trade or business in the United States, and if an applicable income tax treaty so provides, the gain is attributable to a permanent establishment or fixed base maintained by the Non-U.S. Holder in the United States; in these cases, the Non-U.S. Holder will be taxed on a net income basis at the regular graduated rates and in the manner applicable to U.S. persons, and if the Non-U.S. Holder is a corporation, an additional branch profits tax at a rate of 30%, or a lower rate as may be specified by an applicable income tax treaty, may also apply;

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- the Non-U.S. Holder is a nonresident alien present in the United States for 183 days or more in the taxable year of the disposition and certain other requirements are met, in which case the Non-U.S. Holder will be subject to a 30% tax (or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence) on the net gain derived from the disposition, which may be offset by certain U.S.-source capital losses of the Non-U.S. Holder, if any; or
- our common stock constitutes a U.S. real property interest because we are, or have been at any time during the five-year period preceding such disposition (or the Non-U.S. Holder's holding period for the common stock or warrants, if shorter), a "U.S. real property holding corporation," unless our common stock is regularly traded on an established securities market and the Non-U.S. Holder held no more than 5% of our outstanding common stock, directly or indirectly, during the shorter of the five-year period ending on the date of the disposition or the period that the Non-U.S. Holder held our common stock. Special rules may apply to the determination of the 5% threshold in the case of a holder of a warrant. Non-U.S. Holders are urged to consult their own tax advisors regarding the effect of holding our warrants on the calculation of such 5% threshold. Generally, a corporation is a "U.S. real property holding corporation" if the fair market value of its "U.S. real property interests" (as defined in the Code and applicable regulations) equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests plus its other assets used or held for use in a trade or business. Although there can be no assurance, we believe that we are not currently, and we do not anticipate becoming, a "U.S. real property holding corporation" for U.S. federal income tax purposes. No assurance can be provided that our common stock will be regularly traded on an established securities market for purposes of the rules described above. Special rules may apply to non-U.S. holders of pre-funded warrants, who should consult their tax advisors. Non-U.S. Holders are urged to consult their own tax advisors regarding the U.S. federal income tax considerations that could result if we are, or become, a "U.S. real property holding corporation."

### ***Backup Withholding and Information Reporting***

We must report annually to the IRS and to each Non-U.S. Holder the gross amount of the distributions (including constructive distributions) on our common stock or warrants paid to such holder and the tax withheld, if any, with respect to such distributions. Non-U.S. Holders may have to comply with specific certification procedures to establish that the holder is not a U.S. person (as defined in the Code) in order to avoid backup withholding at the applicable rate, currently 24%, with respect to dividends (or constructive dividends) on our common stock or warrants. Generally, a holder will comply with such procedures if it provides a properly executed IRS Form W-8BEN, IRS Form W-8BEN-E (or other applicable IRS Form W-8) or otherwise meets documentary evidence requirements for establishing that it is a Non-U.S. Holder, or otherwise establishes an exemption. Dividends paid to Non-U.S. Holders subject to withholding of U.S. federal income tax, as described above under the heading "—Dividends," will generally be exempt from U.S. backup withholding.

Information reporting and backup withholding generally will apply to the proceeds of a disposition of our common stock or warrants by a Non-U.S. Holder effected by or through the U.S. office of any broker, U.S. or foreign, unless the holder certifies its status as a Non-U.S. Holder and satisfies certain other requirements, or otherwise establishes an exemption. Generally, information reporting and backup withholding will not apply to a payment of disposition proceeds to a Non-U.S. Holder where the transaction is effected outside the United States through a non-U.S. office of a broker. However, for information reporting purposes, dispositions effected through a non-U.S. office of a broker with substantial U.S. ownership or operations generally will be treated in a manner similar to dispositions effected through a U.S. office of a broker. Non-U.S. Holders should consult their own tax advisors regarding the application of the information reporting and backup withholding rules to them.

Copies of information returns may be made available to the tax authorities of the country in which the Non-U.S. Holder resides or is incorporated under the provisions of a specific treaty or agreement.

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Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules from a payment to a Non-U.S. Holder can be refunded or credited against the Non-U.S. Holder's U.S. federal income tax liability, if any, provided that an appropriate claim is timely filed with the IRS.

### *Foreign Accounts*

Code Sections 1471-1474, commonly referred to as the Foreign Account Tax Compliance Act, or FATCA, and the Treasury Regulations issued thereunder generally impose a U.S. federal withholding tax of 30% on dividends on, and, subject to the proposed Treasury Regulations discussed below, the gross proceeds from a sale or other disposition of, our common stock or warrants such institution enters into an agreement with the U.S. government to, among other things, withhold on certain payments and to collect and provide to the U.S. tax authorities substantial information regarding the U.S. account holders of such institution (which include certain equity and debt holders of such institution, as well as certain account holders that are foreign entities with U.S. owners) or otherwise establishes an exemption. FATCA also generally imposes a U.S. federal withholding tax of 30% on dividends on, and, subject to the proposed Treasury Regulations discussed below, the gross proceeds from a sale or other disposition of, our common stock or warrants paid to a "non-financial foreign entity" (as defined under these rules) unless such entity provides the withholding agent with a certification identifying the direct and indirect U.S. owners of the entity, certifies that it does not have any substantial U.S. owners, or otherwise establishes an exemption. The withholding obligations under FATCA generally apply to dividends on our common stock or warrants. The U.S. Department of the Treasury has issued proposed Treasury Regulations providing that, if finalized in their present form, the withholding obligations under FATCA would not apply with respect to payment of gross proceeds from a sale or other disposition of common stock or warrants. The proposed Treasury Regulations may be relied upon until final Treasury Regulations are issued. Under certain circumstances, a non-U.S. holder might be eligible for refunds or credits of taxes withheld under FATCA. An intergovernmental agreement between the United States and an applicable foreign country may modify the requirements described in this paragraph. Non-U.S. Holders are encouraged to consult with their own tax advisors regarding the possible implications of FATCA on their investment in our common stock or warrants.

**The preceding discussion of material U.S. federal tax considerations is for information only. It is not tax advice. Prospective investors should consult their own tax advisors regarding the particular U.S. federal, state, local and non-U.S. tax consequences of purchasing, holding and disposing of our common stock, pre-funded warrants or warrants, including the consequences of any proposed changes in applicable laws.**

## UNDERWRITING

We entered into an underwriting agreement with the underwriters named below on \_\_\_\_\_, 2022. Oppenheimer & Co. Inc. is acting as the representative of the underwriters. The underwriting agreement provides for the purchase of a specific number of shares of common stock and accompanying common warrants to purchase shares of common stock and/or pre-funded warrants and accompanying common warrants by each of the underwriters. The underwriters' obligations are several, which means that each underwriter is required to purchase a specified number of shares of common stock accompanying common warrants and/or pre-funded warrants accompanying common warrants, but is not responsible for the commitment of any other underwriter to purchase shares of common stock and/or pre-funded warrants. Subject to the terms and conditions of the underwriting agreement, each underwriter has severally agreed to purchase the number of shares of common stock, pre-funded warrants and common warrants set forth opposite its name below:

	<b>Number of Shares of Common Stock</b>	<b>Number of Pre-Funded Warrants</b>	<b>Number of Common Warrants</b>
Oppenheimer & Co. Inc.			

The underwriters have agreed to purchase all of the shares of common stock and/or pre-funded warrants and accompanying common warrants offered by this prospectus supplement, if any are purchased.

The shares of common stock and pre-funded warrants and accompanying common warrants offered hereby are expected to be ready for delivery on or about \_\_\_\_\_, 2022 against payment in immediately available funds.

The underwriters are offering the shares of common stock and accompanying common warrants and/or pre-funded warrants and accompanying common warrants subject to various conditions and may reject all or part of any order. The representative of the underwriters has advised us that the underwriters propose initially to offer the shares of common stock and accompanying common warrants and/or pre-funded warrants and accompanying common warrants to the public at the public offering price set forth on the cover page of this prospectus supplement and to dealers at a price less a concession not in excess of \_\_\_\_\_ per share of common stock and accompanying common warrants and/or pre-funded warrants and accompanying common warrants to brokers and dealers. After the shares of common stock and accompanying common warrants and pre-funded warrants and accompanying common warrants are released for sale to the public, the representative may change the offering price, the concession, and other selling terms at various times.

The following table provides information regarding the amount of the discounts and commissions to be paid to the underwriters by us, before expenses:

	<b>PER SHARE</b>	<b>PER PRE-FUNDED WARRANT</b>	<b>PER COMMON WARRANT</b>	<b>TOTAL PER SHARE AND ACCOMPANYING COMMON WARRANT</b>	<b>TOTAL PER PRE-FUNDED WARRANT AND ACCOMPANYING COMMON WARRANT</b>
Public offering price	\$	\$	\$	\$	\$
Underwriting discount and commissions(1)	\$	\$	\$	\$	\$
Proceeds, before expenses, to us	\$	\$	\$	\$	\$

(1) We have agreed to pay the underwriters a commission of 6% of the gross proceeds raised in the offering from investors, except that with respect to certain investors, we have agreed to pay the underwriters 3% of the gross proceeds raised in the offering.

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We estimate that our total expenses of the offering, excluding the estimated underwriting discounts and commissions, will be approximately \$\_\_\_\_\_, which includes the fees and expenses for which we have agreed to reimburse the underwriter, including fees and expenses of its counsel, up to a maximum aggregate amount of \$100,000.

Certain of our existing stockholders, who are affiliated with certain of our directors, have indicated an interest in purchasing securities in this offering at the public offering price. However, because their indications of interest are not binding agreements or commitments to purchase, the underwriters may sell more, less or no securities in this offering to any or all of these persons, or any or all of these persons may determine to purchase more, less or no securities in this offering. Except as otherwise set forth in this prospectus supplement, the underwriters will receive the same underwriting discount on any securities purchased by these stockholders as they will on any other securities sold to the public in this offering.

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

We and our officers and directors have agreed to a 90-day “lock-up” with respect to our shares of common stock and other of our securities that they beneficially own, including securities that are convertible into shares of common stock and securities that are exchangeable for or exercisable into shares of common stock. This means that, subject to certain exceptions, for a period of 90 days following the date of this prospectus supplement, we and such persons may not offer, sell, pledge or otherwise dispose of these securities without the prior written consent of Oppenheimer & Co. Inc.

Rules of the SEC may limit the ability of the underwriters to bid for or purchase shares of common stock before the distribution of the shares of common stock is completed. However, the underwriters may engage in the following activities in accordance with the rules:

- Stabilizing transactions — The representative may make bids or purchases for the purpose of pegging, fixing or maintaining the price of the shares of common stock, so long as stabilizing bids do not exceed a specified maximum.
- Penalty bids — If the representative purchases shares of common stock in the open market in a stabilizing transaction or syndicate covering transaction, it may reclaim a selling concession from the underwriters and selling group members who sold those shares of common stock as part of this offering.
- Passive market making — Market makers in the shares of common stock who are underwriters or prospective underwriters may make bids for or purchases of shares of common stock, subject to limitations, until the time, if ever, at which a stabilizing bid is made.

Similar to other purchase transactions, the underwriters’ purchases to cover the syndicate short sales or to stabilize the market price of our shares of common stock may have the effect of raising or maintaining the market price of our shares of common stock or preventing or mitigating a decline in the market price of our shares of common stock. As a result, the price of the shares of our common stock may be higher than the price that might otherwise exist in the open market. The imposition of a penalty bid might also have an effect on the price of the shares of common stock if it discourages resales of the shares of common stock.

Neither we nor the underwriters make any representation or prediction as to the effect that the transactions described above may have on the price of the shares of common stock or value of the pre-funded warrants. These transactions may occur on Nasdaq or otherwise. If such transactions are commenced, they may be discontinued without notice at any time.

The underwriters and certain of their affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. Some of the underwriters and certain of their affiliates may in the future engage in investment

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banking and other commercial dealings in the ordinary course of business with us and our affiliates, for which they may in the future receive customary fees, commissions and expenses.

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

### **Electronic Delivery of Prospectus**

A prospectus supplement in electronic format may be delivered to potential investors by one or more of the underwriters participating in this offering. The prospectus supplement in electronic format will be identical to the paper version of such prospectus supplement. Other than the prospectus supplement in electronic format, the information on any underwriter's website and any information contained in any other website maintained by an underwriter is not part of this prospectus supplement, the accompanying prospectus or the registration statement of which this prospectus supplement and the accompanying prospectus form a part.

### **Notice to Non-U.S. Investors**

#### *Belgium*

The offering is exclusively conducted under applicable private placement exemptions and therefore it has not been and will not be notified to, and this document or any other offering material relating to the securities has not been and will not be approved by, the Belgian Banking, Finance and Insurance Commission ("Commission bancaire, financière et des assurances/Commissie voor het Bank, Financie en Assurantiewezen"). Any representation to the contrary is unlawful.

The underwriter has undertaken not to offer sell, resell, transfer or deliver directly or indirectly, any securities, or to take any steps relating/ancillary thereto, and not to distribute or publish this document or any other material relating to the securities or to the offering in a manner which would be construed as: (a) a public offering under the Belgian Royal Decree of 7 July 1999 on the public character of financial transactions; or (b) an offering of securities to the public under Regulation (EU) 2017/1129 which triggers an obligation to publish a prospectus in Belgium. Any action contrary to these restrictions will cause the recipient and the company to be in violation of the Belgian securities laws.

#### *Canada*

This document constitutes an "exempt offering document" as defined in and for the purposes of applicable Canadian securities laws. No prospectus has been filed with any securities commission or similar regulatory authority in Canada in connection with the offer and sale of the securities described herein (the "Securities").

No securities commission or similar regulatory authority in Canada has reviewed or in any way passed upon this document or on the merits of the Securities and any representation to the contrary is an offence.

Canadian investors are advised that this document has been prepared in reliance on section 3A.3 of National Instrument 33-105 Underwriting Conflicts ("NI 33-105"). Pursuant to section 3A.3 of NI 33-105, this document is exempt from the requirement to provide investors with certain conflicts of interest disclosure pertaining to "connected issuer" and/or "related issuer" relationships as would otherwise be required pursuant to subsection 2.1(1) of NI 33-105.

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### *Resale Restrictions*

The offer and sale of the securities in Canada is being made on a private placement basis only and is exempt from the requirement to prepare and file a prospectus under applicable Canadian securities laws. Any resale of Securities acquired by a Canadian investor in this offering must be made in accordance with applicable Canadian securities laws, which may vary depending on the relevant jurisdiction, and which may require resales to be made in accordance with Canadian prospectus requirements, a statutory exemption from the prospectus requirements, in a transaction exempt from the prospectus requirements or otherwise under a discretionary exemption from the prospectus requirements granted by the applicable local Canadian securities regulatory authority. These resale restrictions may under certain circumstances apply to resales of the Securities outside of Canada.

### *Representations of Purchasers*

Each Canadian investor who purchases the Securities will be deemed to have represented to the issuer and to each dealer from whom a purchase confirmation is received, as applicable, that the investor (i) is purchasing as principal, or is deemed to be purchasing as principal in accordance with applicable Canadian securities laws, for investment only and not with a view to resale or redistribution; (ii) is an “accredited investor” as such term is defined in section 1.1 of National Instrument 45-106 Prospectus Exemptions (“NI 45-106”) or, in Ontario, as such term is defined in section 73.3(1) of the Securities Act (Ontario); and (iii) is a “permitted client” as such term is defined in section 1.1 of National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligations.

### *Taxation and Eligibility for Investment*

Any discussion of taxation and related matters contained in this document does not purport to be a comprehensive description of all of the tax considerations that may be relevant to a Canadian investor when deciding to purchase the Securities and, in particular, does not address any Canadian tax considerations. No representation or warranty is hereby made as to the tax consequences to a resident, or deemed resident, of Canada of an investment in the Securities or with respect to the eligibility of the Securities for investment by such investor under relevant Canadian federal and provincial legislation and regulations.

### *Rights of Action for Damages or Rescission*

Securities legislation in certain of the Canadian jurisdictions provides certain purchasers of securities pursuant to an offering memorandum, including where the distribution involves an “eligible foreign security” as such term is defined in Ontario Securities Commission Rule 45-501 *Ontario Prospectus and Registration Exemptions* and in Multilateral Instrument 45-107 *Listing Representation and Statutory Rights of Action Disclosure Exemptions*, as applicable, with a remedy for damages or rescission, or both, in addition to any other rights they may have at law, where the offering memorandum, or other offering document that constitutes an offering memorandum, and any amendment thereto, contains a “misrepresentation” as defined under applicable Canadian securities laws. These remedies, or notice with respect to these remedies, must be exercised or delivered, as the case may be, by the purchaser within the time limits prescribed under, and are subject to limitations and defenses under, applicable Canadian securities legislation. In addition, these remedies are in addition to and without derogation from any other right or remedy available at law to the investor.

### *Language of Documents*

Upon receipt of this document, each Canadian investor hereby confirms that it has expressly requested that all documents evidencing or relating in any way to the sale of the securities described herein (including for greater certainty any purchase confirmation or any notice) be drawn up in the English language only. *Par la réception de ce document, chaque investisseur canadien confirme par les présentes qu’il a expressément exigé que tous les documents faisant foi ou se rapportant de quelque manière que ce soit à la vente des valeurs mobilières décrites aux présentes (incluant, pour plus de certitude, toute confirmation d’achat ou tout avis) soient rédigés en anglais seulement.*

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### *France*

Neither this prospectus supplement nor any other offering material relating to the securities has been submitted to the clearance procedures of the Autorité des marchés financiers in France. The securities have not been offered or sold and will not be offered or sold, directly or indirectly, to the public in France. Neither this prospectus supplement nor any other offering material relating to the securities has been or will be: (a) released, issued, distributed or caused to be released, issued or distributed to the public in France; or (b) used in connection with any offer for subscription or sale of the securities to the public in France. Such offers, sales and distributions will be made in France only: (i) to qualified investors (investisseurs qualifiés) and/or to a restricted circle of investors (cercle restreint d'investisseurs), in each case investing for their own account, all as defined in and in accordance with Articles L.411-2, D.411-1, D.411-2, D.734-1, D.744-1, D.754-1 and D.764-1 of the French Code monétaire et financier; (ii) to investment services providers authorised to engage in portfolio management on behalf of third parties; or (iii) in a transaction that, in accordance with article L.411-2-II-1° -or-2° -or 3° of the French Code monétaire et financier and article 211-2 of the General Regulations (Règlement Général) of the Autorité des marchés financiers, does not constitute a public offer (appel public à l'épargne). Such shares of common stock may be resold only in compliance with Articles L.411-1, L.411-2, L.412-1 and L.621-8 through L.621-8-3 of the French Code monétaire et financier.

### *Israel*

This document does not constitute a prospectus under the Israeli Securities Law, 5728-1968 (the "Securities Law"), and has not been filed with or approved by the Israel Securities Authority. In the State of Israel, this document is being distributed only to, and is directed only at, and any offer of the securities is directed only at, investors listed in the first addendum to the Israeli Securities Law (the "Addendum"), consisting primarily of joint investment in trust funds, provident funds, insurance companies, banks, portfolio managers, investment advisors, members of the Tel Aviv Stock Exchange, underwriters, venture capital funds, entities with equity in excess of NIS 50 million and "qualified individuals", each as defined in the Addendum (as it may be amended from time to time), collectively referred to as qualified investors (in each case purchasing for their own account or, where permitted under the Addendum, for the accounts of their clients who are investors listed in the Addendum). Qualified investors will be required to submit written confirmation that they fall within the scope of the Addendum, are aware of the meaning of same and agree to it.

### *Italy*

The offering of the securities offered hereby in Italy has not been registered with the Commissione Nazionale per la Società e la Borsa ("CONSOB") pursuant to Italian securities legislation and, accordingly, the securities offered hereby cannot be offered, sold or delivered in the Republic of Italy ("Italy") nor may any copy of this prospectus supplement or any other document relating to the shares offered hereby be distributed in Italy other than to professional investors (operatori qualificati) as defined in Article 31, second paragraph, of CONSOB Regulation No. 11522 of 1 July, 1998 as subsequently amended. Any offer, sale or delivery of the securities offered hereby or distribution of copies of this prospectus supplement or any other document relating to the securities offered hereby in Italy must be made:

- (a) by an investment firm, bank or intermediary permitted to conduct such activities in Italy in accordance with Legislative Decree No. 58 of 24 February 1998 and Legislative Decree No. 385 of 1 September 1993 (the "Banking Act");
- (b) in compliance with Article 129 of the Banking Act and the implementing guidelines of the Bank of Italy; and
- (c) in compliance with any other applicable laws and regulations and other possible requirements or limitations which may be imposed by Italian authorities.

### *Sweden*

This prospectus supplement has not been nor will it be registered with or approved by Finansinspektionen (the Swedish Financial Supervisory Authority). Accordingly, this prospectus supplement may not be made

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available, nor may the securities offered hereunder be marketed and offered for sale in Sweden, other than under circumstances which are deemed not to require a prospectus under the Financial Instruments Trading Act (1991: 980).

### *Switzerland*

The securities offered pursuant to this prospectus supplement will not be offered, directly or indirectly, to the public in Switzerland and this prospectus supplement does not constitute a public offering prospectus as that term is understood pursuant to art. 652a or art. 1156 of the Swiss Federal Code of Obligations. The company has not applied for a listing of the securities being offered pursuant to this prospectus supplement on the SWX Swiss Exchange or on any other regulated securities market, and consequently, the information presented in this prospectus supplement does not necessarily comply with the information standards set out in the relevant listing rules. The securities being offered pursuant to this prospectus supplement have not been registered with the Swiss Federal Banking Commission as foreign investment funds, and the investor protection afforded to acquirers of investment fund certificates does not extend to acquirers of securities.

Investors are advised to contact their legal, financial or tax advisers to obtain an independent assessment of the financial and tax consequences of an investment in securities.

### *United Kingdom/Germany/Norway/The Netherlands*

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

- (a) to any legal entity which is a qualified investor as defined under Article 2 of the Prospectus Regulation;
- (b) to fewer than 150 natural or legal persons (other than qualified investors as defined under Article 2 of the Prospectus Regulation) subject to obtaining the prior consent of the Joint Global Coordinators for any such offer; or
- (d) in any other circumstances falling within Article 1(4) of the Prospectus Regulation, provided that no such offer of shares of common stock shall result in a requirement for the publication by the company or any underwriter of a prospectus pursuant to Article 23 of the Prospectus Regulation.

For the purposes of this provision, the expression an “offer to the public” in relation to any shares of common stock in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares of common stock to be offered so as to enable an investor to decide to purchase any shares of common stock, as the same may be varied in that Member State by any measure implementing the Prospectus Regulation in that Member State and the expression “Prospectus Regulation” means Regulation (EU) 2017/1129.

Each underwriter has represented, warranted and agreed that:

- (a) it has only communicated or caused to be communicated and will only communicate or cause to be communicated any invitation or inducement to engage in investment activity (within the meaning of section 21 of the Financial Services and Markets Act 2000 (the FSMA)) received by it in connection with the issue or sale of any shares of common stock in circumstances in which section 21(1) of the FSMA does not apply to the company; and

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- (b) it has complied with and will comply with all applicable provisions of the FSMA with respect to anything done by it in relation to the shares of common stock in, from or otherwise involving the United Kingdom.

## **LEGAL MATTERS**

The validity of the shares of common stock and pre-funded warrants offered hereby will be passed upon for us by Wilson Sonsini Goodrich & Rosati, P.C., Palo Alto, California. Certain legal matters in connection with this offering will be passed upon for the underwriters by Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C., New York, New York.

## **EXPERTS**

Marcum LLP, an independently registered public accounting firm has audited our financial statements as of and for each of the years in the two-year period ended December 31, 2020. 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 and other reports, proxy statements and other information with the SEC. The SEC maintains a web site that contains periodic and current reports, proxy and information statements and other information about issuers, such as us, that file electronically with the SEC. The address of that website is [www.sec.gov](http://www.sec.gov).

Our web site address is [www.soleno.life](http://www.soleno.life). The information on our web site, or that can be accessed through our web site, however, is not, and should not be deemed to be, a part of this prospectus supplement.

## INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

We have filed a registration statement on Form S-3 with the SEC under the Securities Act. The accompanying prospectus is part of the registration statement but the registration statement includes and incorporates by reference additional information and exhibits. The SEC permits us to “incorporate by reference” the information contained in documents we file with the SEC, which means that we can disclose important information to you by referring you to those documents rather than by including them in this prospectus supplement or the accompanying prospectus. Information that is incorporated by reference is considered to be part of this prospectus supplement and the accompanying prospectus and you should read it with the same care that you read this prospectus supplement and the accompanying prospectus. Later information that we file with the SEC will automatically update and supersede the information that is either contained, or incorporated by reference, in this prospectus supplement and the accompanying prospectus, and will be considered to be a part of this prospectus supplement and the accompanying prospectus from the date those documents are filed. We have filed with the SEC, and incorporate by reference in this prospectus supplement and the accompanying prospectus:

- Our Annual Report on [Form 10-K](#), or our 2020 Annual Report, for the fiscal year ended December 31, 2020 filed on March 3, 2021;
- Our Quarterly Reports on Form 10-Q, for the fiscal quarters ended March 31, 2021, June 30, 2021 and September 30, 2021 filed on [May 5, 2021](#), [July 28, 2021](#) and [November 10, 2021](#), respectively;
- The information specifically incorporated by reference into our 2020 Annual Report from our definitive proxy statement on [Schedule 14A](#), filed with the SEC on April 21, 2021, that are deemed “filed” with the SEC under the Exchange Act;
- The description of our common stock incorporated by reference from [Exhibit 4.29](#) to our 2020 Annual Report;
- Our Current Reports on Form 8-K filed on [January 13, 2021](#), [February 5, 2021](#), [March 8, 2021](#), [April 15, 2021](#), [June 3, 2021](#), [June 16, 2021](#), [July 16, 2021](#), [September 17, 2021](#), [December 30, 2021](#), [January 24, 2022](#), [January 31, 2022](#), [March 18, 2022](#), and March 28, 2022;
- 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 any future filings (other than current reports furnished under Item 2.02 or Item 7.01 of Form 8-K and exhibits filed on such form that are related to such items unless such Form 8-K expressly provides to the contrary) made with the SEC pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act until we file a post-effective amendment that indicates the termination of the offering of the securities made by this prospectus supplement and will become a part of this prospectus supplement from the date that such documents are filed with the SEC. Information in such future filings updates and supplements the information provided in this prospectus supplement. Any statements in any such future filings will automatically be deemed to modify and supersede any information in any document we previously filed with the SEC that is incorporated or deemed to be incorporated herein by reference to the extent that statements in the later filed document modify or replace such earlier statements.

We will furnish without charge to each person, including any beneficial owner, to whom a prospectus is delivered, upon written or oral request, a copy of any or all of the documents incorporated by reference, including exhibits to these documents. Any such request may be made by writing or telephoning us at the following address or phone number:

Soleno Therapeutics, Inc.  
203 Redwood Shores Parkway  
Suite 500  
Redwood City, California 94065  
(650) 213-8444

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We will not, however, send exhibits to those documents, unless the exhibits are specifically incorporated by reference in those documents.

We make available free of charge on our website our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports, as soon as reasonably practicable after we electronically file or furnish such materials to the SEC. You may obtain a free copy of these reports on the Investor Relations section of our website, [www.soleno.life](http://www.soleno.life).

PROSPECTUS



# SOLENO THERAPEUTICS, INC.

**\$100,000,000**

## **Common Stock Warrants**

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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 supplement. We may also authorize one or more free writing prospectuses to be provided to you in connection with these offerings. Any prospectus 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 over-allotment 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 16 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.

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**This prospectus is dated February 9, 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” “Solenio Therapeutics,” “we,” “us”, and “our” refer to Solenio Therapeutics, Inc.*

### Overview

Solenio 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<sup>+</sup> 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  $29.5 \pm 15$  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 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. 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 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 an 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](http://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

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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.

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.

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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 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;
- 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;

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- 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
- 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 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

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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.

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

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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](http://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

You may also access the documents incorporated by reference in this prospectus through our website at [www.soleno.life](http://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.



**Shares of Common Stock**

<b>Pre-Funded Warrants to Purchase up to</b>	<b>Shares of Common Stock</b>
<b>Warrants to Purchase up to</b>	<b>Shares of Common Stock</b>

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**PROSPECTUS SUPPLEMENT**

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*Sole Book-Running Manager*

**Oppenheimer & Co.**

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