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

FORM 10-K

(Mark One)

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

For the fiscal year ended: December 31, 2024

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

For the transition period from _____ to _____ .

Commission File No.: 001-36593

Soleno Therapeutics, Inc.

(Exact name of Registrant as specified in its charter)

Delaware	**77-0523891**
(State or other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**
100 Marine Parkway, Suite 400 Redwood City, California	**94065**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (650) 213-8444

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value	SLNO	NASDAQ

Securities Registered Pursuant to Section 12(g) of the Act: None.

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

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

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

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

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

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

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

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

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

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

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

The aggregate market value of stock held by non-affiliates of the registrant on June 28, 2024, based on the closing price of $40.80 for shares of the registrant's Common Stock as reported by the Nasdaq Capital Market, was approximately $1.4 billion. Shares of Common Stock held by each executive officer, director and beneficial holder of 5% or more of the outstanding Common Stock have been excluded in that such persons may be deemed affiliates.

As of February 26, 2025, there were 45,857,291 shares of the registrant's Common Stock, par value $0.001 per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Definitive Proxy Statement to be filed with the Commission pursuant to Regulation 14A in connection with the registrant's 2025 Annual Meeting of Stockholders, to be filed subsequent to the date hereof, are incorporated by reference into Part III of this Report. Such Definitive Proxy Statement will be filed with the Securities and Exchange Commission not later than 120 days after the conclusion of the registrant's fiscal year ended December 31, 2024. Except with respect to information specifically incorporated by reference in this Form 10-K, the Proxy Statement is not deemed to be filed as part of this Form 10-K.

Auditor Name: Marcum LLP Auditor Location: San Francisco, CA Auditor Firm ID: 688

Soleno Therapeutics, Inc.
Annual Report on Form 10-K
For the Year Ended December 31, 2024

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

The following discussion and analysis should be read in conjunction with our audited consolidated financial statements and the related notes that appear elsewhere in this Annual Report on Form 10-K. This Annual Report on Form 10-K contains "forward-looking statements" within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, particularly in Part I, Item 1: "Business," Part I, Item 1A: "Risk Factors" and Part 2, Item 7: "Management's Discussion and Analysis of Financial Condition and Results of Operations." These statements are often identified by the use of words such as "may," "will," "expect," "believe," "anticipate," "intend," "could," "should," "estimate," "plan" or "continue," and similar expressions or variations. All statements other than statements of historical fact could be deemed forward-looking, including, but not limited to: any statements regarding the timing of any regulatory process or ultimate approvals and determining a path forward for diazoxide choline extended-release tablets (DCCR) for the treatment of Prader-Willi syndrome; any projections of financial information; any plans or projections regarding the commercialization of DCCR; any statements about historical results that may suggest trends for our business; any statements of the plans, strategies, and objectives of management for future operations; any statements of expectation or belief regarding future events, technology developments, our products, product sales, expenses, liquidity, cash flow, market growth rates or enforceability of our intellectual property rights and related litigation expenses; and any statements of assumptions underlying any of the foregoing. Such forward-looking statements are subject to risks, uncertainties 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. Accordingly, we caution you not to place undue reliance on these statements. Particular uncertainties that could affect future results include: our ability to achieve or maintain profitability; our ability to obtain substantial additional capital that may be necessary to maintain or expand our business; our ability to maintain internal control over financial reporting; our dependence on, and need to attract and retain, key management and other personnel; our ability to obtain, protect and enforce our intellectual property rights; potential advantages that our competitors and potential competitors may have in securing funding or developing products; business interruptions such as earthquakes and other natural disasters; our ability to comply with laws and regulations; potential product liability claims; and our ability to use our net operating loss carryforwards to offset future taxable income. For a discussion of some of the factors that could cause actual results to differ materially from our forward-looking statements, see the discussion on risk factors that appear in Part I, Item 1A: "Risk Factors" of this Annual Report on Form 10-K and other risks and uncertainties detailed in this and our other reports and filings with the Securities and Exchange Commission, or SEC. The forward-looking statements in this Annual Report on Form 10-K represent our views as of the date of this Annual Report on Form 10-K. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Annual Report on Form 10-K.

PART I

ITEM 1. BUSINESS

Company Overview

We are a biopharmaceutical company developing novel therapeutics for the treatment of rare diseases. We have submitted a new drug application (NDA) to the U.S. Food and Drug Administration (FDA) for our lead product candidate, diazoxide choline extended-release tablets (DCCR) for the treatment of Prader-Willi syndrome (PWS) in individuals four years and older who have hyperphagia. On August 27, 2024, we announced that the FDA had accepted the NDA for filing, designated the application for priority review and set a Prescription Drug User Fee Act (PDUFA) target action date of December 27, 2024. On November 26, 2024, we announced that the FDA had extended the review period for our NDA and set a new PDUFA target action date of March 27, 2025. DCCR previously received Breakthrough Therapy and Fast-Track designations in the United States (U.S.) and Orphan Drug designations in the U.S. and European Union (E.U.).

DCCR contains diazoxide choline, a potent ATP-sensitive potassium (K_{ATP}) channel activator. The K_{ATP} channels play 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 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. Its proposed mode of action, with targets in the brain, pancreas and fat tissue, has the potential to broadly impact complex diseases like PWS to reduce appetite, reduce food seeking, decrease insulin and leptin resistance, and reduce body fat. We believe that it has the potential to reduce other problematic behaviors in PWS.

Diazoxide Choline Extended-Release Tablets

DCCR consists 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. It is believed to act 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) and Agouti-related peptile (AgRP), contributing to a reduction in hyperphagia. Activating the K_{ATP} channel in the dorsal motor nucleus of vagus may potentiate the effects of leptin, insulin and α-melanocortin stimulating hormone to reduce hyperinsulinemia and impact appetite and satiety. Activating the K_{ATP} in pancreatic ß-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 ß-oxidation of fat, reducing fat mass.

DCCR was 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 has been 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 potentially reducing the adverse events often associated with transiently high circulating drug levels and providing efficacy at lower diazoxide-equivalent doses.

Prader-Willi Syndrome (PWS)

PWS is a rare, complex genetic 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 (UPD), where the affected individual inherited 2 copies of the 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 has found that PWS affects both genders equally and occurs in people from all geographic regions, The Prader-Willi Syndrome Association USA estimates that PWS occurs in one in every 15,000 live births. The mortality rate among patients with PWS has been estimated at 3% a year across all ages and 7% in those over 30 years of age. The mean age of death reported from a 40-year mortality study in the U.S. was 29.5 ± 15 years (range: 2 months—67 years).

In addition to hyperphagia, typical behavioral disturbances associated with PWS include skin picking, difficulty with change in routine, obsessive and compulsive behaviors, anxiety and mood fluctuations. The majority of older adolescents and adults with PWS 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 was typically thought of as a genetic obesity. However, many patients with PWS 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 patients with PWS ages 4 years and older who have hyperphagia. 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 a very important or the most important symptom to be relieved by a new treatment. 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 are clear unmet needs in patients with PWS to reduce hyperphagia, improve behaviors around food, and to reduce other behavioral and cognitive impacts of this complex disease. In addition, improving metabolic health is also an important unmet need.

Clinical Trials of DCCR for PWS

A Phase 2 clinical trial (Study PC025) was a single-center, randomized withdrawal study to evaluate the safety and preliminary efficacy of DCCR in the treatment of PWS subjects. This study enrolled 13 overweight and obese subjects with genetically-confirmed PWS who were between the ages of 11 and 21. This study included 10-week open-label treatment phase was followed by randomized double-blind, placebo-controlled, withdrawal phase.

Key efficacy results included nominally significant reductions from baseline to the end of the open-label treatment phase in mean hyperphagia score, number of subjects reporting one or more aggressive and destructive

behaviors, mean body fat mass, LDL cholesterol and non-HDL cholesterol. There were also nominally significant mean increases in lean body mass and lean body mass / fat mass ratio that were associated with a nominally significant reduction in mean waist circumference, consistent with the loss of visceral fat.

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.

DCCR was subsequently 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 United Kingdom (U.K.). Participants who completed 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.

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 September 2021, we announced interim one-year data from the C602 open-label extension (OLE) period showing statistically significant reduction from pre-DCCR baseline in mean hyperphagia scores and all other PWS behavioral parameters and statistically significant improvements compared to natural history of PWS from the PATH for PWS Study (PATH) over a one-year treatment period. The PATH study was sponsored by the Foundation for Prader-Willi Research (FPWR) to advance the understanding of the natural history in individuals with PWS. The FDA recommended that additional controlled data be included in an NDA submission.

In March 2022, we submitted an amended protocol that incorporated a randomized withdrawal (RW) period to Study C602 to obtain additional controlled data requested by the FDA and the FDA acknowledged that data from the study had the potential to address its concerns about the efficacy of DCCR. The RW period of Study C602 was a multi-center, randomized, double-blind, placebo-controlled study of DCCR in 77 patients with PWS at 17 sites in the U.S. and 5 sites in the U.K. The RW period consisted only of patients previously enrolled in the Study C602 OLE period and did not enroll any new patients. We announced the initiation of the RW period for Study C602 in October 2022, and completed enrollment in May 2023.

On September 26, 2023, we announced positive statistically significant results for the primary endpoint from the RW period of Study C602. As discussed above, we submitted our NDA for DCCR to the FDA on June 27, 2024. On August 27, 2024, we announced that the FDA had accepted the NDA for filing and priority review and set a PDUFA target action date of December 27, 2024. On November 26, 2024, we announced that the FDA had extended the review period for our NDA and set a new PDUFA target action date of March 27, 2025.

Safety of DCCR in the Treatment of PWS

Across the combined C601 (DESTINY-PWS), and C602 long-term OLE studies (which included DCCR treatment durations of up to ~4.5 years), 98.4% of participants reported treatment emergent adverse events (TEAEs). Most were grade 1 or 2 (75.2%), with no grade 4 or higher events. The most common TEAEs were hypertrichosis (68.8%), peripheral edema (34.4%), hirsutism (47.8% of female participants) and hyperglycemia (27.2%).

The majority of participants with hypertrichosis, hirsutism, or hyperglycemia experienced resolution or improvement of their symptoms with continued DCCR dosing through the end of the study. Infrequently, DCCR dose adjustments or glucose-lowering agents (for hyperglycemia) and diuretics (for peripheral edema) were prescribed to manage participants experiencing these TEAEs.

Two participants, both with known histories of psychiatric illnesses, reported a suspected unexpected serious adverse reaction (SUSAR) in the ongoing C614 open label extension study. One of the participants reported a SUSAR of aggression and the other participant reported a SUSAR of a major depressive episode.

Overall, the safety profile of DCCR in the Phase 3 PWS clinical development program was generally consistent with the known safety profile of diazoxide and prior experience with DCCR.

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 has Breakthrough Therapy and Fast-Track designations in the U.S. and Orphan Drug designations in the U.S. and E.U.

On April 29, 2024, we announced that the FDA granted Breakthrough Therapy Designation to diazoxide choline for the treatment of adults and children ages 4 years and older with genetically confirmed PWS who have hyperphagia. The designation reflects the FDA's determination that, based on an assessment of the preliminary data from the Phase 3 clinical development program, diazoxide choline may demonstrate substantial improvement on a clinically significant endpoint(s) over available therapies. The FDA's Breakthrough Therapy Designation is intended to expedite the development and review of drugs in the United States that are intended to treat a serious condition, when preliminary clinical evidence indicates the drug may demonstrate substantial improvement over available therapy on a clinically significant endpoint(s). With Breakthrough Therapy Designation, the FDA provides intensive guidance and organizational commitment involving senior managers in a proactive, collaborative, cross-disciplinary review, and may also allow for priority review and other actions to expedite review.

Market opportunity

An estimated 300,000 to 400,000 individuals worldwide have PWS with a birth incidence ranging from 1 in 15,000 to 1 in 25,000. Based on an analysis of claims data (Medicare, Medicaid, pharmacy and medical benefit claims), we have identified approximately 10,000 people who have received a PWS-specific treatment or had a PWS-specific IDC10 claim in 2022 or 2023. We believe that the number of identified patients with PWS is growing at a rate that is higher than the rate of general population because of improved rates of diagnosis. If approved on or before the current PDUFA date, DCCR would be the first treatment for hyperphagia in patients with PWS to reach the market in the U.S. and may therefore be likely to be used in a large proportion of patients.

Sales and Marketing

The majority of the PWS population in the U.S. is diagnosed shortly after birth through an affordable genetic test, and the patient, as well as their treating physician, are captured in a commercially available reimbursement claims database. Based on our analysis of this database, we believe that approximately 300 healthcare providers are either directly prescribing or influencing the prescription of approximately 40% of the PWS patient population. Patients with PWS are typically treated by a multi-disciplinary team led by a pediatric or adult endocrinologist and many families and patients receive care at larger clinics that devote specific resources to caring for people with PWS. The PWS care teams with the largest volumes are often in university-associated hospitals or children's hospitals and a portion of adults with PWS live in residential group home settings. Due to these factors, we believe we are positioned to launch DCCR following approval in the U.S. through our commercial organization in a targeted and efficient manner.

In anticipation of FDA approval of DCCR, we are building out our commercial organization across Marketing, Sales, and Patient Support functions to support demand, with the goal of delivering an exceptional provider, patient and caregiver experience. We have substantially completed hiring of all senior leadership roles in the commercial team, including adding industry veterans with extensive experience in the rare disease space and are in process of onboarding a field force of approximately 30 individuals.

The commercial team has already made substantial progress in executing on its foundational commercial strategy, including extensive demand assessment and marketplace analysis, payer research and outreach, selection and submission of a proprietary name, selection of an advertising agency, onboarding of a special pharmacy partner to provide patient, caregiver, prescriber and payer services, obtaining relevant state licensures, the implementation of a customer relationship management system, and the development of a patient services program. The specialty pharmacy will also serve as our point of contact for inbound health care provider and patient inquiries, prescription processing, insurance investigation and patient on-boarding.

We believe a comparable concentration of care exists in Europe and other major markets which may allow us to market DCCR without a partner; however, we may identify commercialization partners for DCCR for many markets. The final decision on commercialization strategy outside the U.S. will be made at a later date.

Pricing

We are in the process of conducting a formal pricing analysis of DCCR in PWS. We anticipate that pricing at launch will be influenced by the product label negotiated with the FDA and data developed to support pricing.

Competition

The biotechnology and pharmaceutical industries are highly competitive and characterized by rapid technological change. We face competition in each of the aspects of our business from other pharmaceutical and biotechnology companies, as well as academic research institutions, clinical reference laboratories and governmental agencies that are pursuing research or development activities similar to ours. Our competitors may succeed in developing products faster than we do and obtaining approvals from the FDA or other regulatory agencies for those products earlier than we do. In addition, our competitors may develop products that are more effective than those we develop or commercialize products more effectively and profitably than we do.

Currently, the only approved products for patients with PWS in the U.S. 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 Acadia Pharmaceuticals, Aardvark Therapeutics, Consynance, Neuren Pharmaceuticals, OT4B and Rhythm Pharmaceuticals.

We believe that our ability to successfully compete with these potentially competitive drug candidates will depend on, among other things:

- the efficacy and safety of DCCR;
- our ability to obtain regulatory approvals for DCCR and complete any post-marketing requirements (PMRs);
- the timing and scope of regulatory approvals of DCCR;
- our ability to obtain product acceptance by physicians and other healthcare providers and secure coverage and adequate reimbursement for DCCR use in approved indications;
- our ability, and the ability of our collaborators, to manufacture and sell commercial quantities of DCCR;
- the skills of our employees and our ability to recruit and retain skilled employees;
- protection of our intellectual property; and
- the availability of substantial capital resources to fund commercialization activities.

We expect that our principal competition for DCCR will include drugs currently in various stages of clinical development specifically for the treatment of PWS and hyperphagia, but may also include drugs approved for other indications, such as appetite suppression.

Manufacturing and Product Supply

We do not own or operate manufacturing or distribution facilities or resources for commercial production and distribution of DCCR. Instead, we have multiple contractual agreements in place with third-party contract manufacturing organizations (CMOs) who, on our behalf, have manufactured clinical supplies of our drug candidates, and will manufacture commercial supplies of DCCR for the foreseeable future. We have selected well-established and reputable global CMOs for our active pharmaceutical ingredient (API) and drug product manufacturing, that have good regulatory standing, large manufacturing capacities, and multiple manufacturing sites

within their business footprint. We employ highly skilled personnel with both technical and manufacturing experience to diligently manage the activities at our CMOs. Our quality department audits these suppliers on a periodic basis. Our commercial suppliers are subject to routine inspection by regulatory agencies. We work closely with our third-party manufacturers to ensure compliance with current good manufacturing practices (cGMP), and other stringent regulatory requirements enforced by the FDA and foreign regulatory agencies in other territories, as applicable.

We store API at third-party facilities in the United States, and provide appropriate amounts to third-party drug product CMOs in the United States who then manufacture, package and label our specified quantities of finished commercial DCCR and clinical goods for our drug candidates. Our third-party CMOs also need to obtain materials such as reagents, excipients and components to manufacture our API and finished drug products. Within our supply chain, we have established safety stock amounts for both our API and drug product, and store those quantities in multiple locations. The quantities that we store are based on our business needs and take into account scenarios for demand, production lead times, potential supply interruptions and shelf life for our API and drug product. We believe that our current manufacturing network has the appropriate capacity to produce sufficient commercial quantities of DCCR.

We plan to utilize a third party logistics provider with multiple locations to provide shipping and warehousing services for our commercial supply of DCCR. We have also entered into a non-exclusive agreement with a specialty pharmacy who will purchase our labeled drug product and dispense DCCR to patients pursuant to prescriptions provided by health care providers.

The manufacturing process for pharmaceutical products is highly regulated and regulators may shut down manufacturing facilities that they believe do not comply with regulations, legislations, and/or guidelines. We and our third-party manufacturers are subject to cGMPs, which are extensive regulations governing manufacturing processes, stability testing, record keeping, and quality standards as defined by the FDA and the EMA. Similar regulations and requirements are in effect in other countries.

Intellectual Property

DCCR Patent Portfolio

Our patent portfolio consists of issued U.S. patents and pending U.S. applications. The 20-year expiration dates of our issued U.S. patents are between 2025 to 2035. We also have 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).

Government Regulation - Pharmaceuticals

Our operations and activities are subject to extensive regulation by government authorities in the U.S. and in other countries in which we elect to develop and/or commercialize our products. Our developmental drug products are subject to rigorous regulation. Federal and state statutes and regulations govern the testing, manufacture, safety, efficacy, labeling, storage, record keeping, approval, advertising and promotion of our products. As a result of these regulations, product development and product approval processes are very expensive and time-consuming.

A country’s regulatory agency, such as the FDA in the U.S., or a region’s agency, such as the EMA for the E.U., must approve a drug before it can be sold in the respective country or countries. The general process for drug development and approval in the U.S. is summarized below. Many other countries, including countries in the E.U., U.K. and Japan, have very similar regulatory development and approval processes.

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 for wanted and unwanted effects. Additional nonclinical

testing may be required during the clinical development process for products intended for long-term use, such as reproductive toxicology, juvenile toxicology studies and carcinogenicity studies in two species.

Investigational New Drug 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 the FDA does not identify significant issues during the initial 30-day IND review, the proposed clinical trial can proceed. 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 Studies. During Phase 1 studies, researchers test a new drug in healthy volunteers. In most cases, 20 to 80 healthy volunteers participate in Phase 1. Phase 1 studies are closely monitored and gather information about how a drug interacts with the human body. Researchers adjust dosing schemes based on animal data to find out how much of a drug the body can tolerate and what its acute side effects are. As a Phase 1 trial continues, researchers answer research questions related to how it works in the body, the side effects associated with increased dosage, and early information about how effective it is to determine how best to administer the drug to limit risks and maximize possible benefits. This is important to the design of Phase 2 studies.

Phase 2 Studies. In Phase 2 studies, researchers administer the drug to a group of people with the disease or condition for which the drug is being developed. Typically involving up to a few hundred patients, these studies are not large enough to show whether the drug will be beneficial. The use of new study designs, such as adaptive designs, can decrease the number of patients required. Instead, Phase 2 studies provide researchers with additional safety data. Researchers use these data to refine research questions, develop research methods, identify target doses, and design new Phase 3 research protocols.

Phase 3 Studies. Researchers design Phase 3 studies to demonstrate whether or not a product offers a treatment benefit to a specific population. Sometimes known as pivotal studies, these studies generally involve a larger number of participants than do Phase 2 studies. Phase 3 studies provide most of the safety data. In Phase 3 studies, it is possible that less common side effects might have gone undetected. Because these studies are larger and longer in duration, the results are more likely to show long-term or rare side effects.

For each clinical trial, an institutional review board (IRB) or independent ethics committee (IEC), covering each site proposing to conduct a clinical trial must review and approve the plan for any clinical trial and written informed consent or assent information for subjects before the trial commences at that site and it must monitor the study until completed. The FDA, other heath authority, the IRB/IEC, 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/IEC'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 good clinical practices (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, 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 would intend to submit an application to market the drug for a particular use, an NDA with the FDA. The 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 is asked by the FDA to provide its perspective and make recommendations that are not binding, but are generally followed by the FDA. If the FDA determines that the compound is safe and effective for a particular use, it will approve the application, allowing the drug product to be marketed in the U.S. and sold for that use. It is not unusual, however, for the 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.

If the drug candidate is approved, the FDA may also require additional studies, or PMRs. These include studies to explore scientific questions to further characterize safety or efficacy of the drug candidate. The FDA may also require us to provide additional data or information, improve our manufacturing processes, procedures analytical methods 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 the FDA approves a drug, it could limit the uses of the drug. The 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 our drug, the manufacturing facilities of the companies who manufacture our drugs for us must also be approved. These facilities are subject to periodic inspections by the FDA. The 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 approved, 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 has the authority to prevent or limit further marketing of a product based on the results of PMRs. 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.

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 the FDA and may be eligible for accelerated and priority review.

Drugs that are developed for rare diseases (i.e., in the U.S., the disease or condition has a prevalence of less than 200,000 persons; in the E.U., the prevalence of the condition must be not more than 5 in 10,000) can be designated as "Orphan Drugs". In the U.S., orphan-designated drugs are granted up to 7-year market exclusivity. In response to the court decision in *Catalyst Pharms., Inc. v. Becerra*, 14 F.4th 1299 (11th Cir. 2021), in January 2023, the FDA published a notice in the Federal Register to clarify that while the agency complies with the court's order in *Catalyst*, the FDA intends to continue to apply its longstanding interpretation of the regulations to matters outside of the scope of the *Catalyst* order – that is, the agency will continue tying the scope of orphan-drug exclusivity to the uses or indications for which a drug is approved, which permits other sponsors to obtain approval of a drug for new

uses or indications within the same orphan designated disease or condition that have not yet been approved. It is unclear how future litigation, legislation, agency decisions and administrative actions will impact the scope of the orphan drug 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.

Ongoing Regulation

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.

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 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 compliance.

Once approved, the FDA may withdraw the approval for a product 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 for approved drugs, 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. The Federal Trade Commission (FTC) also regulates the promotion and advertising of consumer products. 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. Noncompliance may result in warning letters, fines or additional restrictions on subsequent advertising and promotional materials. Manufacturers may not promote a drug that is still under development and has not been approved by the FDA. 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 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. through a single application and review process. After receiving regulatory approval through the E.U. registration procedures, separate pricing and reimbursement approvals are also required in member countries. The E.U. also has requirements for approval of manufacturing facilities for all products that are approved for sale by the European regulatory authorities.

Additional Government Regulations

HIPAA and Other Privacy Laws

Health Insurance Portability and Accountability Act (HIPAA), established for the first-time comprehensive protection for the privacy and security of health information. The HIPAA standards apply to three types of organizations, or "Covered Entities": health plans, healthcare clearing houses, and healthcare providers which conduct certain healthcare transactions electronically. Covered Entities and their Business Associates must have in place administrative, physical, and technical standards to guard against the misuse of individually identifiable health information. Because we are a healthcare provider and we conduct certain healthcare transactions electronically, we are presently a Covered Entity, and we must have in place the administrative, physical, and technical safeguards required by HIPAA, the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH Act) and their implementing regulations. Additionally, some state laws impose privacy protections more stringent than HIPAA. Most of the institutions and physicians from which we obtain biological specimens that we use in our research and validation work are Covered Entities and must obtain proper authorization from their patients for the subsequent use of those samples and associated clinical information. We may perform future activities that may implicate HIPAA, such as providing clinical laboratory testing services or entering into specific kinds of relationships with a Covered Entity or a Business Associate of a Covered Entity.

If we or our operations are found to be in violation of HIPAA, HITECH or their implementing regulations, we may be subject to penalties, including civil and criminal penalties, fines, and exclusion from participation in U.S. federal or state health care programs, and the curtailment or restructuring of our operations. HITECH increased the civil and criminal penalties that may be imposed against Covered Entities, their Business Associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions.

Our activities must also comply with other applicable privacy laws. For example, there are also international privacy laws that impose restrictions on the access, use, and disclosure of health information. All of these laws may impact our business. Our failure to comply with these privacy laws or significant changes in the laws restricting our ability to obtain tissue samples and associated patient information could significantly impact our business and our future business plans.

Federal and State Billing and Fraud and Abuse Laws

Antifraud Laws/Overpayments. As participants in federal and state healthcare programs, we are subject to numerous federal and state antifraud and abuse laws. Many of these antifraud laws are broad in scope, and neither the courts nor government agencies have extensively interpreted these laws. Prohibitions under some of these laws include:

- the submission, or causing the submission of, false claims or false information to government programs;
- deceptive or fraudulent conduct;
- performing medically unnecessary procedures; and
- prohibitions in defrauding private sector health insurers.

We could be subject to substantial penalties for violations of these laws, including denial of payment and refunds, suspension of payments from Medicare, Medicaid or other federal healthcare programs and exclusion from participation in the federal healthcare programs, as well as civil monetary and criminal penalties and imprisonment. One of these statutes, the False Claims Act, is a key enforcement tool used by the government to combat healthcare fraud. The False Claims Act imposes liability on any person who, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal healthcare program. In addition, violations of the federal physician self-referral laws, such as the Stark laws discussed below, may also violate false claims laws. Liability under the False Claims Act can result in treble damages and imposition of penalties. For example, we could be subject to penalties of $14,308 to $28,618 per false claim, adjusted each year for inflation, and each use of our product could potentially be part of a different claim submitted to the government. Separately, the HHS office of the Office of Inspector General, or OIG, can exclude providers found liable under the False Claims Act from

participating in federally funded healthcare programs, including Medicare and Medicaid. The steep penalties that may be imposed on laboratories and other providers under this statute may be disproportionate to the relatively small dollar amounts of the claims made by these providers for reimbursement. In addition, even the threat of being excluded from participation in federal healthcare programs can have significant financial consequences on a provider.

Numerous federal and state agencies enforce the antifraud and abuse laws. In addition, private insurers may also bring private actions. In some circumstances, private whistleblowers are authorized to bring fraud suits on behalf of the government against providers and are entitled to receive a portion of any final recovery.

Federal and State "Self-Referral" and "Anti-Kickback" Restrictions

Self-Referral law. We are subject to a federal "self-referral" law, commonly referred to as the "Stark" law, which provides that physicians who, personally or through a family member, have ownership interests in or compensation arrangements with a laboratory are prohibited from making a referral to that laboratory for laboratory tests reimbursable by Medicare, and also prohibits laboratories from submitting a claim for Medicare payments for laboratory tests referred by physicians who, personally or through a family member, have ownership interests in or compensation arrangements with the testing laboratory. The Stark law contains a number of specific exceptions which, if met, permit physicians who have ownership or compensation arrangements with a testing laboratory to make referrals to that laboratory and permit the laboratory to submit claims for Medicare payments for laboratory tests performed pursuant to such referrals.

We are subject to comparable state laws, some of which apply to all payers regardless of source of payment, and do not contain identical exceptions to the Stark law. For example, we are subject to a North Carolina self-referral law that prohibits a physician investor from referring to us any patients covered by private, employer-funded or state and federal employee health plans. The North Carolina self-referral law contains few exceptions for physician investors in securities that have not been acquired through public trading but will generally permit us to accept referrals from physician investors who buy their shares in the public market.

We have several stockholders who are physicians in a position to make referrals to us. We have included within our compliance plan procedures to identify requests for testing services from physician investors and we do not bill Medicare, or any other federal program, or seek reimbursement from other third-party payers, for these tests.

Providers are subject to sanctions for claims submitted for each service that is furnished based on a referral prohibited under the federal self-referral laws. These sanctions include denial of payment and refunds, civil monetary payments and exclusion from participation in federal healthcare programs and civil monetary penalties, and they may also include penalties for applicable violations of the False Claims Act, which may require payment of up to three times the actual damages sustained by the government, plus civil penalties of $14,308 to $28,618 for each separate false claim. Similarly, sanctions for violations under the North Carolina self-referral laws include refunds and monetary penalties.

Anti-Kickback Statute. The federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce either the referral of an individual, or the furnishing, recommending, or arranging for a good or service, for which payment may be made under a federal healthcare program, such as the Medicare and Medicaid programs. The term "remuneration" is not defined in the federal Anti-Kickback Statute and has been broadly interpreted to include anything of value, including for example, gifts, discounts, the furnishing of supplies or equipment, credit arrangements, payments of cash, waivers of payment, ownership interests and providing anything at less than its fair market value. The reach of the Anti-Kickback Statute was also broadened by the Patient Protection and Affordable Care Act of 2010 (PPACA), which, among other things, amends the intent requirement of the federal Anti-Kickback Statute and certain criminal healthcare fraud statutes, effective March 23, 2010. Pursuant to the statutory amendment, a person or entity does not need to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, PPACA provides 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 or the civil monetary penalties statute, which imposes penalties against any person who is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that

was not provided as claimed or is false or fraudulent. Sanctions for violations of the federal Anti-Kickback Statute may include imprisonment and other criminal penalties, civil monetary penalties and exclusion from participation in federal healthcare programs.

The OIG has criticized a number of the business practices in the clinical laboratory industry as potentially implicating the Anti-Kickback Statute, including compensation arrangements intended to induce referrals between laboratories and entities from which they receive, or to which they make, referrals. In addition, the OIG has indicated that "dual charge" billing practices that are intended to induce the referral of patients reimbursed by federal healthcare programs may violate the Anti-Kickback Statute.

Many states have also adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs, and do not contain identical safe harbors. For example, North Carolina has an anti-kickback statute that prohibits healthcare providers from paying any financial compensation for recommending or securing patient referrals. Penalties for violations of this statute include license suspension or revocation or other disciplinary action. Other states have similar anti-kickback prohibitions.

Both the federal Anti-Kickback Statute and the North Carolina anti-kickback law are broad in scope. The anti-kickback laws clearly prohibit payments for patient referrals. Under a broad interpretation, these laws could also prohibit a broad array of practices involving remuneration where one party is a potential source of referrals for the other.

If we or 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, exclusion from participation in U.S. federal or state health care programs, and the curtailment or restructuring of our operations. To the extent that any product we make is sold in a foreign country in the future, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws, and implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals. To reduce the risks associated with these various laws and governmental regulations, we have implemented a compliance plan. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. 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.

The Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act (FCPA) prohibits any U.S. individual or business from paying, offering or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the U.S. to comply with accounting provisions requiring us to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Employees and Human Capital

As of December 31, 2024, we had 92 full-time employees. None of our employees is represented by a labor union or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and new employees, advisors and consultants. We are committed to providing a work environment that is free of discrimination and harassment. We are an equal-opportunity employer and make employment decisions on the basis of a person's qualifications and the needs of our business. We believe in the richness and quality of a working environment that is informed by people from all walks of life and strive to create a diverse and genuinely inclusive environment. We are committed to ensuring our team members are treated with fairness and respect. We believe that a cooperative work environment, based in trust and mutual respect, is essential to our success. As new employees join us, they learn more about our policies and culture through new hire orientation and onboarding, our Employee Handbook, Code of Conduct, and compliance trainings.

We offer an attractive mix of compensation and benefit plans to support our employees and their families' physical, mental, and financial well-being. We believe that we employ a fair and merit-based total compensation system for our employees. Employees are generally eligible for medical, dental, vision and other comprehensive benefits. The principal purposes of our equity and cash incentive plans are to attract, retain and reward personnel through the granting of stock-based and cash-based compensation awards, in order to increase stockholder value and the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives.

Corporate and Available Information

Our principal corporate offices are located at 100 Marine Parkway, Suite 400, Redwood City, California 94065 and our telephone number is (650) 213-8444. We were incorporated in Delaware on August 25, 1999. Our internet address is www.soleno.life. We make available on our website, free of charge, our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and any amendments to those reports, as soon as reasonably practicable after we electronically file such materials with, or furnish it to, the Securities Exchange and Commission. Our Securities Exchange and Commission reports can be accessed through the Investor Relations section of our internet website. The information found on our internet website is not part of this or any other report we file with or furnish to the Securities Exchange and Commission.

ITEM 1A. RISK FACTORS

An investment in our securities has a high degree of risk. Before you invest you should carefully consider the risks and uncertainties. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial conditions and/or operating results. If any of these risks actually occur, our business, operating results and financial condition could be harmed, and the value of our stock could go down. This means you could lose all or a part of your investment.

Summary Risk Factor

Our business is subject to numerous risks and uncertainties that you should consider before investing in our company, as fully described below. The principal factors and uncertainties that make investing in our company risky include, among others:

- we are a clinical-stage company with no approved products, which makes assessment of our future viability difficult;
- we have no commercialization history as a company and have incurred significant losses since our inception, and we anticipate that we will continue to incur substantial losses for the immediate future;
- we are dependent upon the success of DCCR, our sole therapeutic product candidate;
- 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;
- even if DCCR receives regulatory approval, it may fail to achieve the degree of market acceptance by physicians, patients, caregivers, healthcare payers and others in the medical community necessary for commercial success;
- we expect to continue 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;
- our patent rights may prove to be an inadequate barrier to competition;
- 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; and
- we may 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.

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 have historically been a clinical-stage company 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 have no commercialization history as a company and have incurred significant losses since our inception, and we anticipate that we will continue to incur substantial losses for the immediate future.

We are a developer of therapeutics with no commercialization history as a company. 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 and will incur substantial commercial expenses related to our operations.

We expect that our immediate future financial results will depend primarily on our success in launching, selling and supporting DCCR. This will require us to be successful in a range of activities, including 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 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 are dependent upon the success of DCCR, our sole therapeutic product candidate.

We have invested substantially all 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.

We had previously announced a Prescription Drug User Fee Act (PDUFA) target action date of December 27, 2024 for DCCR. On November 26, 2024, we announced that the FDA had extended the review period for our NDA for DCCR and set a new PDUFA target action date of March 27, 2025. Any further 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 payers, for DCCR, may cause us to be unable to generate the revenues necessary to continue our research and development pipeline activities or support our operations, 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:

- successful and timely completion of nonclinical and clinical development of DCCR, as well as the associated costs, including any unforeseen costs;
- receiving marketing approvals for DCCR in the U.S. and E.U.;
- obtaining a sufficiently broad label that would not unduly restrict patient access;
- building an infrastructure capable of supporting product sales, marketing, and distribution of DCCR in the U.S. and territories where we pursue commercialization directly;
- the success of 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;
- completing any post-marketing requirements or post-approval commitments to applicable regulatory authorities;
- obtaining a commercially viable price once approved;
- 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 once approved; and
- protecting our rights in our intellectual property portfolio.

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.

After our Phase 3 clinical trial, DESTINY PWS (C601), failed to demonstrate statistical significance on the primary efficacy endpoints the FDA asked us to conduct a new clinical trial. Following discussions with the FDA, we provided the agency with data from the C601 clinical trial, the open-label extension study (C602) as well as comparison to the natural history study (PATH for PWS) to allow the FDA to further assess if those data may provide adequate evidence of safety and efficacy to permit us to submit a new drug application (NDA) seeking approval to market DCCR for the treatment of PWS. At that time, the FDA indicated that additional controlled data would be necessary to support our planned NDA and we completed a randomized withdrawal period to Study C602 to obtain additional controlled data. Subsequently, we received preliminary comments from the FDA for our pre-NDA meeting, and as we decided not to proceed with the meeting, they are considered the official record of the meeting. As we previously disclosed, the FDA stated that the potential for data from the DCCR clinical program to provide substantial evidence of effectiveness would be a matter of review following the submission of an NDA. The FDA's concerns regarding our data include the C601 study not meeting its primary efficacy endpoint and the randomized withdrawal period of the C602 study including the same study population as the C601 study. We submitted our NDA for DCCR to the FDA on June 27, 2024 and on August 27, 2024, we announced that the FDA had accepted the NDA for filing and priority review and set a PDUFA target action date of December 27, 2024. On November 26, 2024, we announced that the FDA had extended the review period for our NDA and set a new PDUFA target action date of March 27, 2025.

If, following review of our NDA, the FDA does not determine that DCCR is safe and effective, or requires us to conduct additional studies prior to approval, or if we are unable to adequately address any concerns or requests in a manner satisfactory to the FDA or other regulatory authorities in a timely manner, or at all, we would be significantly delayed or prevented from receiving approval of DCCR for any intended use. Complying with any additional requests for information from the FDA or other regulatory authorities as well as any changes in the regulatory requirements will be time-consuming and expensive. We can provide no assurances regarding the timing of the FDA’s review of the NDA for DCCR or if the FDA will ultimately approve our NDA.

If we fail to obtain regulatory approval for DCCR in the U.S. and the 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. We submitted our NDA for DCCR to the FDA in June 2024 and in August 2024 the FDA accepted the NDA for filing and granted priority review. There is currently a PDUFA target action date of March 27, 2025 for the NDA. 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 or 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.

We may 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, 2024, have generated no revenue from operations. We had a net loss of $175.9 million during the year ended December 31, 2024 (including non-cash stock-based compensation of $100.0 million) and an accumulated deficit of $452.3 million at December 31, 2024 as a result of having incurred losses since our inception. We had $318.6 million in cash, cash equivalents and marketable securities at December 31, 2024, used $69.1 million of cash in operating activities during the year ended December 31, 2024 and expect to continue incurring losses for the foreseeable future.

We may need to raise additional capital, either through debt or equity financings to achieve our business plan objectives, including ongoing expenses related to the review of our NDA submission by the FDA and scaling of a sales and marketing organization to support the launch of DCCR following potential approval.

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 trials, our ability to obtain FDA approval for DCCR, the condition of the capital markets and the other risks described in this "Risk Factors" section. 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.

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 generated no product revenue and may never become profitable.

To date, we have not generated revenue from the commercialization of DCCR. 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 DCCR following approval also depends on a number of additional factors, including our ability to:

- develop a commercial organization capable of sales, marketing and distribution of DCCR;
- achieve market acceptance of DCCR;
- set a commercially viable price for DCCR;
- 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 payers, including government and private payers;
- find suitable distribution partners to help us market, sell and distribute DCCR 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 enforce our intellectual property rights and avoid third-party patent interference, intellectual property challenges or intellectual property 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.

We have a significant amount of debt, which may affect our ability to operate our business and secure additional financing in the future.

As of December 31, 2024, we had $50.0 million outstanding under our loan and security agreement with Oxford Financing LLC and its affiliates (collectively, Oxford). Under the terms of the loan agreement with Oxford, an additional $100 million may become available in three additional tranches, with tranches of $50 million and $25 million contingent upon FDA approval of DCCR for the treatment of PWS and one tranche of $25 million contingent upon certain commercial milestones. A final $50 million may be made available upon mutual consent with Oxford. The loan carries an interest-only period of 48 months and a total term of 60 months; provided that if specific milestones are achieved prior to September 30, 2026, the interest-only period and maturity date will be extended by 12 months. Subject to certain conditions, the term loans accrue interest at a floating rate equal to (a) 1-month term SOFR plus (b) 5.50%. Our debt with Oxford is collateralized by substantially all of our assets and contains customary financial and operating covenants limiting our ability to, among other things, dispose of assets, undergo a change in control, merge or consolidate, enter into certain transactions with affiliates, make acquisitions, incur debt, incur liens, pay dividends, repurchase stock and make investments, in each case subject to certain exceptions. The covenants in our loan agreement with Oxford, as well as in any future financing agreements into which we may enter, may restrict our ability to finance our operations and engage in, expand or otherwise pursue our business activities and strategies. Our ability to comply with these covenants may be affected by events beyond our control and future breaches of any of these covenants could result in a default under the loan agreement. If not waived, future defaults could cause all of the outstanding indebtedness under the loan agreement to become immediately due and payable and terminate commitments to extend further credit. If we do not have or are unable to generate sufficient cash to repay our debt obligations when they become due and payable, either upon maturity or in the event of a default, we may not be able to obtain additional debt or equity financing on favorable terms, if at all, which may negatively impact our ability to operate and continue our business as a going concern.

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. The timing of the commencement of the commercial launch of DCCR is dependent upon the FDA's approval, if any, of the NDA we submitted in June 2024. In addition to the risks related to a company launching its first commercial drug described elsewhere in this "Risk Factors" section, the success of a new drug product is inherently difficult to predict and we may not recognize revenue as quickly, consistently or in the amounts that we, analysts or investors anticipate following the launch.

Additionally, 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 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, 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 design, timing and outcomes of clinical trials;
- any delays in regulatory review or approval in the U.S. or globally, of any of our planned products;
- 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;
- changes in the competitive landscape of our industry, including consolidation among our competitors or potential partners;
- 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 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 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 trials 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 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 DCCR receives regulatory approval, it may fail to achieve the degree of market acceptance by physicians, patients, caregivers, healthcare payers and others in the medical community necessary for commercial success.

If DCCR receives regulatory approval from the FDA or other regulatory agencies in jurisdictions in which it is not currently approved, it may nonetheless fail to gain sufficient market acceptance by physicians, hospital administrators, patients, healthcare payers and others in the medical community. The degree of market acceptance of DCCR, if approved for commercial sale, will depend on a number of factors, including the following:

- the incidence and severity of any side effects;
- its effectiveness and potential advantages compared to alternative treatments;
- the price we charge for DCCR;
- 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;
- patients' perception of the efficacy of DCCR and interest in remaining on-drug long-term;
- the strength or effectiveness of marketing and distribution support of 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 DCCR, are estimates based on data analysis of the reported patient population. If our estimates of the prevalence of PWS, or of the number of patients who may benefit from treatment with DCCR prove to be incorrect, the market opportunity for DCCR may

be smaller than we believe it is, our prospects for generating revenue may be adversely affected and our business may suffer.

If we are unable to execute our sales and marketing strategy for our products or 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 represents a promising commercial opportunity, DCCR 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, the provisions of the approved label for DCCR, 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 trials sufficiently novel or worthy of publication. Failure to have our trials 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 trials 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 DCCR provides clinical utility; and
- whether health insurers, government health programs and other payers will cover and pay for DCCR and, if so, whether they will adequately reimburse us.

We may rely on third parties, who we do not control, to distribute and sell DCCR. If these distributors are not committed to DCCR or otherwise run into their own financial or other difficulties, it may result in failure to achieve widespread market acceptance of DCCR, 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, we will not be able to effectively commercialize DCCR and may not reach profitability.

We have a limited sales and marketing infrastructure and have no experience as a company 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 robust sales and marketing organization. We have begun to build a targeted sales, marketing, training and support infrastructure to market DCCR in the U.S. and to establish relationships with collaborations to market, distribute and support DCCR outside of the U.S. 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. Additionally commercialization of therapeutic 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. 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;
- 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 prescribe DCCR in significant numbers, we may be unable to generate sufficient revenue to sustain our business.

To generate demand for DCCR, 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 physicians, hospital administrators, patients, healthcare payers and others in the medical community that the clinical and economic utility of our products justifies payment for DCCR at adequate pricing levels. We will need to hire additional commercial, scientific, technical and other personnel to support this process.

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 DCCR.

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 products could negatively impact the development or commercialization of our products, particularly in geographic regions like the Europe, 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 products or bring them to market, and our business may be materially and adversely affected.

If clinical trials of any of our planned products, including DCCR, 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 trials to demonstrate that the product candidate is safe and effective for its intended use. Clinical trials 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 trials could occur at any stage of testing.

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

- clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- the number of patients required for clinical trials may be larger than we anticipate, enrollment in these clinical trials may be insufficient or slower than we anticipate, or patients may drop out of these clinical trials at a higher rate than we anticipate;
- the cost of clinical trials 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 trials 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) or independent ethics committees (IECs), may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective site;
- regulators or IRBs/IECs 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 trials 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 trials or other testing cannot be successfully completed, if the results of these trials 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 future clinical trials for DCCR will be required by the FDA or EMA or whether such clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant clinical trial 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.

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.

Before obtaining regulatory approvals for the commercial sale of our product candidates, we must obtain data through lengthy, complex and expensive nonclinical studies and clinical trials for regulatory authorities to assess if our product candidates are both safe and effective for each target indication. Nonclinical and clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the nonclinical study and clinical trial processes. The results of nonclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Although product candidates may demonstrate promising results in nonclinical studies and early clinical trials, they may not prove to be safe or effective in subsequent clinical trials. For example, testing on animals occurs under different conditions than testing in humans and therefore, the results of animal studies may not accurately predict safety and effectiveness in humans. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through nonclinical studies and clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through nonclinical studies and initial clinical trials. Further, clinical trial disruptions or protocol deviations during the COVID-19 pandemic may introduce bias or other factors that can impact the reliability of our clinical data collected at the peak of the COVID-19 public health emergency.

Earlier conducted smaller-scale studies, biomarker analyses, and clinical trials with a single or relatively few clinical trial sites may not be predictive of eventual outcomes in large-scale, placebo-controlled, pivotal clinical trials across multiple clinical trial sites. Even if data from a pivotal clinical trial are positive, regulators may not agree that such data are sufficient for approval and may require that we conduct additional clinical trials (including potential Phase 3 trials) or generate other forms of confirmatory evidence, which could materially delay our anticipated development timelines, require additional funding for such additional clinical trials or confirmatory studies, and adversely impact our business.

If the results of our current and future clinical trials are inconclusive with respect to the efficacy of our product candidates, including DCCR, if we do not meet the clinical endpoints with statistical and clinically meaningful significance, or if there are safety concerns associated with our product candidates, we may:

- incur unplanned costs;
- be delayed in or prevented from obtaining marketing approval for our product candidates;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings including boxed warnings;
- be subject to changes in the way the product is administered;
- be required to perform additional clinical trials to support approval or be subject to additional post-marketing testing requirements;
- have regulatory authorities withdraw their approval of the product or impose restrictions on its distribution in the form of a risk evaluation and mitigation strategy (REMS);
- be subject to the addition of labeling statements, such as warnings or contraindications;
- become subject to litigation; or
- experience damage to our reputation.

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/IEC 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/IECs of the institutions in which such trials are being conducted suspend or terminate the participation of their clinical investigators and sites 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.

Any "topline", interim, initial, or preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary or topline data from our nonclinical studies and clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or clinical trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data become available.

Furthermore, regulatory agencies may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and investors or regulatory authorities may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. If the interim, topline, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

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;
- 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 product candidates are being developed by our competitors 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 trial sites and patient registration for clinical trials, 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 at least nine other current or proposed clinical trials evaluating PWS therapies, including with glucagon-like peptide-1 (GLP-1) receptors in patients with PWS.

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 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 Europe 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.

We may become exposed to costly and damaging liability claims, either when testing our product candidates in clinical trials or at the commercial stage after regulatory approval, and our product liability insurance may not cover all damages arising from such claims. Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.

We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing, sale and use of pharmaceutical products, including maintaining consistent quality, safety and efficacy profiles for our products and product candidates. The marketing, sale and use of our products could lead to the filing of product liability claims against us if someone alleges that our products or product candidates failed to perform as intended. We may also be subject to liability for a misunderstanding of, or inappropriate reliance upon, the information we provide. These claims might be made by patients that use the products or product candidates, healthcare providers, pharmaceutical companies, or others selling such products. Any claims against us, regardless of their merit, could be costly to defend and could materially adversely affect the market for our product candidates or any prospects for commercialization of our product candidates.

Although the clinical trial process is designed to identify and assess potential side effects, it is always possible that a drug, even after regulatory approval, may exhibit unforeseen side effects. Physicians and patients may not comply with any warnings that identify known potential adverse effects and patients who should not use our product candidates. If any of our product candidates were to cause adverse side effects during clinical trials or after approval, we may be exposed to substantial liabilities.

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;
- injury to our reputation and significant negative media attention;
- withdrawal of patients from clinical trials or cancellation of clinical trials;
- 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 $10.0 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.

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 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, tariffs, 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 and the Middle East, 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

We expect to continue 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, 2024, we had 92 employees, up from 33 full-time employees as of December 31, 2023. We have experienced significant growth in the number of our employees and the scope of our operations, particularly in the areas of drug development, quality assurance, engineering, product development, regulatory affairs and sales and marketing. To manage this 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 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.

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. 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 executive 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.

Any future development or commercialization agreements we may enter into for our products may place the development or distribution 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 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 trail 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 trials, provide insufficient funding for a clinical trial program, stop a clinical trial, abandon a product, repeat or conduct new clinical trials 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.

Because we intend to do business 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, trade restrictions, export or import sanctions, 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, the Middle East, or natural disasters including earthquakes, typhoons, floods and fires.

In particular, there is currently significant uncertainty about the future relationship between the United States and various other countries with respect to trade policies, treaties, tariffs, taxes and other limitations on cross-border operations. Since beginning his second term in office, President Trump has made and continues to make significant additional changes in U.S. trade policy and may continue to take future actions that could negatively impact U.S. trade. Such trade policies and tariff implementations, and any related retaliatory trade policies and tariff implementations by foreign governments, may result in any materials that we import to the U.S. from countries subject to tariffs becoming more expensive or increase the price of DCCR in other countries, which could have a material adverse impact on our business, financial condition and results of operations. We cannot predict what actions may ultimately be taken with respect to trade relations between the United States and other countries, what products and services may be subject to such actions or what actions may be taken by the other countries in retaliation. If we are unable to obtain or use services from existing service providers or become unable to export or sell our products to any of our customers or service providers, our business, liquidity, financial condition, and results of operations would be materially and adversely affected.

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, 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 (SOX) 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, our Board committees, or as executive officers.

SOX 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 SOX (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 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.

We are required by Section 404 to evaluate the effectiveness of our internal control over financial reporting. If we are unable to achieve and maintain effective internal controls, our operating results and financial condition could be harmed and the market price of our common stock may be negatively affected.

As a public company with SEC reporting obligations, we are required to document and test our internal control procedures to satisfy the requirements of Section 404, which requires annual assessments by management of the effectiveness of our internal control over financial reporting. Effective December 31, 2024, we no longer qualify as a smaller reporting company and the reduced compliance requirements to smaller reporting companies no longer apply to us. As such, our auditor is required to attest to the effectiveness of our internal control over financial reporting beginning with this annual report on Form 10-K. We must implement and maintain substantial internal control systems and procedures to satisfy the reporting requirements under the Securities Exchange Act of 1934. During our assessments, we may identify deficiencies that we are unable to remediate in a timely manner. Testing and maintaining our internal control over financial reporting may also divert management's attention from other matters that are important to the operation of our business. We may not be able to conclude on an ongoing basis that we have effective internal control over financial reporting in accordance with Section 404. If we conclude that our internal control over financial reporting is not effective, the cost and scope of remediation actions and their effect on our operations may be significant. Moreover, any material weaknesses or other deficiencies in our internal control over financial reporting may impede our ability to file timely and accurate reports with the SEC. Any of the above could cause investors to lose confidence in our reported financial information or our common stock listing on Nasdaq to be suspended or terminated, which could have a negative effect on the trading price of our common stock.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results in a timely manner or prevent fraud, which would harm our business.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations in a timely manner, or at all. In addition, any testing by us conducted in connection with Section 404 or any subsequent testing by our independent registered public accounting firm in connection with Section 404, may reveal deficiencies in our internal controls over financial reporting that are deemed to be significant deficiencies or material weaknesses or that may require prospective or retroactive changes to our consolidated financial statements or identify other areas for further attention or improvement. We are also required to disclose material changes made in our internal controls over financing reporting and procedures on a quarterly basis and our management is required to assess the effectiveness of these controls annually. Ineffective internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock. To achieve compliance with Section 404 within the prescribed period, we have engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a plan to assess and document the adequacy of our internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are designed and operating effectively and implement a continuous reporting and improvement process for internal control over financial reporting. An independent assessment of the effectiveness of our internal controls could detect problems that our management's assessment might not identify. Undetected material weaknesses in our internal controls could lead to financial statement restatements and require us to incur the expense of remediation.

If our estimates or judgments relating to our critical accounting policies are based on assumptions that change or prove to be incorrect, our results of operation could fall below our publicly announced guidance or the expectations of securities analysts and investors, resulting in a decline in the market price of our common stock.

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in our financial statements and accompanying notes. We

base our estimates on historical experience and estimates and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets, liabilities, equity, revenue and expenses that are not readily apparent from other sources. For example, in connection with the implementation of the new revenue accounting standard if and when we have product sales, management makes judgments and assumptions based on our interpretation of the new standard. The new revenue standard is principle-based and interpretation of those principles may vary from company to company based on their unique circumstances. It is possible that interpretation, industry practice and guidance may evolve as we apply the new standard. If our assumptions underlying our estimates and judgments relating to our critical accounting policies change or if actual circumstances differ from our assumptions, estimates or judgments, our operating results may be adversely affected and could fall below our publicly announced guidance or the expectations of securities analysts and investors, resulting in a decline in the market price of our common stock.

In the future we may identify additional material weaknesses, fail to remediate our current material weakness or otherwise fail to maintain an effective system of internal controls, which may result in material misstatements of our financial statements or cause us to fail to meet our periodic reporting obligations.

As discussed in Item 9A of this Annual Report on Form 10-K, in preparing our consolidated financial statements as of and for the year ended December 31, 2024, our management concluded that our disclosure controls and procedures and our internal control over financial reporting were not effective at the reasonable assurance level. To address these material weakness, we plan to take actions designed to improve our internal control over financial reporting and remediate the control deficiencies that led to the material weakness. If we discover additional weaknesses in our system of internal financial and accounting controls and procedures, our consolidated financial statements may contain material misstatements, and we could be required to restate our financial results. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

Any failure to implement and maintain effective internal control over financial reporting could cause investors to lose confidence in our reported financial and other information, adversely impact our stock price, cause us to incur increased costs to remediate any deficiencies, and attract regulatory scrutiny or lawsuits that could be costly to resolve and distract management's attention, limit our ability to access the capital markets, or cause our stock to be delisted from The Nasdaq Capital Market or any other securities exchange on which it is then listed. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

If we experience an interruption in supply from a material sole source supplier, our business may be harmed.

We do not currently have nor do we plan to acquire the infrastructure or capability internally to manufacture or distribute DCCR. We will initially be dependent on sole source suppliers to produce raw materials, active pharmaceutical ingredients (APIs), the finished drug product and the associated packaging for DCCR. If there is an interruption in supply of our raw materials from these sole source suppliers, for any reason, there can be no assurance that we will be able to obtain adequate quantities of the raw materials within a reasonable time or at commercially reasonable prices. Interruptions in supplies due to pricing, timing, availability, or other issues with our sole source suppliers could have a negative impact on our contract manufacturer's ability to manufacture DCCR, which in turn could adversely affect the commercialization of DCCR.

Regardless of whether a sole source supplier enters into a written supply arrangement with us, such supplier could still delay, suspend, or terminate supply of raw materials to us for a number of reasons, including manufacturing or quality issues, payment disputes with us, or bankruptcy or insolvency situations.

Manufacturing or quality assurance difficulties at our contractors and suppliers, the failure or refusal of a supplier or contract manufacturer to supply contracted quantities, or increases in demand on a supplier with constrained capacity could result in delays and disruptions in the manufacturing, distribution, and sale of DCCR, leading to lost revenue or reduced market opportunities. Supply constraints may also lead to pauses, discontinuations, or other product availability issues, which could have a material adverse effect on our consolidated results of operations and cash flows. Further, cost inflation and transportation and logistics challenges in the future may cause delays in, and increase costs related to, procurement activity, and supplier or contract manufacturer arrangements.

If a sole source supplier ceases supply of drug substance, drug product or labeled finished product, there is no guarantee that we will find an alternative supplier on terms acceptable to us, or at all. Finding alternative suppliers may not be feasible or could take a significant amount of time and involve significant expense due to the nature of DCCR. Further the qualification process for a new vendor could take months or years, and any such delay in qualification could significantly harm our business.

In the United States, we intend to rely on one or more specialty pharmacies to dispense DCCR, deliver customer support, and provide us with related services, and our business could be harmed and we could be subject to liabilities if these services are performed inadequately or in a manner that does not comply with applicable laws and regulations.

If approved, our DCCR sales in the United States will initially be through specialty pharmacies and therefore our sales of DCCR will be highly dependent on the performance of these specialty pharmacies. A specialty pharmacy is a pharmacy that specializes in the dispensing of medications which often require a high level of patient education and ongoing management. The use of a specialty pharmacy involves risks, including, but not limited to, risks that a specialty pharmacy:

- does not effectively dispense or support DCCR;
- fails to properly administer copay mitigation programs;
- does not provide us with accurate or timely information regarding their inventories or the number of patients who are using DCCR;
- fails to provide timely and accurate information regarding product adverse events or product complaints;
- does not devote the resources necessary to dispense DCCR in a manner that meets patient needs;
- is unable to satisfy financial obligations to us or others;
- loses the required licenses to distribute DCCR; or
- ceases operations.

If a specialty pharmacy partner does not fulfill its contractual obligations to us or fails to adequately dispense DCCR and deliver customer support, our product sales and business could be harmed or we could be subject to legal or regulatory liabilities or sanctions. Furthermore, arrangements between manufacturers and specialty pharmacies can be subject to government scrutiny and challenge under fraud and abuse laws if not structured properly.

We rely on third parties to conduct certain components of our clinical trials, 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 our clinical trials 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 trials 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 trials 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 trials 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.

Our commercial success depends in part on our avoiding infringement and other violations of the patents and proprietary rights of third parties. Patent and other intellectual property litigation is prevalent in our sectors. There is a substantial amount of litigation, both within and outside the U.S., involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, derivation and administrative law proceedings, *inter partes* review and post-grant review before the U.S. Patent and Trademark Office (USPTO), as well as oppositions and similar processes in foreign jurisdictions. 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. As the biotechnology and pharmaceutical industries expand and more patents are issued, and as we gain greater visibility and market exposure, the risk increases that our commercialization of DCCR or other business activities may be subject to claims of infringement of the patent and other proprietary rights of third parties. Third parties may assert that we are infringing their patents or employing their proprietary technology without authorization. We may become party to, or be threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our products. 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. 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 intellectual property licensed to us and could require us to pay significant royalties and other fees.

Also, there may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of DCCR. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product may infringe.

In addition, third parties may obtain patent rights in the future and claim that use of our products infringes upon these rights. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of DCCR, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize DCCR unless we obtained a license under the applicable patents, or until such patents expire. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy, the holders of any such patent may be able to block our ability to develop and commercialize our product unless we obtained a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms or at all. In addition, we may be subject to claims that we are infringing other intellectual property rights, such as trademarks or copyrights, or misappropriating the trade secrets of others, and to the extent that our employees, consultants or contractors use intellectual property or proprietary information owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

We could be forced, including by court order, to cease commercializing the infringing 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. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a

substantial diversion of employee resources from our business. In the event of a successful infringement or other intellectual property claim against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms.

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 products may be materially adversely affected if we are unable to obtain and maintain effective intellectual property rights for our 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 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 products or which effectively prevent others from commercializing competitive products. The laws of foreign countries may not protect our rights to the same extent as the laws of the U.S. For example, many countries restrict the patentability of methods of treatment of the human body. 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. As a result of these and other factors, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect products, in whole or in part, or which effectively prevent others from commercializing competitive 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.

Moreover, we may be subject to a third-party pre-issuance submission of prior art to the USPTO or become involved in opposition, derivation, reexamination, *inter partes* review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. The costs of defending our patents or enforcing our proprietary rights in post-issuance administrative proceedings and litigation can be substantial and the outcome can be uncertain. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our 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. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize DCCR.

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. Generally, issued patents are granted a term of 20 years from the earliest claimed non-provisional filing date. In certain instances, patent term can be adjusted to recapture a portion of delay by the USPTO in examining the patent application (patent term adjustment) or extended to account for term effectively lost as a result of the FDA regulatory review period (patent term extension), or both. The scope of patent protection may also be limited. Without patent protection for DCCR, we may be open to competition from generic versions of DCCR. 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 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 or defense proceedings could put one or more patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing. In patent litigation in the U.S., defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement, written description, or lack of patentable subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant material information from the USPTO, or made a materially misleading statement, during prosecution. Third parties may also raise similar validity claims before the USPTO in post-grant proceedings such as *ex parte* reexaminations, *inter partes* review or post-grant review, or oppositions or similar proceedings outside the U.S., in parallel with litigation or even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. We cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. For the patents and patent applications that we have licensed, we may have limited or no right to participate in the defense of any licensed patents against challenge by a third party. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of any future patent protection on our current or future vaccine candidates. Such a loss of patent protection could harm our business.

We may not be able to prevent misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the U.S. Our business could be harmed if in litigation the prevailing party does not offer us a license on commercially reasonable terms. Any litigation or other proceedings to enforce our intellectual property rights may fail, and even if successful, may result in substantial costs and distract our management and other employees.

Interference or derivation proceedings provoked by third parties or brought by the 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.

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.

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 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.

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.

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.

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 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. For example, recent decisions raise questions regarding the award of patent term adjustment (PTA) for patents in families where related patents have issued without PTA. Thus, it cannot be said with certainty how PTA will be viewed in future and whether patent expiration dates may be impacted. 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. For example, the complexity

and uncertainty of European patent laws have also increased in recent years. In Europe, a new unitary patent system took effect June 1, 2023, which will significantly impact European patents, including those granted before the introduction of such a system. Under the unitary patent system, European applications have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the Unitary Patent Court (UPC). As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. Patents granted before the implementation of the UPC have the ability to opt out of the jurisdiction of the UPC and remain as national patents in the UPC countries. Patents that remain under the jurisdiction of the UPC will be potentially vulnerable to a single UPC-based revocation challenge that, if successful, could invalidate the patent in all countries who are signatories to the UPC. We cannot predict with certainty the long-term effects of any potential changes.

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.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of their former employers or other third parties.

From time to time we may employ individuals who 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. Additionally, while we seek to protect our ownership of intellectual property rights by ensuring that our agreements with our employees, collaborators and other third parties with whom we do business include provisions requiring such parties to assign rights in inventions to us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. 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.

Additionally, we may also be subject to claims that former employers or other third parties have an ownership interest in our patents. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and if we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees.

Risks related to government regulation

The regulatory approval process is expensive, time consuming and uncertain, and we may not be successful in 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 submitted an NDA for DCCR, but have not 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 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 will be required to demonstrate with substantial evidence from well-controlled clinical trials, 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 trials 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 trials 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 trials or perform additional preclinical studies and clinical trials. The number of preclinical studies and clinical trials 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 trials 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 trials or do not gain regulatory approval, our business and results of operations will be materially and adversely harmed.

Of the large number of drugs in development, only a small percentage successfully complete the FDA or comparable foreign regulatory approval processes and are commercialized. The lengthy approval processes as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our product candidates, which would significantly harm our business, results of operations and prospects.

Applications for our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or other comparable foreign regulatory authorities may disagree with the design, implementation or results of our clinical trials;

- the FDA may reject some or all of our data from clinical trials due to concerns related to bias, unblinding before statistical analysis plan is finalized, and/or reliability of data when the analysis is considered exploratory and not planned prospectively;
- the FDA may not accept data pooled from different studies, especially if the studies features are not sufficiently similar;
- the FDA finds that our data are not adequate to support the safety and efficacy of our product candidate for the proposed indication;
- the FDA may disagree with our statistical analysis plan;
- the FDA or other comparable foreign regulatory authorities may determine that our product candidates are not safe and effective or have undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use;
- the population studied in the clinical trial may not be sufficiently broad or representative to assure efficacy and safety in the full population for which we seek approval;
- the FDA or other comparable foreign regulatory authorities may disagree with our interpretation of data from nonclinical studies or clinical trials;
- our clinical trials may not meet the statutory standard for substantial evidence of effectiveness or may fail to demonstrate statistical significance on the primary endpoint;
- we may be unable to demonstrate to the FDA or other comparable foreign regulatory authorities that our product candidate's risk-benefit ratio for its proposed indication is acceptable;
- changes in priorities, reduction in staffing, large staff turnover or inadequate funding for the FDA or comparable foreign regulatory authorities could hinder those agencies from performing normal business functions and increase the time necessary for regulatory submissions, such as our NDA for DCCR, to be reviewed and approved, or decrease the likelihood of an approval;
- the FDA or other comparable foreign regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or other comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval or resulting in delays in our regulatory approval.

As noted above, we received preliminary comments from the FDA for our pre-NDA meeting, and as we decided not to proceed with the meeting, they are considered the official record of the meeting. While the FDA has raised concerns regarding our clinical data, we believe the data has the potential to support our NDA for DCCR. If the FDA disagrees with our interpretation of the data, or if we are required to conduct additional studies or clinical trials, our regulatory approval will be significantly delayed. This lengthy approval process, as well as the unpredictability of the results of clinical trials, may result in our failing to obtain regulatory approval to market DCCR, which would significantly harm our business, results of operations and prospects.

In addition, even if we obtain approval of DCCR, regulatory authorities may approve DCCR for fewer or more limited indications than we initially request, or may impose significant limitations in the form of narrow indications, warnings, contraindications, or a risk evaluation and mitigation strategy (REMS). Regulatory authorities may not approve the price we intend to charge for DCCR, may grant approval contingent on the performance of costly post-marketing clinical trials or other post-marketing studies, or may approve DCCR with a label that does not include the labeling claims necessary or desirable for the successful commercialization of DCCR. Any of the foregoing scenarios could seriously harm our business.

We received fast track designation for DCCR for the treatment of PWS, and we may seek fast track designation for other product candidates in the future. Even if received, fast track designation may not actually lead to a faster review process or faster marketing approval.

We aim to benefit from the FDA's fast track and priority review processes, and we previously received fast track designation for DCCR for the treatment of PWS and priority review was granted for our NDA for DCCR. Under the fast track program, the FDA may initiate a rolling review of sections of a fast track-designated drug's NDA before the application is complete, although the FDA's performance goal for reviewing an application does not begin until the last section of the NDA is submitted. In addition, under the FDA's policies, a product candidate is eligible for priority review if it provides a significant improvement compared to marketed drugs in the treatment, diagnosis or prevention of a disease.

The fast track designation for DCCR, or for other future product candidates that we may develop, may not actually lead to a faster review process. Any delays in the review process or in the approval of DCCR or our future potential products will delay revenue from their potential sales and will have a material adverse impact on our business. Moreover, a fast track designation may be withdrawn by the FDA if the agency believes that the designation is no longer supported by data emerging in the clinical trial process.

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 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 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 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 the 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.

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 trials 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.

Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the PPACA. In June 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the PPACA without specifically ruling on the constitutionality of the ACA. Thus, the ACA remains in force in its current form. 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 how any additional legislative changes or changes in presidential administrations 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.

There has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted legislation designed, among other things, to bring more transparency to product pricing, to review the relationship between pricing and manufacturer patient programs, and to reform government program reimbursement methodologies for pharmaceutical products. For example, in August 2022, Congress passed the Inflation Reduction Act of 2022 (IRA), which includes prescription drug provisions that have significant implications for the pharmaceutical industry and Medicare beneficiaries, including allowing the federal government to negotiate a maximum fair price for certain high-priced single source Medicare drugs, imposing penalties and excise tax for manufacturers that fail to comply with the drug price negotiation requirements, requiring inflation rebates for all Medicare Part B and Part D drugs, with limited exceptions, if their drug prices increase faster than inflation, and redesigning Medicare Part D to reduce out-of-pocket prescription drug costs for beneficiaries, among other changes. Various industry stakeholders, including certain pharmaceutical companies and the Pharmaceutical Research and Manufacturers of America, have initiated lawsuits against the federal government asserting that the price negotiation provisions of the IRA are unconstitutional. The impact of these judicial challenges, legislative, executive, and administrative actions and any future healthcare measures and agency rules implemented by the government on us and the pharmaceutical industry

as a whole is unclear. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product candidates if approved.

In addition, individual states in the U.S. have also become increasingly active in implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures and, in some cases, mechanisms to encourage importation from other countries and bulk purchasing. A number of states are considering or have recently enacted state drug price transparency and reporting laws that could substantially increase our compliance burdens and expose us to greater liability under such state laws once we begin commercialization after obtaining regulatory approval for any of our products. Further, the FDA recently authorized the State of Florida to import certain prescription drugs from Canada for a period of two years to help reduce drug costs, provided that Florida's Agency for Health Care Administration meets the requirements set forth by the FDA. Other states may follow Florida. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our product candidates.

Further, changes in regulatory requirements and guidance may occur and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial. 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 trials and the drug approval process. Data from clinical trials may receive greater scrutiny with respect to safety, which may make the FDA or other regulatory authorities more likely to terminate or suspend clinical trials before completion or require longer or additional clinical trials 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.

In addition, in June 2024, the U.S. Supreme Court in *Loper Bright Enterprises v. Raimondo* reversed its longstanding approach under the *Chevron* doctrine, which gave deference to regulatory agencies in litigation against the FDA and other agencies. As a result, more companies may bring lawsuits against the FDA to challenge longstanding decisions and policies of the FDA, which could undermine the FDA's authority, lead to uncertainties in the industry, and disrupt the FDA's normal operations, which could delay the FDA's review of our marketing applications.

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;
- Health Insurance Portability and Accountability Act (HIPAA), as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH 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.

Our relationships with healthcare providers, other customers, and third-party payers will be subject to applicable anti-kickback, fraud and abuse, and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, exclusion from government healthcare programs, contractual damages, reputational harm, and diminished profits and future earnings.

Although we do not currently have any drug products on the market, once we begin commercializing DCCR following potential approval, we will be subject to additional healthcare statutory and regulatory requirements and enforcement by the federal government and the states and foreign governments in which we conduct our business. Healthcare providers, physicians, and third-party payers will play a primary role in the recommendation and prescription of DCCR. Our future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell, and distribute DCCR. Restrictions under applicable federal and state healthcare laws and regulations include, but are not limited to, the Anti-Kickback Statute, the False Claims Act, HIPAA and the HITECH Act.

Efforts to ensure that our future business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs and may require us to undertake or implement additional policies or measures. We may face claims and proceedings by private parties, and claims, investigations and other proceedings by governmental authorities, relating to allegations that our business practices do not comply with statutes, regulations or case law involving applicable fraud and abuse, privacy or data protection, or other healthcare laws and regulations, and it is possible that courts or governmental authorities may conclude that we have not complied with

them, or that we may find it necessary or appropriate to settle any such claims or other proceedings. In connection with any such claims, proceedings, or settlements, we may be subject to significant civil, criminal, and administrative penalties, damages, fines, other damages, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

We are subject to U.S. and foreign laws regarding privacy, data protection, and data security that could entail substantial compliance costs, while the failure to comply could subject us to significant liability.

Privacy, data protection, and data security have become significant issues in the U.S., Europe, and other jurisdictions where we conduct or may in the future conduct our operations. The regulatory framework for the collection, use, safeguarding, sharing, and transfer of health and other personal information is rapidly evolving worldwide and is likely to remain in flux for the foreseeable future. The scope and interpretation of the laws that are or may be applicable to us are often uncertain, subject to differing interpretations, and may be inconsistent among different jurisdictions.

In the U.S., HIPAA, as amended by the HITECH Act, imposes on covered entities certain requirements relating to the privacy, security, and transmission of individually identifiable health information. The legislation also increased the civil and criminal penalties that may be assessed for violations and gave state attorneys general the authority to file civil actions in federal courts to enforce the HIPAA rules. In addition, for clinical trials conducted in the U.S., any personal information that is collected is further regulated by the Federal Policy for the Protection of Human Subjects. Privacy laws are also being enacted or considered at the state level, including significant new legislation in California, the California Consumer Privacy Act, as amended by the California Privacy Rights Act. While there is currently an exception for protected health information subject to HIPAA and clinical trial regulations, these and other state privacy laws may impact our business activities, and there continues to be uncertainty about how these laws will be interpreted and enforced. Other states have passed privacy legislation, including general privacy legislation similar to the CCPA, and legislation such as Washington's My Health, My Data Act, that also may impact our business activities, in the future and additional states are evaluating similar legislation. In the event we enroll subjects in clinical trials in the E.U. or other jurisdictions, or otherwise acquire or process personal data of individuals in those jurisdictions, we may be subject to additional restrictions and obligations relating to the collection, use, storage, transfer, and other processing of this data. Clinical trial activities in the European Economic Area (EEA), for example, are governed by the E.U. General Data Protection Regulation (GDPR).

We may need to take additional steps, such as new contractual negotiations or modifications to our policies or practices relating to cross-border transfers of personal data, to comply with these restrictions and obligations. More generally, laws and regulations governing privacy and data protection exist in many other countries around the world, and these laws (which are evolving and expanding) create complicated and potentially inconsistent obligations that may impact our business.

The increasing number, complexity, and potential inconsistency of current and future laws and regulations relating to privacy, data protection, and data security in the U.S. and other countries make our compliance obligations more difficult and costly. If we fail to comply with applicable laws and regulations or experience a breach of security that results in unauthorized disclosure of personal information - or if a third party with whom we share personal information or who processes such information for us fails to comply with applicable requirements or experiences a security breach or incident- or if any of these is reported or perceived to have occurred, it could lead to government investigations, enforcement actions, and other proceedings, as well as civil claims and litigation against us. We could incur substantial costs to defend against any such claims or proceedings and may also be held liable for significant fines, penalties, and monetary judgments. Any of the foregoing could have a material adverse effect on our business, results of operations, reputation, and prospects.

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 companies in particular, have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. 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 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 trials 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 trials, 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 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). The Company has completed a Section 382 analysis from January 1, 2017 through December 31, 2023 and determined that a change in ownership has occurred on March 7, 2017, December 21, 2018, June 30, 2020 and September 26, 2023. As a result, the net operating loss carryforwards and tax credit carryforwards maybe subject to annual limitations before being applied to reduce future income tax liabilities. For years ended after December 31, 2024, the utilization of net operating losses and tax credit carryforwards are subject to further limitation in the event an additional ownership change were to occur for tax purposes. In addition, we also raised capital in May 2024 that 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.

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.

If securities or industry analysts do not continue to publish research, or publish inaccurate or unfavorable research, about our business, our stock price and trading volume could decline.

The trading market for our common stock will continue to depend, in part, on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. In addition, if our operating results fail to meet the forecast of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our common stock could decrease, which might cause our stock price and trading volume to decline.

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 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 equity 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.

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 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.

General risks

Our information technology systems may fail or experience security breaches and incidents that could adversely impact our business and operations and subject us to liability.

We have experienced significant growth in the complexity of our data and the software tools that we rely upon. We rely significantly upon information technology systems and infrastructure owned and maintained by us or by third party providers to generate, collect, store, and transmit confidential and proprietary information and data (including but not limited to intellectual property, proprietary business information, and personal information) and to operate our business.

We expect to continue to incur significant costs related to technical and procedural controls to reduce the risks to our information technology systems. Despite these measures, our information technology and other internal infrastructure systems face the risk of failures, interruptions, security breaches and incidents, or other harm from various causes or sources, and third parties with whom we share confidential or proprietary information face similar risks and may experience similar events that materially impact us.

The techniques used by cyber criminals change frequently, may not be recognized until launched, and can originate from a wide variety of sources, including outside groups and individuals with a range of motives (including industrial espionage) and expertise, such as organized crime affiliates, terrorist organizations, or hostile foreign governments or agencies. The costs to us to investigate and mitigate actual and suspected cybersecurity breaches and incidents could be significant. We may not be able to anticipate all types of security threats and implement preventive measures effective against all such threats. In addition, an increased amount of work is occurring remotely, including through the use of mobile devices. This could increase our cybersecurity risk, create data accessibility concerns, and make us more susceptible to communication disruptions.

If we do not accurately predict and identify our information technology systems requirements and failures and timely enhance our information technology systems, or if our remediation efforts are not successful, it could result in a material disruption of our business operations, including the loss or unauthorized disclosure of our trade secrets, individuals' personal information, or other proprietary or sensitive data.

Moreover, any security breach or other event that leads to loss of, unauthorized access to, disclosure of, or other processing of personal information could harm our reputation, compel us to comply with federal and/or state notification laws and foreign law equivalents, subject us to mandatory corrective action, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information. For more information see "Risk Factors- We are subject to U.S. and foreign laws regarding privacy, data protection, and data security that could entail substantial compliance costs, while the failure to comply could subject us to significant liability".

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 and the Middle East 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 maintain our cash at financial institutions, often in balances that exceed federally insured limits.

Our cash is held in accounts at U.S. banking institutions that we believe are of high quality. Cash held in non-interest-bearing and interest-bearing operating accounts may exceed the Federal Deposit Insurance Corporation (FDIC) insurance limits. If such banking institutions were to fail, we could lose all or a portion of those amounts held in excess of such insurance limitations. Any material loss that we may experience in the future could have an adverse effect on our ability to pay our operational expenses or make other payments and may require us to move our accounts to other banks, which could cause a temporary delay in making payments to our vendors and employees and cause other operational inconveniences.

Environmental, social, and governance (ESG) matters are subject to increasing scrutiny and evolving expectations from customers, regulators, investors and other stakeholders and may expose us to reputational, cost and other risks.

Companies across all industries are subject to increasing scrutiny and evolving expectations regarding ESG matters. In particular, customers, regulators, investors and other stakeholders are increasingly focusing on environmental issues, including climate change, energy use, industrial waste, and other sustainability concerns. Failure to implement sufficient standards and practices for responsible corporate citizenship, support for local communities, employee diversity and human capital management, health and safety practices, supply chain management, and corporate governance can increase our costs of production, decrease our revenue, and negatively affect our reputation, employee retention, and the general willingness of customers and suppliers to do business with us and investors to invest in us. If we do not adapt to or comply with evolving ESG standards and regulations, the resulting consequences could have a material adverse effect on our reputation, business and financial condition.

If our facilities or our third-party manufacturers' facilities become unavailable or inoperable, our research and development program and commercialization plan could be adversely impacted and manufacturing of our products could be interrupted.

Our Redwood City, California, facilities house our corporate, research and development and quality assurance teams. Our drug product is manufactured and packaged at various locations in the United States. Our facilities in Redwood City and those of our third-party manufacturers are vulnerable to natural disasters, public health crises, climate change and catastrophic events. For example, our Redwood City facilities are located near earthquake fault zones and are vulnerable to damage from earthquakes as well as other types of disasters, including fires, wildfires, floods, power loss, communications failures and similar events. If any disaster, public health crisis or catastrophic event were to occur, our ability to operate our business would be seriously, or potentially completely, impaired. If our facilities or our third-party manufacturer's facilities become unavailable for any reason, we cannot provide assurances that we will be able to secure alternative manufacturing facilities with the necessary capabilities and equipment on acceptable terms, if at all. The inability to manufacture our drug product, combined with our limited inventory of drug product, may result in the loss of future customers or harm our reputation, and we may be unable to re-establish relationships with those customers in the future. If our or our third-party manufacturer's capabilities are impaired, we may not be able to manufacture and ship our products in a timely manner, which would adversely impact our business.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 1C. CYBERSECURITY

Item 1C. Cybersecurity

Our board of directors is responsible for overseeing our risk management program and cybersecurity is a critical element of this program. Management is responsible for the day-to-day administration of our risk management program and our cybersecurity policies, processes, and practices. Our cybersecurity policies, standards, processes, and practices are based on recognized frameworks established by the Center for Internet Security (CIS) and other applicable industry standards and are integrated into our overall risk management system and processes. We have not identified any risks from known cybersecurity threats, including as a result of any prior cybersecurity incidents, that have materially affected or are reasonably likely to materially affect us, including our operations, business strategy, results of operations, or financial condition. We face certain ongoing risks from cybersecurity threats that, if realized, are reasonably likely to materially affect us, including our operations, business strategy, results of operations, or financial condition. See "Risk Factors - Our information technology systems may fail or experience security breaches and incidents that could adversely impact our business and operations and subject us to liability."

Cybersecurity Risk Management and Strategy

Our cybersecurity risk management strategy focuses on several areas:

- Identification and Reporting: We have implemented a cross-functional approach to assessing, identifying and managing material cybersecurity threats and incidents. Our program includes controls and procedures to identify, classify and escalate certain cybersecurity incidents to provide management visibility and obtain direction from management as to the public disclosure and reporting of material incidents in a timely manner.
- Technical Safeguards: We implement technical safeguards that are designed to protect our information systems from cybersecurity threats, including firewalls, intrusion prevention and detection systems, anti-malware functionality, and access controls, which are evaluated and improved through cybersecurity threat intelligence, as well as outside audits and certifications.
- Incident Response and Recovery Planning: We are establishing incident response, business continuity, and disaster recovery plans designed to address our response to a cybersecurity incident.
- Third-Party Risk Management: We maintain a risk-based approach to identifying and overseeing material cybersecurity threats presented by third parties, including vendors, service providers, and other external users of our systems, as well as the systems of third parties that could adversely impact our business in the event of a material cybersecurity incident affecting those third-party systems, including any outside auditors or consultants who advise on our cybersecurity systems.
- Periodic Assessments: We conduct periodic assessments and testing of our policies, standards, processes, and practices in a manner intended to address cybersecurity threats and events. The results of such assessments, audits, and reviews are evaluated by management and reported to our Audit Committee and our board of directors, and we adjust our cybersecurity policies, standards, processes, and practices as necessary based on the information provided by these assessments, audits, and reviews.

Governance

Our board of directors oversees our risk management program, including the management of cybersecurity threats as part of its general oversight function. Our Audit Committee is taking the lead on behalf of the board of directors on oversight of our cybersecurity risk management program and receives reports from management concerning our cybersecurity risk management program.

Our cybersecurity risk assessment and management processes are implemented and maintained by various members of our management team, IT department and other employees, including but not limited to the individuals on our cybersecurity incident management team, which includes individuals who have a diverse combination of relevant expertise, experience, education and training, with representation from our IT, finance, legal, human resources, among others. Our team includes individuals with relevant experience in enterprise risk management and disclosure controls and procedures. Additionally, certain members of our IT department have experience managing cybersecurity programs and are specifically assigned cybersecurity oversight. Our cybersecurity incident response processes are designed to escalate certain cybersecurity incidents to members of management depending on the

circumstances, including in some cases to our executive team. Our cybersecurity incident management team, and other individuals as needed, work to help us mitigate and remediate cybersecurity incidents of which we are notified.

ITEM 2. PROPERTIES

Facilities

Our principal facilities consist of two office spaces in Redwood City, California. We currently occupy 18,026 square feet of office space under a non-cancelable operating lease that expires in August 2029 and 6,368 square feet of office space under a non-cancelable operating lease that expires in May 2025.

We believe that the facilities that we currently lease are adequate for our needs for the immediate future and that, should it be needed, additional space can be leased on commercially reasonable terms to accommodate any future needs.

ITEM 3. LEGAL PROCEEDINGS

We may, from time to time, be party to litigation and subject to claims that arise in the ordinary course of business. In addition, third parties may, from time to time, assert claims against us in the form of letters and other communications. We currently believe that these ordinary course matters will not have a material adverse effect on our business; however, the results of litigation and claims are inherently unpredictable. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our common stock is quoted on The Nasdaq Capital Market under the symbol "SLNO". Our March 2022 common warrants, May 2023 Tranche B warrants, and October 2023 pre-funded warrants are not traded on a national securities exchange.

As of February 26, 2025, there were 33 shareholders of record for our common stock. A substantially greater number of stockholders may be "street name" or beneficial holders, whose shares are held of record by banks, brokers and other financial institutions.

Dividend Policy

We have never declared or paid cash dividends on our common stock, and currently do not plan to declare dividends on shares of our common stock in the foreseeable future. We expect to retain our future earnings, if any, for use in the operation and expansion of our business. The payment of cash dividends in the future, if any, will be at the discretion of our board of directors and will depend upon such factors as earnings levels, capital requirements, our overall financial condition and any other factors deemed relevant by our board of directors.

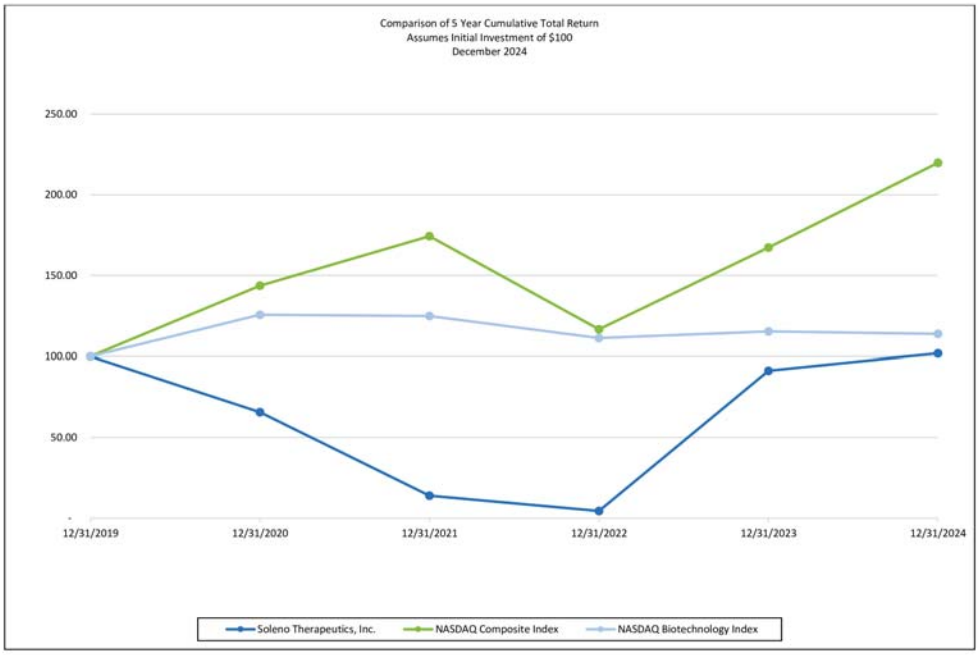
Securities Authorized for Issuance under Equity Compensation Plan

See Item 12, Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters for information regarding securities authorized for issuance.

Performance Graph

This graph is not "soliciting material," is not deemed "filed" with the SEC and is not to be incorporated by reference into any filing of Soleno Therapeutics, Inc. under the Securities Act or the Exchange Act, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.

The following graph shows the total stockholder return of an investment of $100 in cash at market close on December 31, 2019, through December 31, 2024 for (i) our common stock, (ii) the NASDAQ Composite Index (U.S.), and (iii) the NASDAQ Biotechnology Index. Pursuant to applicable SEC rules, all values assume reinvestment of the full amount of all dividends, however no dividends have been declared on our common stock to date. The stockholder return shown on the graph below is not necessarily indicative of future performance, and we do not make or endorse any predictions as to future stockholder returns.



	12/31/2019	12/31/2020	12/31/2021	12/31/2022	12/31/2023	12/31/2024
Soleno Therapeutics, Inc.	100.00	65.65	13.95	4.49	91.27	101.93
NASDAQ Composite Index	100.00	143.64	174.36	116.65	167.30	219.80
NASDAQ Biotechnology Index	100.00	125.69	124.89	111.27	115.42	113.84

Unregistered Sales of Equity Securities and Use of Proceeds

N/A.

ITEM 6. RESERVED

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis should be read in conjunction with our audited consolidated financial statements and the related notes that appear elsewhere in this Annual Report on Form 10-K. This Annual Report on Form 10-K contains "forward-looking statements" within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act). These statements are often identified by the use of words such as "may," "will," "expect," "believe," "anticipate," "intend," "could," "should," "estimate," "plan," or "continue," and similar expressions or variations. Such forward-looking statements are subject to risks, uncertainties 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 in Part I, Item 1A of this Annual Report on Form 10-K and elsewhere in this report. The forward-looking statements in this Annual Report on Form 10-K represent our views as of the date of this Annual Report on Form 10-K. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Annual Report on Form 10-K.

Business Overview

We are a biopharmaceutical company developing novel therapeutics for the treatment of rare diseases. We have submitted a new drug application (NDA) to the U.S. Food and Drug Administration (FDA) for our lead product candidate, diazoxide choline extended-release tablets (DCCR) for the treatment of Prader-Willi syndrome (PWS) in individuals four years and older who have hyperphagia. On August 27, 2024, we announced that the FDA had accepted the NDA for filing, designated the application for priority review and set a Prescription Drug User Fee Act (PDUFA) target action date of December 27, 2024. On November 26, 2024, we announced that the FDA had extended the review period for our NDA and set a new PDUFA target action date of March 27, 2025. DCCR previously received Breakthrough Therapy and Fast-Track designations in the United States (U.S.) and Orphan Drug designations in the U.S. and European Union (E.U.).

Financial overview

Summary

We have not generated net income from operations to date, and at December 31, 2024 we had an accumulated deficit of $452.3 million, primarily as a result of research and development and general and administrative expenses. We may not receive marketing approval or be successful in commercializing DCCR. Accordingly, we expect to incur significant losses from operations for the foreseeable future, and there can be no assurance that we will ever generate significant revenue or profits. As of December 31, 2024, we had cash and cash equivalents of $87.9 million and marketable securities of $230.7 million.

Revenue recognition

To date, we have earned no revenue from the commercial development and sale of DCCR.

Research and development expenses

Research and development expenses consist primarily of expenses incurred by contract research organizations (CROs) associated with our clinical trials, contract manufacturing organizations (CMOs) associated with the manufacture of our drug product, employee related expenses, including salaries and benefits, and professional consultant costs. These expenses will vary with the cadence and success of DCCR progressing from clinical to commercial stage.

General and administrative expenses

General and administrative expenses consist principally of salaries and benefits, stock-based compensation expense, professional fees for legal, consulting, audit and tax services, insurance, rent, pre-commercial activities, and other general operating expenses not otherwise included in research and development. We anticipate general and administrative expenses will increase in future periods, reflecting an expanding infrastructure, an increase in pre-commercial activities, other administrative expenses, and increased professional fees associated with being a public reporting company.

Change in fair value of contingent consideration

Change in fair value of contingent consideration represents the change in the fair value of the additional consideration that we expect to pay to the former Essentialis stockholders in accordance with the terms of our 2017 merger agreement with Essentialis based on our assessment of the expected likelihood of achieving two commercial sales milestones of $100.0 million in revenue and $200.0 million in revenue related to DCCR in future years.

Other income (expense), net

Other income (expense), net is comprised of interest income, and recently interest expense from our loan and security agreement with Oxford Financing LLC and its affiliates (collectively, Oxford), and the change in the fair value of the 2018 PIPE common stock warrant liabilities.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of financial condition and results of operations are based upon our audited financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses. On an on-going basis, we evaluate our critical accounting policies and estimates. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable in the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions and conditions. Our significant accounting policies are more fully described in Note 3 to our audited financial statements contained herein.

Marketable Securities

We classify our marketable securities as available-for-sale and records such assets at estimated fair value in the balance sheets, with unrealized gains and non-credit related losses that are determined to be temporary, if any, reported as a component of other comprehensive income (loss) within the statements of operations and comprehensive loss and as a separate component of stockholders' equity. We classify marketable securities with remaining maturities greater than three months but less than one year as marketable securities, and those with remaining maturities greater than one year are classified as long-term marketable securities. Realized gains and losses are calculated using the specific identification method and recorded as interest income and were immaterial for all periods presented. To the extent the amortized cost basis of the available-for-sale debt securities exceeds the fair value, management assesses the debt securities for credit loss; however, management considers the risk of credit loss to be minimized by our policy of investing in financial instruments issued by highly-rated financial institutions. When assessing the risk of credit loss, management considers factors such as the severity and the reason of the decline in value (i.e., any changes to the rating of the security by a rating agency or other adverse conditions specifically related to the security) and management's intended holding period and time horizon for selling. During the year ended December 31, 2024, we did not recognize any credit losses related to our available-for-sale debt securities. Further, as of December 31, 2024, we did not record an allowance for credit losses related to our available-for-sale debt securities. During 2023 and 2022, we did not hold any marketable securities.

Research and development expenses

Research and development expenses are charged to operations as incurred. Research and development expenses consist primarily of salaries, benefits, bonus, stock-based compensation, consultant fees, certain facility costs and other costs associated with clinical trials and the manufacture of our drug product. Clinical trial costs are a significant component of research and development expenses and include costs associated with CROs and other vendors. Invoicing from CROs and CMOs for services performed can often occur several months later. We accrue the costs incurred for clinical trial activities as measured by patient progression and the timing of various aspects of the trial. For other services, we accrue the costs in connection with third-party contractor activities based on our estimate of fees and costs associate with the contract that were rendered during the period and they are expensed as incurred.

Costs to acquire technologies to be used in research and development that have not reached technological feasibility and have no alternative future use are expensed to research and development costs when incurred.

Stock-based compensation expense

Stock-based compensation expense related to stock options and restricted stock units granted to employees, directors and consultants are measured at the date of grant based on the estimated fair value of the award. For restricted stock units this fair value is based on our common stock price on the grant date. We estimate the grant date fair value of stock options, and the resulting stock-based compensation expense, using the Black-Scholes option-pricing model. The grant date fair value of stock-based awards is recognized on a straight-line basis over the requisite service period, which is generally the vesting period for service-based awards. For performance-based awards the requisite service period is the longest explicit, implicit or derived service period based on management's estimate of the probability of the performance criteria being satisfied, adjusted at each balance sheet date.

The Black-Scholes option-pricing model requires the use of highly subjective assumptions to estimate the fair value of stock-based awards. If we had made different assumptions, our stock-based compensation expense, net loss and net loss per share of common stock could have been significantly different. These assumptions include:

- *Volatility:* The estimated volatility rate is based on the volatilities of our common stock for a historical period equal to the expected life of the stock options.
- *Expected life:* The expected life of stock options represents the period of time that the options are expected to be outstanding. Due to the lack of historical exercise history, the expected life of our service-based stock options has been determined utilizing the "simplified method", based on the average of the contractual term of the options and the weighted-average vesting period. The expected life for the performance-based options was determined based on consideration of the contractual term of the stock options, an estimate of the date the performance criteria would be met and expectations of employee behavior.
- *Risk-free interest rate:* The risk-free interest rate is based on the yields of U.S. Treasury securities with maturities similar to the expected life of the stock options.
- *Dividend rate:* We have never declared or paid any cash dividends and do not presently plan to pay cash dividends in the foreseeable future. Consequently, we used an expected dividend yield of zero.

We account for forfeitures as they occur.

Contingent consideration

Contingent consideration elements of a business combination are recorded in accordance with ASC 805 which provides that, when contingent consideration terms provide for future payment obligations, the obligation is measured at its fair value on the acquisition date, and the subsequent increase or decrease of the value of the estimated amounts of contingent consideration to be paid is be recognized as expense or income, respectively, in the consolidated statements of operations and comprehensive loss.

Our agreement to pay the former Essentialis stockholders for achieving certain commercial milestones resulted in the recognition of contingent consideration, which was recorded at the inception of the transaction, and subsequent changes to estimate the amount of contingent consideration to be paid is recognized as expenses or income in the consolidated statements of operations and comprehensive loss. The fair value of the contingent

consideration is based on our analysis of the likelihood of the drug indication being approved by the FDA and then reaching the cumulative revenue milestones.

Common Stock Purchase Warrants and Other Derivative Financial Instruments

We account for warrants in accordance with the guidance in ASC 815 *Derivatives and Hedging*. We classify common stock purchase warrants and other free standing derivative financial instruments as equity if the contracts (i) require physical settlement or net-share settlement or (ii) give us a choice of net-cash settlement or settlement in shares (physical settlement or net-share settlement). We classify any contracts that (i) require net-cash settlement (including a requirement to net cash settle the contract if an event occurs and if that event is outside our control), (ii) give the counterparty a choice of net-cash settlement or settlement in shares (physical settlement or net-share settlement), or (iii) contain reset provisions, as either an asset or a liability. We assess classification of freestanding derivatives at each reporting date to determine whether a change in classification between equity and liabilities is required. We determined that certain freestanding derivatives, which principally consist of the 2018 PIPE Warrants, do not satisfy the criteria for classification as equity instruments due to the existence of certain cash settlement features that are not within our sole control or variable settlement provision that cause them to not be indexed to our stock.

We classified the 2018 PIPE Warrants at their fair value and re-measured them at each balance sheet date until they were exercised or expired. Any changes in the fair value were recognized as Other income (expense), net in the consolidated statements of operations and comprehensive loss. The 2018 PIPE Warrants expired in December 2023.

Income Taxes

We use the liability method of accounting for income taxes, whereby deferred tax assets or liability account balances are calculated at the balance sheet date using current tax laws and rates in effect for the year in which the differences are expected to affect taxable income. We have provided a valuation allowance to reduce deferred tax assets to the amount that will more likely than not be realized.

We make certain estimates and judgments in determining income tax expense for financial statement purposes. These estimates and judgments occur in the calculation of tax credits, benefits and deductions and in the calculation of certain tax assets and liabilities, which arise from differences in the timing of recognition of revenues and expenses for tax and financial statement purposes. Significant changes to these estimates may result in an increase or decrease to our tax provision in a subsequent period.

We make estimates and judgments about our future taxable income that are based on assumptions that are consistent with our plans and estimates. Should the actual amounts differ from our estimates, the amount of our valuation allowance could be materially impacted. Any adjustment to the deferred tax asset valuation allowance would be recorded in the income statement for the periods in which the adjustment is determined to be required.

We account for uncertainty in income taxes as required by the provisions of ASC Topic 740, *Income Taxes*, which clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates that it is more likely than not that the position will be sustained on audit, including resolution of related appeals or litigation processes, if any. The second step is to estimate and measure the tax benefit as the largest amount that is more than 50% likely of being realized upon ultimate settlement. It is inherently difficult and subjective to estimate such amounts, as this requires us to determine the probability of various possible outcomes. We consider many factors when evaluating and estimating our tax positions and tax benefits, which may require periodic adjustments and may not accurately anticipate actual outcomes.

In addition, the use of net operating loss and tax credit carryforwards may be limited under Section 382 of the Internal Revenue Code in certain situations where changes occur in the stock ownership of a company. In the event that we have had a change in ownership, utilization of the carryforwards could be restricted. For more information, see the section titled "Our ability to use our net operating loss carry forwards and certain other tax attributes will be limited." at Part 1, Item 1A of this Annual Report on Form 10-K

Results of Operations

Comparison of the Years Ended December 31, 2024 and 2023

	Years Ended December 31,		Increase (decrease)	
	2024	2023	Amount	Percentage
	(in thousands)			
Operating expenses:				
Research and development	$ 78,568	$ 25,189	$ 53,379	212%
General and administrative	105,861	13,481	92,380	685%
Change in fair value of contingent consideration	3,242	2,714	528	19%
Total operating expenses	187,671	41,384	146,287	353%
Operating loss	(187,671)	(41,384)	(146,287)	353%
Other income (expense), net				
Change in fair value of warrant liabilities	-	(182)	182	100%
Interest income, net	12,052	2,578	9,474	367%
Interest expense	(231)	-	(231)	(100%)
Total other income (expense), net	11,821	2,396	9,425	393%
Net loss	$ (175,850)	$ (38,988)	$(136,862)	351%

Revenue

We have not commenced commercialization of DCCR, our current sole novel therapeutic drug candidate, and accordingly, through December 31, 2024, have generated no revenue.

Research and development expenses

Research and development expenses were $78.6 million for the year ended December 31, 2024, which includes $33.7 million of non-cash stock-based compensation expense, an increase of $53.4 million from $25.2 million in 2023, which included $2.4 million of non-cash stock-based compensation. Personnel and associated headcount costs increased $6.4 million as we hired additional employees in support of our research and development and potential commercialization activities. Costs in support of our NDA submission increased $9.0 million and supply chain and related activities increased $6.5 million in preparation for commercial launch. The cadence of our research and development expenditures will fluctuate depending upon the state of our clinical programs, the timing of manufacturing and other projects necessary to support the submission of an NDA and prepare for commercial launch. The $31.3 million of additional non-cash stock-based compensation being recognized in the period is predominantly due to performance-based RSU grants which partially vested upon the acceptance by the FDA of the NDA submission and will fully vest upon the approval of our NDA by the FDA.

General and administrative expenses

General and administrative expenses were $105.9 million for the year ended December 31, 2024, which includes $66.2 million of non-cash stock-based compensation, an increase of $92.4 million from $13.5 million in 2023, which included $3.5 million of non-cash stock-based compensation. Personnel costs including hiring expense and other associated headcount costs increased $10.7 million as we have hired additional employees in preparation for commercial launch and in support of our increased business activities. New program costs associated with preparation for commercial launch, including disease state education, analytics, other marketing programs, medical affairs and patient advocacy activities, totaled $15.8 million and professional services and consulting costs increased $2.9 million. The $62.7 million of additional non-cash stock-based compensation being recognized in the period is predominantly due to performance-based RSU grants which partially vested upon acceptance by the FDA of the NDA submission and will fully vest upon approval of our NDA by the FDA. General and administrative expenses will increase in support of commercializing DCCR if we receive FDA approval.

Change in fair value of contingent consideration

We are obligated to make cash payments of up to a maximum of $21.2 million to the former Essentialis stockholders upon the achievement of certain future commercial milestones associated with the sales of DCCR in accordance with the terms of our 2017 merger agreement with Essentialis. The fair value of the liability for the contingent consideration payable by us achieving two commercial sales milestones of $100 million and $200 million in revenue, respectively, in future years was estimated to be $14.8 million as of December 31, 2024, a $3.2 million increase from the estimate as of December 31, 2023.

Other income (expense), net

We had other income (expense), net of $11.8 million, an increase of $9.4 million from $2.4 million in 2023. The increase was primarily due to an increase in interest income driven by higher cash and cash equivalents, and marketable securities during the year ended December 31, 2024 compared to the year ended December 31, 2023.

Comparison of the Years Ended December 31, 2023 and 2022

	Years Ended December 31,		Increase (decrease)	
	2023	2022	Amount	Percentage
	(in thousands)			
Operating expenses:				
Research and development	$ 25,189	$ 15,265	$ 9,924	65%
General and administrative	13,481	9,844	3,637	37%
Change in fair value of contingent consideration	2,714	(712)	3,426	481%
Total operating expenses	41,384	24,397	16,987	70%
Operating loss	(41,384)	(24,397)	(16,987)	70%
Other income (expense), net				
Change in fair value of warrant liability	(182)	30	(212)	(707%)
Interest income	2,578	300	2,278	759%
Total other income (expense), net	2,396	330	2,066	626%
Net loss	$ (38,988)	$ (24,067)	$ (14,921)	62%

Revenue

We have not commenced commercialization of DCCR, our current sole novel therapeutic drug candidate, and accordingly, through December 31, 2023, had generated no revenue.

Research and development expenses

Research and development expenses were $25.2 million for the year ended December 31, 2023, an increase of $9.9 million from $15.3 million in 2022. The increase is primarily due to increased spending in clinical trials and manufacturing efforts, and expenditures in support of an NDA submission.

General and administrative expenses

General and administrative expenses were $13.5 million for the year ended December 31, 2023, an increase of $3.6 million from $9.8 million in 2022. The increase was primarily related to higher stock-based compensation expense, higher costs as a result of an increase in headcount, and higher professional and consulting expenses in 2023.

Change in fair value of contingent consideration

We are obligated to make cash payments of up to a maximum of $21.2 million to the former Essentialis stockholders upon the achievement of certain future commercial milestones associated with the sales of DCCR in accordance with the terms of our 2017 merger agreement with Essentialis. The fair value of the liability for the contingent consideration payable by us achieving two commercial sales milestones of $100 million and $200 million in revenue, respectively, in future years was estimated to be $11.5 million as of December 31, 2023, a $2.7 million increase from the estimate as of December 31, 2022.

Other income (expense), net

We had other income (expense), net of $2.4 million, an increase of $2.1 million from $0.3 million in 2022. Interest income during 2023 was $2.3 million higher than in 2022, partially offset by a decrease in fair value of the 2018 PIPE Warrants of $0.2 million during 2023 compared to 2022.

Liquidity and Capital Resources

We used $69.1 million of cash in operating activities and had a net loss of $175.9 million during 2024. We had an accumulated deficit of $452.3 million at December 31, 2024 as a result of having incurred losses since our inception. We had $87.9 million in cash and cash equivalents, $230.7 million of marketable securities, and $275.1 million of working capital as of December 31, 2024 and we had lease obligations totaling $3.0 million to be paid through August 2029, consisting of two operating leases for office space in Redwood City, California, one of which terminates in May 2025.

As of December 31, 2024, we had $50.0 million outstanding under our loan and security agreement with Oxford. Under the terms of the loan agreement with Oxford, an additional $100 million may become available in three additional tranches, with tranches of $50 million and $25 million contingent upon FDA approval of DCCR for the treatment of PWS and one tranche of $25 million contingent upon certain commercial milestones. A final $50 million may be made available upon mutual consent with Oxford. The loan carries an interest-only period of 48 months and a total term of 60 months; provided that if specific milestones are achieved prior to September 30, 2026, the interest-only period and maturity date will be extended by 12 months. The term loans accrue interest at a floating rate equal to, subject to certain conditions, (a) 1-month term SOFR plus (b) 5.50%.

Prior to entering into the Oxford loan and security agreement, we had historically financed our operations principally through issuance of equity securities. In May 2024, we closed an underwritten public offering of 3,450,000 shares of our common stock at a public offering price of $46.00 per share, which included the exercise in full by the underwriters of their option to purchase additional shares. The gross proceeds of the public offering were $158.7 million, before deducting the underwriter discount and other offering expenses of $9.7 million. In July 2024, we entered into an Open Market Sale Agreement℠ with Jefferies LLC, as sales agent (Jefferies), pursuant to which we may offer and sell, from time to time, through Jefferies, shares of our common stock having an aggregate offering price of up to $150 million.

In October 2023, we announced the closing of the underwritten public offering of 3,450,000 shares of our common stock at a public offering of $20.00 per share, which included the exercise in full by the underwriters of their option to purchase additional shares. The gross proceeds of the public offering were $69.0 million, before deducting the underwriting discount and other estimated offering expenses. We also announced the closing shares of our common stock and pre-funded warrants in a concurrent private offering pursuant to the securities purchase agreement with certain investors, including entities affiliated with existing stockholders, at a price per share of common stock equal to the public offering price of $20.00 and a price per pre-funded warrant of $19.99, for gross proceeds of approximately $60.0 million.

In December 2022, we entered into a securities purchase agreement providing for the sale of up to $60.0 million in warrants and the common stock issuable upon the exercise thereof. Through December 31, 2024, we have received $10.0 million from the sale of these warrants and $44.8 million in proceeds from the exercise of certain of these warrants. Warrants with an aggregate exercise price of $5.2 million are still outstanding.

We expect to continue incurring losses for the foreseeable future and may require additional capital to penetrate markets for the sale of our product, and pursue product development initiatives. We believe that our

existing cash, cash equivalents and marketable securities will be sufficient to meet the company's working capital needs for the next 12 months. Our long term-term capital requirements will depend on several factors, most notably the timing of the potential approval and commercialization of DCCR. We believe that we will continue to have access to capital resources through possible public or private equity offerings, debt financings, corporate collaborations or other means, but the access to such capital resources is uncertain and is not assured. In the future, if we are unable to secure additional capital, we may be required to curtail our commercial launch activities and take additional measures to reduce costs in order to conserve our cash in amounts sufficient to sustain operations and meet our obligations. These measures could cause significant delays in our efforts to commercialize our products, which is critical to the realization of our business plan and our future operations.

Cash Flows

The following table sets forth the primary sources and uses of cash and cash equivalents for each of the periods presented below:

	Years Ended December 31,		
	2024	2023	2022
	(in thousands)		
Net cash used in operating activities	$ (69,096)	$ (24,940)	$ (20,781)
Net cash used in investing activities	(225,682)	-	(13)
Net cash provided by financing activities	213,025	180,019	14,092
Net increase (decrease) in cash and cash equivalents	$ (81,753)	$ 155,079	$ (6,702)

Cash used in operating activities

During 2024, operating activities used net cash of $69.1 million, which was primarily due to the loss of $175.9 million which included $100.0 million of stock-based compensation expense, $2.0 million of depreciation and amortization, $0.4 million of non-cash lease expense, non-cash expense of $3.2 million for the change in fair value of contingent consideration, and $4.9 million added back for accretion of premium/discount on marketable securities. Additionally, there was a $6.1 million net decrease usage of cash during 2024 due to changes in operating assets and liabilities.

During 2023, operating activities used net cash of $24.9 million, which was primarily due to the loss of $39.0 million which included $5.9 million of stock-based compensation expense, non-cash expense of $2.7 million for the change in fair value of contingent consideration, $2.0 million of depreciation and amortization, $0.3 million of non-cash lease expense, and $0.2 million for the change in fair value of common stock warrant liability. Additionally, there was a $3.0 million net decrease usage of cash during 2023 due to changes in operating assets and liabilities.

During 2022, operating activities used net cash of $20.8 million, which was primarily due to the loss of $24.1 million which included non-cash income of $0.7 million for the change in fair value of contingent consideration, adjusted for non-cash expense of $2.5 million of stock-based compensation expense, $2.0 million of depreciation and amortization, and $0.3 million of non-cash lease expense. Additionally, there was a $0.8 million net increase usage of cash during 2022 due to changes in operating assets and liabilities.

Cash used in investing activities

During 2024, we used $356.5 million for purchases of marketable securities and $0.2 million for purchases of property and equipment. We received proceeds of $131.0 million from maturities of marketable securities.

During 2023, there were no investing activities and minimal cash used during 2022 for the costs of acquiring property and equipment.

Cash provided by financing activities

During 2024, we received $149.0 million from the sale of common stock, net of issuance costs, $49.9 million from issuance of debt, net of issuance costs, and $12.9 million from the exercise of common stock and pre-funded stock warrants. We also received $1.3 million from the exercise of stock options.

During 2023, we received $43.1 million from the sale and issuance of the warrants and $129.0 million gross proceeds from the sale of common stock. We also received $9.3 million of net cash proceeds from the exercise of warrants and $7.1 million of net cash proceeds through an at-the-market offering program. The total net proceeds amount was slightly offset by payments for the taxes from net share-settled vesting of restricted stock units.

During 2022, we received $13.8 million of net cash proceeds from the sale of common stock, net of issuance costs. We also received $0.3 million of net cash proceeds through an at-the-market offering program. The total net proceeds amount was slightly offset by payments for the taxes from net share-settled vesting of restricted stock units.

Off-Balance Sheet Arrangements

As of December 31, 2024 and December 31, 2023, we had no off-balance sheet arrangements as defined in Item 303(a)(4) of Regulation S-K as promulgated by the SEC.

Accounting Guidance Update

Recently Issued Accounting Guidance

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board (FASB), or other standard setting bodies and adopted by us as of the specified effective date.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Sensitivity

Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments, including cash equivalents, are in the form, or may be in the form of, money market funds or marketable securities and are or may be invested in U.S. Treasury or corporate debt.

As of December 31, 2024, we had unrestricted cash and cash equivalents totaling $87.9 million and $230.7 million of marketable securities held for working capital purposes. We do not enter into investments for trading or speculative purposes. We believe we do not have material exposure to changes in fair value as a result of changes in interest rates. Declines in interest rates, however, will reduce future interest income.

ITEM 8. CONSOLIDATED FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Soleno Therapeutics, Inc.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of Directors of
Soleno Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Soleno Therapeutics, Inc. (the Company) as of December 31, 2024 and 2023, the related consolidated statements of operations and comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2024, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024 and 2023, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2024, in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2024, based on the criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in 2013 and our report dated February 28, 2025, expressed an adverse opinion on the effectiveness of the Company's internal control over financial reporting because of the existence of a material weakness.

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Fair Value of Contingent Consideration

Description of the Matter

As discussed in Notes 3 and 4 to the consolidated financial statements, the Company's acquisition-related purchase price contingent liability, which is estimated using scenario-based methods based upon the Company's analysis of the likelihood of obtaining specified approvals from the Federal Drug Administration as well as reaching cumulative revenue milestones, is remeasured to its estimated fair value each reporting period, with changes in fair value recorded in the statements of operations and comprehensive loss.

Auditing the valuation of the acquisition-related contingent consideration liability was complex and highly judgmental due to the significant estimation required in determining the fair value. In particular, the fair value estimate was sensitive to significant assumptions such as the Company's projected future sales, which are affected by expectations about approval of a New Drug Application and future industry, market or economic conditions.

How We Addressed the Matter in Our Audit

Addressing this matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the financial statements. These procedures included, among others:

- We assessed the terms of the arrangement
- With the assistance of our valuation specialists, we evaluated the appropriateness of the valuation methodologies used by management. This included testing the completeness, accuracy, relevance and reliability of the market data inputs and evaluating the significant assumptions for reasonableness.
- We evaluated the adequacy of the Company's disclosures related to the fair value of contingent liability in the consolidated financial statements.

/s/ Marcum LLP

Marcum LLP

We have served as the Company's auditor since 2014.

San Francisco, CA
February 28, 2025

Soleno Therapeutics, Inc.
Consolidated Balance Sheets
(in thousands, except share and per share data)

	December 31, 2024	December 31, 2023
Assets		
Current assets		
Cash and cash equivalents	$ 87,928	$ 169,681
Marketable securities	203,509	—
Prepaid expenses and other current assets	2,452	1,677
Total current assets	293,889	171,358
Long-term assets		
Property and equipment, net	186	12
Operating lease right-of-use assets	2,798	407
Intangible assets, net	6,805	8,749
Long-term marketable securities	27,211	—
Other long-term assets	83	165
Total assets	$ 330,972	$ 180,691
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 8,882	$ 3,149
Accrued compensation	4,776	3,135
Accrued clinical trial site costs	1,826	3,393
Operating lease liabilities	526	273
Other current liabilities	2,737	1,555
Total current liabilities	18,747	11,505
Long-term liabilities		
Contingent liability for Essentialis purchase price	14,791	11,549
Long-term debt, net	49,828	—
Long-term lease liabilities	2,472	130
Other long-term liabilities	21	—
Total liabilities	85,859	23,184
Commitments and contingencies (Note 7)		
Stockholders' equity		
Preferred stock, $0.001 par value; 10,000,000 shares authorized, no shares issued and outstanding	—	—
Common stock, $0.001 par value, 100,000,000 shares authorized, 45,703,811 and 31,678,159 shares issued and outstanding at December 31, 2024 and 2023, respectively	46	32
Additional paid-in-capital	696,966	433,885
Accumulated other comprehensive gain	361	—
Accumulated deficit	(452,260)	(276,410)
Total stockholders' equity	245,113	157,507
Total liabilities and stockholders' equity	$ 330,972	$ 180,691

See accompanying notes to consolidated financial statements

Soleno Therapeutics, Inc.
Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share data)

	For the Years Ended December 31,		
	2024	2023	2022
Operating expenses			
Research and development	$ 78,568	$ 25,189	$ 15,265
General and administrative	105,861	13,481	9,844
Change in fair value of contingent consideration	3,242	2,714	(712)
Total operating expenses	187,671	41,384	24,397
Operating loss	(187,671)	(41,384)	(24,397)
Other income (expense), net			
Change in fair value of warrant liability	—	(182)	30
Interest income, net	12,052	2,578	300
Interest expense	(231)	—	—
Total other income (expense), net	11,821	2,396	330
Net loss	$ (175,850)	$ (38,988)	$ (24,067)
Other comprehensive income (loss)			
Net unrealized gain on marketable securities	361	—	—
Total comprehensive loss	$ (175,489)	$ (38,988)	$ (24,067)
Net loss per common share, basic and diluted	$ (4.38)	$ (2.36)	$ (2.87)
Weighted-average common shares outstanding used to calculate basic and diluted net loss per common share	40,175,926	16,492,132	8,397,088

See accompanying notes to consolidated financial statements.

Soleno Therapeutics, Inc.
Consolidated Statements of Stockholders' Equity
(in thousands, except share data)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balances at December 31, 2021	5,324,287	$ 5	$ 231,143	$ —	$ (213,355)	$ 17,793
Stock-based compensation	-	—	2,530	—	—	2,530
Issuance of common stock in connection with vesting of restricted stock units	18,650	—	—	—	—	—
Tax withholding payments for net share-settled equity awards	(3,683)	—	(16)	—	—	(16)
Sale of common stock in public offering, net of issuance costs of $701	2,666,667	3	9,324	—	—	9,327
Sale of pre-funded warrants in public offering, net of issuance costs of $333	—	—	4,439	—	—	4,439
Sale of common stock, net of issuance costs of $10	104,773	—	342	—	—	342
Exercise of common stock warrants	48,688	—	—	—	—	—
Net loss	—	—	—	—	(24,067)	(24,067)
Balances at December 31, 2022	8,159,382	$ 8	$ 247,762	$ —	$ (237,422)	$ 10,348
Stock-based compensation	-	—	5,809	—	—	5,809
Issuance of common stock in connection with exercise of stock options and vesting of restricted stock units	510,241	1	482	—	—	483
Tax withholding payments for net share-settled equity awards	(128)	—	—	—	—	—
Sale of common stock and issuance of common stock warrants and pre-funded common stock warrants, net of issuance costs of $8,449	7,047,397	6	137,851	—	—	137,857
Exercise of common stock warrants	15,961,267	17	41,981	—	—	41,998
Net loss	—	—	—	—	(38,988)	(38,988)
Balances at December 31, 2023	31,678,159	$ 32	$ 433,885	$ —	$ (276,410)	$ 157,507
Stock-based compensation	—	—	99,958	—	—	99,958
Issuance of common stock in connection with exercise of stock options and vesting of restricted stock units	1,125,054	1	1,315	—	—	1,316
Sale of common stock, net of issuance costs of $9,746	3,450,000	4	148,951	—	—	148,955
Exercise of common stock warrants and pre-funded common stock warrants	9,450,598	9	12,857	—	—	12,866
Unrealized gain on marketable securities	—	—	—	361	—	361
Net loss	—	—	—		(175,850)	(175,850)
Balances at December 31, 2024	45,703,811	$ 46	$ 696,966	$ 361	$ (452,260)	$ 245,113

See accompanying notes to consolidated financial statements

Soleno Therapeutics, Inc.
Consolidated Statements of Cash Flows
(in thousands)

	For the Years Ended December 31,		
	2024	**2023**	**2022**
Cash flows from operating activities:			
Net loss	$ (175,850)	$ (38,988)	$ (24,067)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	1,987	1,958	1,964
Accretion of premium/discount on marketable securities	(4,895)	—	—
Noncash lease expense	444	321	290
Stock-based compensation expense	99,958	5,945	2,530
Change in fair value of stock warrants	—	182	(30)
Change in fair value of contingent consideration	3,242	2,714	(712)
Change in operating assets and liabilities:			
Prepaid expenses, other current assets and other assets	(750)	(837)	113
Accounts payable	5,672	1,372	(1,477)
Accrued compensation	1,641	1,460	947
Accrued clinical trial site costs	(1,567)	171	(198)
Operating lease liabilities	(183)	(309)	(302)
Other liabilities	1,205	1,071	161
Net cash used in operating activities	(69,096)	(24,940)	(20,781)
Cash flows from investing activities:			
Purchases of property and equipment	(218)	—	(13)
Purchases of marketable securities	(356,464)	—	—
Maturities of marketable securities	131,000	—	—
Net cash used in investing activities	(225,682)	—	(13)
Cash flows from financing activities:			
Proceeds from issuance of debt, net of issuance costs	49,888	—	—
Proceeds from the sale of common stock, net of issuance costs	148,955	—	—
Proceeds from the sale of common stock, common stock warrants and pre-funded stock warrants, net of issuance costs	—	137,857	14,108
Proceeds from exercise of common stock and pre-funded stock warrants	12,866	41,815	—
Proceeds from exercise of stock options	1,316	347	—
Tax withholding payments for net share-settled equity awards	—	—	(16)
Net cash provided by financing activities	213,025	180,019	14,092
Net increase (decrease) in cash and cash equivalents	(81,753)	155,079	(6,702)
Cash and cash equivalents, beginning of period	169,681	14,602	21,304
Cash and cash equivalents, end of period	$ 87,928	$ 169,681	$ 14,602
Supplemental disclosure of non-cash operating and financing information			
Operating lease right-of-use assets obtained in exchange for operating lease obligations	$ 2,835	$ 597	$ —
Non-cash exercise of 2018 PIPE Warrants	$ —	$ 183	$ —
Purchases of property and equipment included in accounts payable	$ 1	$ —	$ —
Debt issuance costs included in accounts payable	$ 62	$ —	$ —

See accompanying notes to consolidated financial statements.

Soleno Therapeutics, Inc.
December 31, 2024

Notes to Consolidated Financial Statements

Note 1. Overview

Soleno Therapeutics, Inc. (the Company or Soleno) is a biopharmaceutical company developing novel therapeutics for the treatment of rare diseases. The Company has submitted a new drug application (NDA) to the U.S. Food and Drug Administration (FDA) for its lead product candidate, diazoxide choline extended-release tablets (DCCR) for the treatment of Prader-Willi syndrome (PWS) in individuals four years and older who have hyperphagia. On August 27, 2024, the Company announced that the FDA had accepted the NDA for filing, designated the application for priority review and set a Prescription Drug User Fee Act (PDUFA) target action date of December 27, 2024. On November 26, 2024, the Company announced that the FDA had extended the review period for the NDA and set a new PDUFA target action date of March 27, 2025. DCCR previously received Breakthrough Therapy and Fast-Track designations in the United States (U.S.) and Orphan Drug designations in the U.S. and European Union (E.U.).

The Company incorporated in the State of Delaware on August 25, 1999, and is located in Redwood City, California. It initially established its operations as Capnia, a diversified healthcare company that developed and commercialized innovative diagnostics, devices and therapeutics addressing unmet medical needs. During 2017, the Company merged with Essentialis, Inc. (Essentialis) and subsequently received stockholder approval to amend its Amended and Restated Certificate of Incorporation to change its name from “Capnia, Inc.” to “Soleno Therapeutics, Inc.”. Essentialis was a privately held clinical-stage 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. After the merger, the Company’s primary focus has been the development and commercialization of novel therapeutics for the treatment of rare diseases and the Company divested all prior business efforts.

Note 2. Liquidity

The Company used $69.1 million of cash in its operating activities, had a net loss of $175.9 million during 2024 and has an accumulated deficit of $452.3 million at December 31, 2024 resulting from having incurred losses since its inception. The Company had $87.9 million of cash and cash equivalents and $230.7 million of marketable securities on December 31, 2024.

As of December 31, 2024, the Company had $50.0 million outstanding under the loan and security agreement with Oxford Financing LLC and its affiliates (collectively, Oxford) entered into in December 2024. Under the terms of the loan agreement with Oxford, an additional $100 million may become available in three additional tranches, with tranches of $50 million and $25 million contingent upon FDA approval of DCCR for the treatment of PWS and one tranche of $25 million contingent upon certain commercial milestones. A final $50 million may be made available upon the Company's mutual consent with Oxford. The loan carries an interest-only period of 48 months and a total term of 60 months; provided that if specific milestones are achieved prior to September 30, 2026, the interest-only period and maturity date will be extended by 12 months. The term loans accrue interest at a floating rate equal to, subject to certain conditions, (a) 1-month term SOFR plus (b) 5.50%.

Prior to entering into the Oxford loan and security agreement, the Company had historically financed its operations principally through issuance of equity securities. On May 9, 2024, the Company closed an underwritten public offering of 3,450,000 shares of its common stock at a public offering price of $46.00 per share, which included the exercise in full by the underwriters of their option to purchase additional shares. The gross proceeds of the public offering were $158.7 million, before deducting the underwriter discount and other offering expenses, totaling approximately $9.7 million. On July 19, 2024, the Company entered into an Open Market Agreement℠ (the Sales Agreement) with Jefferies LLC, as sales agent (Jefferies), pursuant to which the Company may offer and sell, from time to time, through Jefferies shares of its common stock having an aggregate offering price of up to $150 million.

In December 2022, the Company entered into a Securities Purchase Agreement providing for the sale of up to $60.0 million in warrants (Tranche A and Tranche B) and the common stock issuable upon the exercise thereof. Cumulative to date through December 31, 2024, the Company has received $10.0 million from the sale of these warrants and $44.8 million in proceeds from the exercise of certain of these warrants. Warrants with an aggregate exercise price of $5.2 million are still outstanding.

The Company expects to continue incurring losses for the foreseeable future. However, the Company expects that its current cash and cash equivalents and marketable securities balances will be sufficient to enable the Company to meet its obligations for at least the next twelve months from the date of this filing.

Note 3. Basis of Presentation and Summary of Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements of the Company have been prepared in accordance with U.S. generally accepted accounting principles (GAAP), and the applicable rules and regulations of the Securities and Exchange Commission (SEC). Certain reclassifications on the consolidated statements of cash flows have been made to conform to current period presentation.

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All intercompany transactions and balances have been eliminated in consolidation.

Use of Estimates

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities, and reported amounts of expenses in the financial statements and accompanying notes. Actual results could differ from those estimates. Key estimates included in the financial statements include the valuation of deferred income tax assets, the valuation of financial instruments, stock-based compensation, accrued costs for services rendered in connection with third-party contractor clinical trial activities, and the valuation of contingent liabilities for the purchase price of assets obtained through acquisition.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash and cash equivalents and marketable securities at U.S. banking institutions. At December 31, 2024 and 2023, the Company's cash and cash equivalents and marketable securities were held by three and two separate financial institutions, respectively, and at times these balances may exceed the federally-insured limits. Operating cash in excess of federally-insured limits is custodied at a separate financial institution with an overnight sweep feature into a U.S. government money market fund.

Segments

The Company operates in one segment. Management uses one measurement of profitability and does not segregate its business for internal reporting, making operating decisions, and assessing financial performance. All long-lived assets are maintained in the U.S.

Cash and Cash Equivalents

The Company considers all highly liquid investments, including its money market funds, purchased with an original maturity of three months or less to be cash equivalents. The Company's cash and cash equivalents are held primarily in institutions in the U.S. and include deposits in a money market funds which were unrestricted as to withdrawal or use.

Marketable Securities

The Company classifies its marketable securities as available-for-sale and records such assets at estimated fair value in the balance sheets, with unrealized gains and non-credit related losses that are determined to be temporary, if any, reported as a component of other comprehensive income (loss) within the statements of operations and comprehensive loss and as a separate component of stockholders' equity. The Company classifies marketable securities with remaining maturities greater than three months but less than one year as marketable securities, and those with remaining maturities greater than one year are classified as long-term marketable securities. Realized gains and losses are calculated using the specific identification method and recorded as interest income and were immaterial for all periods presented. To the extent the amortized cost basis of the available-for-sale debt securities exceeds the fair value, management assesses the debt securities for credit loss; however, management considers the risk of credit loss to be minimized by the Company's policy of investing in financial instruments issued by highly-rated financial institutions. When assessing the risk of credit loss, management considers factors such as the severity and the reason of the decline in value (i.e., any changes to the rating of the security by a rating agency or other adverse conditions specifically related to the security) and management's intended holding period and time horizon for selling. During the year ended December 31, 2024, the Company did not recognize any credit losses related to its available-for-sale debt securities. Further, as of December 31, 2024, the Company did not record an allowance for credit losses related to its available-for-sale debt securities. During 2023 and 2022, the Company did not hold any marketable securities.

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of payments primarily related to clinical trials, insurance and short-term deposits. Prepaid expenses are initially recorded upon payment and are expensed as goods or services are received.

Property and Equipment, Net

Property and equipment are stated at cost net of accumulated depreciation and amortization calculated using the straight-line method over the estimated useful lives of the assets, generally between three and five years. Leasehold improvements are amortized on a straight-line basis over the lesser of their useful life or the remaining term of the lease. Maintenance and repairs are charged to expense as incurred, and improvements are capitalized. When assets are retired or otherwise disposed of, the cost and accumulated depreciation are removed from the balance sheet and any resulting gain or loss is reflected in operations in the period realized.

Leases

The Company determines whether an arrangement is a lease at inception. Specifically, it considers whether it controls the underlying asset and has the right to obtain substantially all the economic benefits or outputs from the asset. If the contractual arrangement contains a lease, the Company then determines whether it is an operating or finance lease. Right-of-Use (ROU) assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. ROU assets and lease liabilities are recognized at commencement date based on the present value of lease payments over the lease term. Lease expense for operating lease payments is recognized on a straight-line basis over the lease term. Finance lease classification results in a front-loaded expense recognition pattern over the lease term as it recognizes interest expense and amortization expense as separate components of lease expense.

The Company does not separate lease components from non-lease components for all classes of underlying assets, and instead accounts for the lease and non-lease components as a single component. Variable lease payments are recognized as they are incurred and primarily include common area maintenance, utilities, real estate taxes, insurance and other operating costs that are passed on from the lessor in proportion to the space leased by the Company. The Company does not recognize lease assets and lease liabilities for leases with an original lease term of less than one year.

Long-Lived Assets

The Company reviews its long-lived assets for impairment annually and whenever events or changes in circumstances indicate that the carrying amount of the assets may not be fully recoverable. The Company evaluates assets for potential impairment by comparing estimated future undiscounted net cash flows to the carrying amount of the asset. If the carrying amount of the assets exceeds the estimated future undiscounted cash flows, impairment is measured based on the difference between the carrying amount and the fair value of the assets.

Intangible Assets

In March 2017, the Company completed the acquisition of Essentialis in accordance with the merger agreement by and between the Company and Essentialis dated December 22, 2016 (the Merger Agreement). The merger transaction was accounted for as an asset acquisition under the acquisition method of accounting and accordingly, the value of $22.0 million was assigned to the identifiable intangible asset relating to the patent for DCCR, which patent is currently set to expire in June 2028.

Intangible assets with finite lives are amortized on a straight-line basis over their estimated useful lives, which for the patent is 11 years. The useful life of the intangible asset is evaluated each reporting period to determine whether events and circumstances warrant a revision to the remaining useful life.

Debt

Debt is recognized at its principal amounts upon issuance, net of any issuance costs. The Company categorizes its debt into current and long-term liabilities based on the maturity date. Interest expense on debt is recorded in the period in which it is incurred. Debt issuance costs are accreted into interest expense using the straight-line method over the contractual term of the debt. The Company regularly reviews its debt agreements for compliance with covenants and assesses its ability to meet future obligations.

Research and Development

Research and development costs are charged to operations as incurred. Research and development costs consist primarily of salaries, benefits, bonus, stock-based compensation, consultant fees, certain facility costs and other costs associated with clinical trials and the manufacture of our drug product. Clinical trial costs are a significant component of research and development expenses and include costs associated with CROs and other vendors. Invoicing CROs and CMOs for services performed can often occur several months later. The Company accrues the costs incurred for clinical trial activities as measured by patient progression and the timing of various aspects of the trial. For other services the Company accrues the costs in connection with third-party contractor activities based on its estimate of fees and costs associate with the contract that were rendered during the period and they are expensed as incurred.

Costs to acquire technologies to be used in research and development that have not reached technological feasibility and have no alternative future use are expensed to research and development costs when incurred.

Change in fair value of contingent consideration

The Company recorded the value of contingent future consideration to be paid for the acquisition of Essentialis as a liability in March 2017 at the date of the acquisition. The changes in value of the liability for the contingent consideration since the acquisition date are recorded as operating expense in the consolidated statements of operations and comprehensive loss.

Income Taxes

The Company accounts for income taxes using the asset and liability method. Under this method, deferred income tax assets and liabilities are recorded based on the estimated future tax effects of differences between the amounts at which assets and liabilities are recorded for financial reporting purposes and the amounts recorded for income tax purposes. A valuation allowance is provided against the Company's deferred income tax assets when their realization is not reasonably assured.

The Company assesses all material positions taken in any income tax return, including all significant uncertain positions, in all tax years that are still subject to assessment or challenge by relevant taxing authorities. Assessing an uncertain tax position begins with the initial determination of the position's sustainability and is measured at the largest amount of benefit that is greater than fifty percent likely of being realized upon ultimate settlement. As of each balance sheet date, unresolved uncertain tax positions must be reassessed, and the Company will determine whether (i) the factors underlying the sustainability assertion have changed and (ii) the amount of the recognized tax benefit is still appropriate. The recognition and measurement of tax benefits requires significant judgment. Judgments concerning the recognition and measurement of a tax benefit might change as new information becomes available.

Common Stock Purchase Warrants and Other Derivative Financial Instruments

The Company classifies common stock purchase warrants and other free standing derivative financial instruments as equity if the contracts (i) require physical settlement or net-share settlement or (ii) give the Company a choice of net-cash settlement or settlement in its own shares (physical settlement or net-share settlement). The Company classifies any contracts that (i) require net-cash settlement (including a requirement to net cash settle the contract if an event occurs and if that event is outside the control of the Company), (ii) give the counterparty a choice of net-cash settlement or settlement in shares (physical settlement or net-share settlement), or (iii) contain reset provisions as either an asset or a liability. The Company assesses classification of its freestanding derivatives at each reporting date to determine whether a change in classification between equity and liabilities is required.

The Company determined that certain freestanding derivatives, which principally consist of 2018 PIPE Warrants, do not satisfy the criteria for classification as equity instruments due to the existence of certain cash settlement features that are not within the sole control of the Company or variable settlement provision that cause them to not be indexed to the Company's own stock.

The Company classified the 2018 PIPE Warrants at their fair value and re-measured them at each balance sheet date until they were exercised or expired. Any changes in the fair value were recognized as Other income (expense), net in the consolidated statements of operations. The 2018 PIPE Warrants expired in December 2023.

Stock-Based Compensation

Stock-based compensation costs related to stock options and restricted stock units granted to employees, directors and consultants are measured at the date of grant based on the estimated fair value of the award. For restricted stock units this fair value is based on the Company's common stock price on the grant date. The Company estimates the grant date fair value of stock options, and the resulting stock-based compensation expense, using the Black-Scholes option-pricing model. The grant date fair value of stock-based awards is recognized on a straight-line basis over the requisite service period, which is generally the vesting period for service-based awards. For performance-based awards the requisite service period is the longest explicit, implicit or derived service period based on management's estimate of the probability of the performance criteria being satisfied, adjusted at each balance sheet date.

The Black-Scholes option-pricing model requires the use of highly subjective assumptions to estimate the fair value of stock-based awards. If the Company had made different assumptions, its stock-based compensation expense, net loss and net loss per share of common stock could have been significantly different. These assumptions include:

- *Expected life:* The expected life of stock options represents the period of time that the options are expected to be outstanding. Due to the lack of historical exercise history, the expected life of the Company's service-based stock options has been determined utilizing the "simplified method", based on the average of the contractual term of the options and the weighted-average vesting period. The expected life for the performance-based options was determined based on consideration of the contractual term of the stock options, an estimate of the date the performance criteria would be met and expectations of employee behavior.

- *Risk-free interest rate:* The risk-free interest rate is based on the yields of U.S. Treasury securities with maturities similar to the expected life of the stock options.
- *Volatility:* The estimated volatility rate is based on the volatilities of the Company's common stock for a historical period equal to the expected life of the stock options.
- *Dividend rate:* The Company has never declared or paid any cash dividends and does not presently plan to pay cash dividends in the foreseeable future. Consequently, the Company used an expected dividend yield of zero.

The Company accounts for forfeitures as they occur.

Recent Adopted Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board (FASB) or other standard setting bodies that are adopted by the Company as of the specified effective date.

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting – Improvements to Reportable Segment Disclosures*, which provides updates to qualitative and quantitative reportable segment disclosure requirements, including enhanced disclosures about significant segment expenses and increased interim disclosure requirements, among others. The ASU requires disclosures to include significant segment expenses that are regularly provided to the chief operating decision maker (CODM), a description of other segment items by reportable segment, and any additional measures of a segment's profit or loss used by the CODM when deciding how to allocate resources. The ASU also requires all annual disclosures to be disclosed in interim periods. This ASU is effective for fiscal years beginning after December 15, 2023, and interim periods in fiscal years beginning after December 15, 2024. The Company adopted ASU 2023-07 on October 1, 2024 for the fiscal year ended December 31, 2024.

In December 2023, the FASB issued ASU 2023-09, *Improvements to Income Tax Disclosures,* which amends the guidance in *ASC 740, Income Taxes*. This amendment is intended to improve the transparency of income tax disclosures by requiring (1) consistent categories and greater disaggregation of information in the rate reconciliation and (2) income taxes paid disaggregated by jurisdiction. It also includes certain other amendments to improve the effectiveness of income tax disclosures. The amendment is effective for fiscal years beginning after December 15, 2024. Adoption is permitted either prospectively or retrospectively, and the Company will adopt the amendment on a prospective basis. The Company is currently evaluating the impact of adopting this ASU on its consolidated financial statements and disclosures.

In November 2024, the FASB issued ASU 2024-03, *Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expense,* which requires the disclosure of additional information related to certain costs and expenses, including amounts of inventory purchases, employee compensation, and depreciation and amortization included in each income statement line item. The guidance also requires disclosure of the total amount of selling expenses and the Company's definition of selling expenses. The guidance is effective for the Company for fiscal years beginning after December 15, 2026, and for interim periods within fiscal years beginning after December 15, 2027. The Company is currently assessing the impacts of the new guidance on its financial statement disclosures.

Other accounting standards that have been issued or proposed by FASB or other standards-setting bodies that do not require adoption until a future date are not currently expected to have a material impact on the Company's financial statements upon adoption.

Note 4. Fair Value of Financial Instruments

The carrying value of the Company's cash, cash equivalents and accounts payable, approximate fair value due to the short-term nature of these items.

Fair value is defined as the exchange price that would be received for an asset or an exit price paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs.

The fair value hierarchy defines a three-level valuation hierarchy for disclosure of fair value measurements as follows:

- Level I — Unadjusted quoted prices in active markets for identical assets or liabilities;
- Level II — Inputs other than quoted prices included within Level I that are observable, unadjusted quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the related assets or liabilities; and
- Level III — Unobservable inputs that are supported by little or no market activity for the related assets or liabilities.

The categorization of a financial instrument within the valuation hierarchy is based upon the lowest level of input that is significant to the fair value measurement.

The fair value of marketable securities, which are Level 2 financial instruments, is based upon market prices quoted on the last day of the fiscal period or other observable market inputs. The Company obtains pricing information from its investment manager and generally determines the fair value of investment securities using standard observable inputs, including reported trades, broker/dealer quotes, bids and/or offers. Marketable securities, all of which are classified as available-for-sale securities, consisted of the following at December 31, 2024 (in thousands):

	December 31, 2024			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
U.S. treasury securities	$ 197,678	$ 449	$ (62)	$ 198,065
Corporate debt securities and commercial paper	32,681	2	(28)	32,655
Total	$ 230,359	$ 451	$ (90)	$ 230,720

The following table sets forth the Company's financial instruments that were measured at fair value on a recurring basis by level within the fair value hierarchy (in thousands):

	Fair Value Measurements at December 31, 2024			
	Total	Level 1	Level 2	Level 3
Assets				
Cash equivalents:				
Money market funds	$ 59,885	$ 59,885	$ —	$ —
Total cash equivalents	$ 59,885	$ 59,885	$ —	$ —
Marketable securities:				
U.S. treasury securities	$ 198,065	$ —	$ 198,065	$ —
Corporate debt securities and commercial paper	32,655	—	32,655	—
Total marketable securities	$ 230,720	$ —	$ 230,720	$ —
Total assets	$ 290,605	$ 59,885	$ 230,720	$ —
Liabilities				
Essentialis purchase price contingency liability	$ 14,791	$ —	$ —	$ 14,791
Total liabilities	$ 14,791	$ —	$ —	$ 14,791

	Fair Value Measurements at December 31, 2023			
	Total	Level 1	Level 2	Level 3
Assets				
Cash equivalents:				
Money market funds	$ 157,281	$ 157,281	$ —	$ —
Total cash equivalents and assets	$ 157,281	$ 157,281	$ —	$ —
Liabilities				
Essentialis purchase price contingency liability	$ 11,549	$ —	$ —	$ 11,549
Total liabilities	$ 11,549	$ —	$ —	$ 11,549

Based on the terms of the completed merger with Essentialis on March 7, 2017, the Company is obligated to make cash earnout payments of up to a maximum of $21.2 million to the former Essentialis stockholders. The fair value of the Essentialis purchase price contingent liability is estimated using scenario-based methods based upon the Company's analysis of the likelihood of obtaining specified approvals from the U.S. Food and Drug Administration (FDA) as well as achieving two commercial sales milestones of $100 million and $200 million in cumulative revenue. The Level 3 estimates are based, in part, on subjective assumptions. In determining the likelihood of this occurring, the analysis relied on published research relating to clinical development success rates. Based on management's assessment, an 88% probability of achieving all three milestones was determined to be reasonable as of both December 31, 2024 and December 31, 2023. During the periods presented, the Company has not changed the manner in which it values its Essentialis purchase price contingent liability.

The Company recognizes transfers between levels of the fair value hierarchy as of the end of the reporting period. There were no transfers within the hierarchy during the periods presented.

The following table sets forth a summary of the changes in the fair value of the Company's Level 3 assets and liabilities (dollars in thousands):

	Purchase Price Contingent Liability
Balance at January 1, 2024	$ 11,549
Change in value of contingent liability	3,242
Balance at December 31, 2024	$ 14,791

	2018 PIPE Warrants		Purchase Price Contingent Liability
	Number of Warrants	Liability	
Balance at December 31, 2022	34,241	$ 1	$ 8,835
Change in value of 2018 PIPE Warrants	—	419	—
Exercise of 2018 PIPE Warrants	(21,789)	(183)	—
Expiration of 2018 PIPE Warrants	(12,452)	(237)	—
Change in value of contingent liability	—	—	2,714
Balance at December 31, 2023	0	$ —	$ 11,549

The Company's estimated fair value of the 2018 PIPE Warrants was calculated using a Black-Scholes pricing model. The Black-Scholes pricing model requires the input of highly subjective assumptions including

the expected stock price volatility, the expected term, the expected dividend yield and the risk-free interest rate. The 2018 PIPE Warrants expired on December 21, 2023.

Note 5. Other Financial Statement Details

Property and Equipment, Net

Property and equipment are summarized in the following table (in thousands):

	December 31, 2024	December 31, 2023
Computer hardware	$ 24	$ 72
Leasehold Improvements	52	—
Furniture and fixtures	180	29
	256	101
Less accumulated depreciation and amortization	(70)	(89)
Total	$ 186	$ 12

Depreciation expense was approximately $43 thousand, $14 thousand, and $20 thousand for the years ended December 31, 2024, 2023, and 2022, respectively.

Intangible Assets, Net

Intangible assets consist of the following (in thousands):

	December 31, 2024			December 31, 2023		
	Amount	Accumulated Amortization	Net Amount	Amount	Accumulated Amortization	Net Amount
Patents and merger costs	$ 22,003	$ (15,198)	$ 6,805	$ 22,003	$ (13,254)	$ 8,749

Future amortization expense for intangible assets over their remaining useful lives is as follows (in thousands):

Year ending December 31	Patents and trademarks
2025	1,944
2026	1,944
2027	1,944
2028 and thereafter	973
Total	$ 6,805

Amortization expense was $1.9 million for the years ended December 31, 2024, 2023 and 2022.

Note 6. Warrants

The Company has issued multiple warrant series, of which the 2018 PIPE Warrants were determined to be liabilities pursuant to the guidance established by *ASC 815 Derivatives and Hedging.*

Warrants Issued as Part of the Units in the 2018 PIPE Offering

The 2018 PIPE Warrants were issued on December 19, 2018 in the 2018 PIPE Offering, pursuant to a Warrant Agreement with each of the investors in the 2018 PIPE Offering, and prior to their expiration on December 21, 2023, entitled the holders to purchase 34,241 shares of the Company's common stock at an exercise price equal to $30.00 per share, subject to adjustments.

In the event of a change of control of the Company, the holders of unexercised warrants had the option to present their unexercised warrants to the Company, or its successor, to be purchased by the Company, or its successor, in an amount equal to the per share value determined by the Black-Scholes methodology.

Since the Company may have been obligated to settle the 2018 PIPE Warrants in cash, the Company classified the 2018 PIPE Warrants as long-term liabilities at their fair value and re-measured the warrants at each balance sheet date until they were exercised or expire. Any change in the fair value is recognized as Other income (expense), net in the Company's consolidated statements of operations and comprehensive loss.

The 2018 PIPE Warrants were either exercised prior to or expired on December 21, 2023.

Note 7. Commitments and Contingencies

Facility Leases

On June 13, 2024, the Company entered into a new office lease in Redwood City, California for office space for its headquarters facility. The lease provides office space of approximately 18,026 square feet and for base monthly rent payments beginning at $57,400 that increase annually by approximately 3.0% over the term of five years from the date of occupancy. In addition to base rent, the Company has agreed to reimburse the landlord for certain operating expenses under the terms of the lease. The lease commencement date was September 1, 2024 when the premises became available for occupancy and the related operating lease ROU assets and liabilities were recorded in the Company's consolidated balance sheet as of December 31, 2024.

The Company's operating lease ROU assets, current operating lease liabilities and long-term operating lease liabilities each appear as a separate line within the Company's consolidated balance sheets. In September 2024, the Company recorded an increase to its right-of-use assets by $2.8 million and an increase to its lease liability of $2.8 million as a result of the June 2024 office lease. As of December 31, 2024 and December 31, 2023, the Company's short-term liabilities were equal to $0.5 million and $0.3 million, respectively, and the long-term operating lease liabilities were equal to $2.5 million and $0.1 million, respectively.

The Company's prior operating lease for its predecessor headquarters facility office space in Redwood City, California began in June 2021 and expired in May 2023. In April 2023, the Company entered into a twenty-four month lease extension commencing on June 1, 2023. The term of the lease extension expires in May 2025. As a result of the lease extension, in 2023, the Company recorded an increase to its right-of-use assets by $0.6 million and an increase to its lease liability by $0.6 million.

The weighted average discount rate related to the Company's lease liabilities was 8.5% as of December 31, 2024 over a remaining term of 4.7 years, and 8.25% as of December 31, 2023 over the remaining term of 17 months. The discount rates were determined based on estimates of the Company's incremental borrowing rate, as the discount rates implicit in the Company's leases cannot be readily determined.

The components of lease expense were as follows (in thousands):

	Years Ended December 31,		
	2024	2023	2022
Operating lease cost:			
Operating lease cost	$ 548	$ 312	$ 324
Variable lease cost	16	-	-
Short-term lease cost	157	44	29
Total operating lease cost	$ 721	$ 356	$ 353

Supplemental cash flow information related to leases was as follows (in thousands):

	Years Ended December 31,		
	2024	2023	2022
Cash paid for amounts included in the measurement of lease liabilities:			
Operating cash flows from operating leases	$ 344	$ 341	$ 354

The following is a schedule by year of future maturities of the Company's operating lease liabilities as of December 31, 2024 (in thousands):

2025	$ 494
2026	751
2027	861
2028	942
2029	665
Total lease payments	3,713
Less interest	(715)
Total	$ 2,998

Other Commitments

The Company enters into agreements in the normal course of business, including with contract research organizations for clinical trials, contract manufacturing organizations for certain manufacturing services, and vendors for preclinical studies as well as other services and products for operating purposes, which are generally cancelable upon written notice. As of December 31, 2024, the Company's non-cancelable other commitments aggregated $0.9 million.

Contingencies

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for general indemnifications. The Company's exposure under these agreements is unknown because it involves claims that may be made against the Company in the future but have not yet been made. The Company accrues a liability for such matters when it is probable that future expenditures will be made, and such expenditures can be reasonably estimated.

Note 8. Long-term Debt

On December 17, 2024, the Company entered into a loan and security agreement for up to $200 million with Oxford. The loan is collateralized by substantially all of the Company's assets, including its intellectual property, subject to certain limitations.

As of December 31, 2024, the Company had $50.0 million outstanding under the Oxford loan agreement. An additional $100 million may become available in three tranches, with tranches of $50 million and $25 million contingent upon FDA approval of DCCR for the treatment of PWS and one tranche of $25 million contingent upon certain commercial milestones. A final $50 million may be made available upon the mutual consent of the Company and Oxford. The loan carries an interest-only period of 48 months and a total term of 60 months; provided that if specific milestones are achieved prior to September 30, 2026, the interest-only period and maturity date will be extended by 12 months. The term loans accrue interest, payable monthly, at a floating rate equal to, subject to certain conditions, (a) 1-month term SOFR plus (b) 5.50%. The principal portion of the loan is due in eleven equal monthly installments beginning February 1, 2029, through December 1, 2029. However, if a specified milestone is achieved on or after December 17, 2025, then the term loan will begin to amortize in equal monthly installments beginning on February 1, 2030, and the maturity date will be extended to December 1, 2030. At maturity, the final principal payment will include a fee of 5% of the total

principal borrowed. The $2.5 million final interest payment related to the $50 million borrowed as of December 31, 2024 is accrued over the term of loan as long-term accrued interest payable. However, if a specified milestone is achieved on or after December 17, 2025, then the term loan will begin to amortize in equal monthly installments beginning on February 1, 2030, the maturity date will be extended to December 1, 2030, and the final payment will include a fee of 6.5% of the total principal borrowed. As of December 31, 2024, $21 thousand was accrued as part of other long-term liabilities on the consolidated balance sheet. Loan issuance costs of $174 thousand are recorded as a reduction of the principal loan balance on the consolidated balance sheet and are amortized as interest expense over the term of the loan. For the year ended December 31, 2024, the Company recorded $231 thousand in interest expense and $209 thousand of interest was paid.

The loan and security agreement provides for both affirmative and negative covenants. including covenants limiting the ability of the Company and their subsidiaries to, among other things, dispose of assets, incur debt, grant liens, pay dividends and distributions on their capital stock, make investments and acquisitions, and enter into transactions with affiliates, in each case subject to customary exceptions for a loan facility of this size and type. In addition, the loan and security agreement contains (1) a minimum cash covenant commencing on June 30, 2025 if the Company has not obtained FDA approval for DCCR for the treatment of Prader-Willi syndrome and at all times thereafter until such approval is received and (2) a minimum revenue covenant commencing on the earlier of the date that the more than $50 million principal amount of term loans have been funded under the loan and security agreement and June 30, 2026; provided that such minimum revenue covenant shall not be tested during periods when the Company's market capitalization or unrestricted cash meet certain minimum thresholds. The occurrence of an event of default could result in the acceleration of the Borrowers' obligations under the loan and security agreement, the termination of the Lenders' commitments, a 5.0% increase in the applicable rate of interest and the exercise by the Lender of other rights and remedies provided for under the loan and security agreement.

Note 9. Stockholders' Equity

Preferred Stock

The Company is authorized to issue 10,000,000 shares of Preferred Stock.

Public Offering of Common Stock

On May 9, 2024, the Company closed an underwritten public offering of 3,450,000 shares of its common stock at a public offering price of $46.00 per share, which included the exercise in full by the underwriters of their option to purchase additional shares. The gross proceeds of the public offering were $158.7 million, before deducting the underwriter discount and other offering expenses, totaling approximately $9.7 million.

Public Offering of Common Stock and Concurrent Private Placement of Common Stock and Pre-Funded Warrants

On October 2, 2023, the Company closed an underwritten public offering of 3,450,000 shares of its common stock at a public offering of $20.00 per share, which included the exercise in full by the underwriters of their option to purchase additional shares. The gross proceeds of the public offering were $69.0 million, before deducting the underwriting discount and other offering expenses. Concurrently, the Company also completed the closing of approximately $60.0 million for 1,825,000 shares of its common stock and 1,175,000 pre-funded warrants in a private offering pursuant to a securities purchase agreement with certain investors, including entities affiliated with existing stockholders, at a price per share of common stock equal to the public offering price of $20.00 and a price per per-funded warrant of $19.99. In aggregate, the Company received $129.0 million of gross proceeds less offering costs of $8.2 million The Company is not required under any circumstance to settle any of the pre-funded warrants for cash, and therefore classified the pre-funded warrants as permanent equity.

Securities Purchase Agreement

On December 16, 2022, the Company entered into a Securities Purchase Agreement for a private placement (Private Placement) with certain entities and members of management (collectively, Purchasers). Pursuant to the Securities Purchase Agreement, the Company agreed to sell to the Purchasers warrants to purchase up to an aggregate of 22,598,870 shares of the Company's common stock, at a purchase price of $0.4425 per warrant. The closing of the Private Placement occurred on May 8, 2023 (the Issue Date), following the satisfaction of certain closing conditions, including the completion of enrollment in the randomized withdrawal period of Study C602. The Company received gross proceeds of $10.0 million for the sale and issuance of warrants to purchase common stock.

The warrants were separated into two tranches with 8,598,870 Tranche A warrants with an exercise price of $1.75 and aggregate proceeds of up to approximately $15.0 million, and 14,000,000 Tranche B warrants with an exercise price of $2.50 and aggregate proceeds of up to $35.0 million. The Tranche A warrants were immediately exercisable and were required to be exercised within 30 days of announcement of positive top-line data from the randomized withdrawal period of Study C602. On September 26, 2023, the Company announced positive top-line data and subsequently received $15.0 million from the exercise of the Tranche A warrants. The Tranche B warrants are also immediately exercisable and expire upon the earlier of 3.5 years from the date of issuance or 30 days following receipt of FDA approval of DCCR for the treatment of PWS. Through December 31, 2024, certain investors had exercised their Tranche B warrants and the Company has received $29.8 million. The receipt of the aggregate exercise price of up to $5.2 million for the remaining Tranche B warrants is contingent upon the exercise of such warrants.

Underwritten Public Offering

On March 31, 2022, the Company sold 2,666,667 shares of its common stock at a public offering price of $3.75, and for certain investors, in lieu of common stock, pre-funded warrants (the March 2022 pre-funded warrants) to purchase 1,333,333 shares of its common stock at a public offering price $3.60 per pre-funded warrant, which represents the per share public offering price for the common stock less the $0.15 per share exercise price for each March 2022 pre-funded warrant. The March 2022 pre-funded warrants are immediately exercisable and may be exercised at any time until all of the March 2022 pre-funded warrants are exercised in full. Each share of common stock or March 2022 pre-funded warrant was sold together with one, immediately exercisable, common warrant (the 2022 common warrants) with a five-year term to purchase one share of common stock at an exercise price of $4.50 per share. The net proceeds of the offering were $13.8 million, after deducting the underwriting discount and other offering expenses. The Company is not required under any circumstance to settle any of the 2022 pre-funded warrants or the 2022 common warrants for cash, and therefore classified both types of warrants as permanent equity.

In 2024, 254,664 of the March 2022 common warrants were exercised for gross proceeds of $1.1 million and 419,056 warrants were exercised using the cashless exercise option with no proceeds to the Company. In 2023, 2,070,934 March 2022 warrants were exercised for gross proceeds of $9.3 million and the remainder of the March 2022 pre-funded warrants totaling 1,280,965 were exercised using the cashless exercise option with no additional proceeds received by the Company. As of December 31, 2024, 1,255,346 of the March 2022 common warrants remain outstanding.

At the Market Offering

In July 2024, the Company entered into the Sales Agreement with Jefferies, pursuant to which the Company may offer and sell up to $150.0 million of shares of its common stock, from time to time, through Jefferies.

The Company will pay Jefferies a commission of 3.0% of the aggregate gross proceeds from the sale of shares and has agreed to provide Jefferies with customary indemnification and contribution rights. The Company has also agreed to reimburse Jefferies for certain specified expenses. The Company is not obligated to sell any shares under the Sales Agreement. The offering of the shares pursuant to the Sales Agreement will terminate upon the termination of the Sales Agreement by Jefferies or the Company, as permitted therein.

In July 2021, the Company entered into a Controlled Equity Offering Sales Agreement with Cantor Fitzgerald under which the Company may sell shares of its common stock having an aggregate offering price of up to $25.0 million from time to time in any method permitted by law deemed to be an "at the market" Rule 415 under the Securities Act of 1933, as amended. As of December 31, 2023, the Company had sold 1,877,170 shares of common stock through the at the market program, totaling $7.4 million in net proceeds. The Controlled Equity Offering Sales Agreement was terminated in connection with the October 2, 2023 financing.

Common Stock Warrants

As of December 31, 2024, 2023 and 2022, the following table summarizes the Company's outstanding common stock warrants:

	As of December 31, 2024		As of December 31, 2023		As of December 31, 2022		
	Number of Common Warrant Shares	Weighted Average Exercise Price per Share	Number of Common Warrant Shares	Weighted Average Exercise Price per Share	Number of Common Warrant Shares	Weighted Average Exercise Price per Share	Expiration Date
Common stock warrants	—	$ —	7,904	$ 388.94	7,904	$ 388.94	November 2024
2018 PIPE warrants	—	$ —	—	$ —	34,241	$ 30.00	December 2023
March 2022 Common warrants	1,255,346	$ 4.50	1,929,066	$ 4.50	4,000,000	$ 4.50	March 2027
March 2022 Pre-funded warrants	—	$ —	—	$ —	1,280,965	$ 0.15	March 2027
May 2023 Tranche A Pre-funded warrants	—	$ —	2,758,281	$ 0.01	—	$ —	November 2026
May 2023 Tranche B warrants	2,065,305	$ 2.50	6,750,000	$ 2.50	—	$ —	November 2026 [1]
May 2023 Tranche B Pre-funded warrants	—	$ —	451,632	$ 0.01	—	$ —	November 2026
October 2023 Pre-funded warrants	250,000	$ 0.01	1,175,000	$ 0.01	—	$ —	N/A
Total	3,570,651		13,071,883		5,323,110		

[1] Subject to earlier expiration as described above.

Equity Incentive Plans

2014 Plan

The Company maintains the 2014 Equity Incentive Plan (the 2014 Plan). Under the 2014 Plan the Company may grant stock options, stock appreciation rights, restricted stock, restricted stock units, performance units or performance shares to employees, directors, advisors, and consultants. Options granted under the 2014 Plan may be incentive stock options (ISOs) or nonqualified stock options (NSOs). ISOs may be granted only to Company employees, including officers and directors.

The Board has the authority to determine to whom stock options will be granted, the number of options, the term, and the exercise price. Options are to be granted at an exercise price not less than fair value. For individuals holding more than 10% of the voting rights of all classes of stock, the exercise price of an option will not be less than 110% of fair value. Performance-based grants have vesting contingent upon the achievement of certain performance criteria related to the Company's commercialization of its therapeutics. The contractual term of an option is no longer than five years for ISOs for which the grantee owns greater than 10% of the voting power of all classes of stock and no longer than ten years for all other options. The terms and conditions governing restricted stock units is at the sole discretion of the Board.

On January 17, 2024, the Company filed a Registration Statement on Form S-8 which registered an additional 1 million shares automatically available for issuance under the 2014 Plan as of January 1, 2024. On June 6, 2024, the stockholders approved the Amended and Restated 2014 Plan which included an increase of 2 million shares, which became immediately available for issuance. As of December 31, 2024, a total of 155,517 shares were available for future grant under the 2014 Plan.

Inducement Plan

The Company maintains the 2020 Inducement Equity Incentive Plan (the Inducement Plan). The Inducement Plan provides for the grant of equity-based awards, including non-statutory stock options, restricted stock units, restricted stock, stock appreciation rights, performance shares and performance units, and its terms are substantially similar to the Company's 2014 Equity Incentive Plan.

In accordance with Rule 5635(c)(4) and Rule 5635(c)(3) of the Nasdaq Listing Rules, awards under the Inducement Plan may only be made to individuals not previously employees or non-employee directors of the Company (or following such individuals' bona fide period of non-employment with the Company), as an inducement material to the individuals' entry into employment with the Company, or, to the extent permitted by Rule 5635(c)(3) of the Nasdaq Listing Rules, in connection with a merger or acquisition. On January 31, 2024, the Company filed a Registration Statement on Form S-8 which registered 500,000 shares available for issuance under the Inducement Plan, which became available for issuance following approval of the Board of Directors on January 24, 2024.

As of December 31, 2024, a total of 5,318 shares were available for future grant under the Inducement Plan.

Stock-based compensation expense

The Company recognized stock-based compensation expense related to options and restricted stock units granted to employees, directors and consultants for the years ended December 31, 2024, 2023 and 2022 of $100.0 million, $5.9 million and $2.5 million, respectively. The compensation expense is allocated on a departmental basis, based on the classification of the option holder. For the years ended December 31, 2024, 2023 and 2022, the total income tax benefit related to stock-based compensation was $5.7 million, $1.9 million and zero, respectively, however, due to net operating losses and a full valuation allowance, no tax benefit was recognized in the financial statements.

Stock-based compensation expense was recognized in the consolidated statements of operations and comprehensive loss as follows (in thousands):

	Years Ended December 31,		
	2024	2023	2022
Research and development	$ 33,743	$ 2,434	$ 692
General and administrative	66,215	3,511	1,838
Total	$ 99,958	$ 5,945	$ 2,530

Stock Options

The Company granted options to purchase 1,819,324 of the Company's common stock to employees and a consultant during year ended December 31, 2024, and 1,821,784 and 283,919 to employees during year ended December 31, 2023 and 2022, respectively. There were no performance-based options granted in 2024, 2023 and 2022. The fair value of each award granted was estimated on the date of grant using the Black-Scholes option pricing model with the following assumptions:

	Years Ended December 31,		
	2024	2023	2022
Expected life (years)	5.8-6.1	5.3-6.1	5.5-6.0
Risk-free interest rate	3.7%-4.6%	3.5%-4.5%	1.7%-3.1%
Volatility	121%-124%	98%-122%	88%-95%
Dividend rate	— %	— %	— %

The Black-Scholes option-pricing model requires the use of highly subjective assumptions to estimate the fair value of stock-based awards. These assumptions include the following estimates:

- *Expected life:* The expected life of stock options represents the period of time that the options are expected to be outstanding. Due to the lack of historical exercise history, the expected life of the Company’s service-based stock options has been determined utilizing the “simplified method”, based on the average of the contractual term of the options and the weighted-average vesting period. The expected life for the performance-based options was determined based on consideration of the contractual term of the stock options, an estimate of the date the performance criteria would be met and expectations of employee behavior.
- *Risk-free interest rate:* The risk-free interest rate is based on the yields of U.S. Treasury securities with maturities similar to the expected life of the stock options.
- *Volatility:* The estimated volatility rate is based on the volatilities of the Company’s common stock for a historical period equal to the expected life of the stock options.
- *Dividend rate:* The Company has never declared or paid any cash dividends and does not presently plan to pay cash dividends in the foreseeable future. Consequently, the Company used an expected dividend yield of zero.

The following table summarizes stock option transactions for the year ended December 31, 2024 under the 2014 Plan and the Inducement Plan:

	Number of Options Outstanding	Weighted-Average Exercise Price per Share	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Balance at December 31, 2023	2,369,665	$ 11.56	8.72	
Options granted	1,819,324	45.54		
Options exercised	(171,520)	7.59		
Options canceled/forfeited	(45,671)	59.01		
Balance at December 31, 2024	3,971,798	$ 26.75	8.48	$ 79,578
Options exercisable at December 31, 2024	1,301,183	$ 14.45	7.33	$ 41,417
Options vested and expected to vest at December 31, 2024	3,971,798	$ 26.75	8.48	$ 79,578

The weighted-average grant date fair value of employee options granted was $40.13, $5.04 and $2.62 per share for the years ended December 31, 2024, 2023 and 2022, respectively. The intrinsic value of the stock options exercised was $6.7 million, $2.2 million and zero for the years ended December 31, 2024, 2023 and 2022, respectively. At December 31, 2024, total unrecognized employee stock-based compensation for options that are expected to vest was $65.4 million, which is expected to be recognized over the weighted-average remaining vesting period of 2.7 years.

Restricted Stock Units

There were 1,249,375 performance-based restricted stock units and 763,270 restricted stock units granted to employees and directors during the year ended December 31, 2024. During the year ended December 31, 2023, the Company granted 420,710 restricted stock units, of which 414,710 were granted to employees with a six-month vesting period, and all such restricted stock units vested during 2023. The Company granted 8,965 restricted stock units to employees and certain directors during the year ended December 31, 2022. The restricted stock units granted to certain directors in 2022 were 100% vested on the grant date and represent compensation for past board services.

The following table summarizes restricted stock unit transactions for the year ended December 31, 2024 under the 2014 Plan:

	Number of Restricted Stock Units	Weighted-Average Grant-Date Fair Value per Share
Outstanding at December 31, 2023	15,534	$ 43.92
Restricted stock units granted	2,012,645	46.47
Restricted stock units vested	(1,088,314)	44.64
Restricted stock units cancelled/forfeited	-	-
Outstanding at December 31, 2024	939,865	$ 48.55

The weighted-average grant-date fair value of all restricted stock units granted was $46.47, $5.49, and $5.33 per share during the year ended December 31, 2024, 2023 and 2022, respectively. The fair value of all restricted stock units vested during the year ended December 31, 2024, 2023 and 2022, was $50.9 million, $12.0 million and $0.1 million, respectively. At December 31, 2024, total unrecognized employee stock-based compensation related to restricted stock units was $10.9 million, which is expected to be recognized over the weighted-average remaining vesting period of 0.7 years. 137,780 restricted stock units vested on December 31, 2024 and are included in the Restricted stock units vested line item above. The shares of common stock were

subsequently issued after December 31, 2024 and therefore are not included in the outstanding common stock as of December 31, 2024.

2014 Employee Stock Purchase Plan

The Company's board of directors and stockholders have adopted the 2014 Employee Stock Purchase Plan (the ESPP). The ESPP has become effective, and the board of directors will implement commencement of offers thereunder in its discretion. A total of 1,864 shares of the Company's common stock has been made available for sale under the ESPP. In addition, the ESPP provides for annual increases in the number of shares available for issuance under the plan on the first day of each year beginning in the year following the initial date that the board of directors authorizes commencement, equal to the least of:

- 1.0% of the outstanding shares of the Company's common stock on the first day of such year;
- 3,729 shares; or
- such amount as determined by the board of directors.

As of December 31, 2024, there were no purchases by employees under this plan.

Note 10. Income Taxes

The geographical distribution of loss before income taxes are summarized below (in thousands):

	Years Ended December 31,		
	2024	2023	2022
United States	$ (175,921)	$ (39,180)	$ (24,173)
Foreign	71	192	106
Loss before income taxes	$ (175,850)	$ (38,988)	$ (24,067)

The provision for income tax benefit differs from the amount estimated by applying the statutory federal income tax rate to the operating loss due to the following (in thousands):

	Years Ended December 31,		
	2024	2023	2022
Tax (benefit) on the loss before income tax expense computed at the federal statutory rate	$ (36,928)	$ (8,187)	$ (5,055)
State tax (benefit) at statutory rate, net of federal benefit	(1,083)	(505)	(527)
Foreign rate differential	(5)	6	-
Change in valuation allowance	17,626	8,934	5,702
Change in research and development credits	(7,052)	(1,631)	(652)
Stock-based compensation	8,694	(600)	(734)
Change in fair value of warrants	-	38	(6)
Change in fair value of contingent consideration	681	570	(150)
Section 162(m) limitation	—	589	-
Change in net operating loss true up	18,025	39	739
Change in capital losses	432	—	405
Change in state rates	(424)	653	375
Other	34	94	(97)
Provision for income tax benefit	$ —	$ —	$ —

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets and liabilities are as follows at December 31, 2024 and 2023 (in thousands):

	December 31,	
	2024	2023
Non-current deferred tax assets:		
Federal and state net operating loss carryforwards	$ 44,319	$ 51,481
Research and other credits	14,127	6,352
Capitalized research and development	17,200	6,778
Reserves and accruals	555	655
Fixed assets	23	29
Capital loss carryover	-	432
Stock-based compensation	8,628	2,013
Lease liability	636	85
Other deferred tax assets	57	54
Gross non-current deferred tax assets	85,545	67,879
Intangible assets	(1,445)	(1,837)
Right-of-use assets	(594)	(86)
Total non-current deferred tax liabilities	(2,039)	(1,923)
Total deferred tax assets	83,506	65,956
Valuation allowance	(83,506)	(65,956)
Net deferred tax assets	$ —	$ —

The Company has recorded a full valuation allowance against its net deferred tax assets due to the uncertainty as to whether such assets will be realized. The valuation allowance increased by $17.6 million from December 31, 2023 to December 31, 2024 primarily due to the generation of current year net operating losses, research and development and orphan drug tax credits claimed, capitalized research and experimental costs, and stock-based compensation.

As of December 31, 2024, the Company had $173.5 million of federal, $113.5 million of state and no foreign net operating losses available to offset future taxable income. The Federal net operating loss carryforwards arising from years prior to 2018 began to expire in 2022, however post 2017 federal net operating loss carryforwards of $152.6 million may be carried forward indefinitely. The state net operating loss carryforwards will begin to expire in 2028. As of December 31, 2024, the Company also had $16.3 million of federal orphan drug and research and development credits and $5.0 million of state research and development credit carryforwards. The federal research and development credit carryforward begin to expire in 2024 and the state research and development credit can be carried forward indefinitely. Beginning in fiscal year 2023, the Tax Cuts and Jobs Act of 2017 eliminates the option to deduct research and development expenditures currently and requires taxpayers to amortize such costs over a period of five or fifteen years. While it is possible that Congress may modify, defer, or repeal such provision, we have no assurance that the provision will be modified, deferred or repealed.

Utilization of net operating loss and tax credit carryforwards may be subject to certain limitations under Section 382 of the Internal Revenue Code of 1986, as amended, in the event of a change in the Company's ownership, as defined. The annual limitation may result in the expiration of the net operating loss and tax credit before utilization. The Company has completed a Section 382 analysis from January 1, 2017 through December 31, 2023 and determined that a change in ownership has occurred on March 7, 2017, December 21, 2018, June 30, 2020 and September 26, 2023. As a result, the net operating loss carryforwards generated on or prior to September 26, 2023 are subject to annual limitations before being applied to reduce future income tax liabilities. Of the $214.7 million net operating loss carryforwards generated on or before December 31, 2023, approximately $90 million are expected to be unavailable for future utilizations. For years ended after

December 31, 2023, the utilization of such net operating losses and tax credit carryforwards maybe subject to further limitation in the event an additional ownership change were to occur for tax purposes.

U.S. taxes and foreign withholding taxes have not been provided on undistributed earnings for certain non-U.S. subsidiaries as of December 31, 2024, as the earnings, if any, are intended to be indefinitely reinvested.

The following tables summarize the activities of gross unrecognized tax benefits (in thousands):

	Years Ended December 31,		
	2024	2023	2022
Beginning balance	$ 2,938	$ 1,936	$ 1,557
Increase related to current year tax positions	2,884	1,002	379
Increase related to prior year tax positions	1,332	—	—
Decrease related to prior year tax positions	(787)	—	—
Ending balance	$ 6,367	$ 2,938	$ 1,936

The Company uses the “more likely than not” criterion for recognizing the tax benefit of uncertain tax positions and to establish measurement criteria for income tax benefits. The Company has determined it has $6.4 million of unrecognized assets and liabilities related to uncertain tax positions as of December 31, 2024. Changes in the unrecognized tax benefits within the next 12 months are expected to be similar to prior years and should not significantly increase or decrease. In the event the Company should need to recognize interest and penalties related to unrecognized tax liabilities, this amount will be recorded as a component of other expense.

There were no unrecognized tax benefits that would impact the effective tax rate as of December 31, 2024 and December 31, 2023. As of December 31, 2024, unrecognized tax benefits of $6.4 million would be offset by a change in valuation allowance.

The Company files income tax returns in the U.S. federal jurisdiction, certain state jurisdictions, United Kingdom and Ireland. The Company paid minimal foreign taxes in 2024 and zero in each of 2023 and 2022. In the normal course of business, the Company is subject to examination by federal, state, local and foreign jurisdictions, where applicable. In the U.S federal jurisdiction, tax years 2003 forward remain open to examination, in the state tax jurisdiction, years 2008 forward remain open to examination and in the foreign jurisdiction, years 2015 forward remain open to examination. The Company is currently not under audit by any federal, state, local or foreign jurisdiction.

Note 11. Net Loss per Share

Basic net loss per share is computed by dividing net loss by the weighted-average number of common stock outstanding during the period. Shares of common stock that are potentially issuable for little or no cash consideration at issuance, such as the Company's pre-funded warrants issued in March 2022 and October 2023 and in connection with the exercise of certain May 2023 Tranche A and Tranche B warrants, are considered outstanding common stock and are included in the calculation of basic and diluted net loss per share in connection with *ASC 260 Earnings Per Shares*. Diluted net loss per share is computed by dividing net loss by the weighted-average number of common stock outstanding and dilutive potential common stock that would be issued upon the exercise or vesting of common stock awards and exercise of common stock warrants that are not pre-funded. The Company applies the two-class method to calculate basic and diluted earnings per share as its warrants issued in March 2022, May 2023 and October 2023 are participating securities. However, the two-class method does not impact the net loss per share of common stock as the March 2022, May 2023 and October 2023 common warrants issued do not participate in losses. For the years ended December 31, 2024, 2023 and 2022, the effect of issuing the respective potential common stock is anti-dilutive due to the net losses in those periods and therefore the number of shares used to compute basic and diluted net loss per share are the same in each of those periods.

The following securities are included in the weighted-average common shares outstanding used to calculate basic and diluted net loss per common share:

	Years Ended December 31,		
	2024	2023	2022
Common stock	37,689,804	15,040,036	7,409,165
March 2022 pre-funded warrants	-	290,665	987,923
May 2023 Tranche A pre-funded exchange warrants	1,685,181	778,904	-
May 2023 Tranche B pre-funded exchange warrants	373,892	92,801	-
October 2023 pre-funded warrants	427,049	289,726	-
Total	40,175,926	16,492,132	8,397,088

The following potentially dilutive securities outstanding have been excluded from the computations of diluted weighted-average shares outstanding because such securities have an antidilutive impact due to losses reported (in common stock equivalent shares):

	Years Ended December 31,		
	2024	2023	2022
Warrants issued to 2010/2012 convertible note holders to purchase common stock	-	6,804	6,804
Warrants issued to underwriter to purchase common stock	-	1,100	1,100
2018 PIPE warrants	-	-	34,241
March 2022 common warrants	1,255,346	1,929,066	4,000,000
May 2023 Tranche B warrants	2,065,305	6,750,000	-
Options to purchase common stock	3,971,798	2,369,665	686,574
Outstanding restricted stock units	939,865	15,534	19,068
Total	8,232,314	11,072,169	4,747,787

Note 12. Defined Contribution Plan

The Company sponsors a 401(k) Plan, which stipulates that eligible employees can elect to contribute to the 401(k) Plan, subject to certain limitations of eligible compensation. The Company may match employee contributions in amounts to be determined at the Company's sole discretion. In 2024, the Company made matching contributions of $0.2 million and no matching contributions in 2023 or 2022.

Note 13. Segment Reporting

The Company has one operating and reporting segment focused on the development and commercialization of its lead therapeutic candidate, DCCR. The Company's chief operating decision maker (CODM) is the chief executive officer who reviews cash operating expenses on a consolidated basis to make

decisions about allocating resources and assessing performance for the entire Company. The CODM does not review assets at a level or category different than the amounts disclosed in the consolidated balance sheet.

Cash operating expenses reconciled to net loss on a consolidated basis were as follows (in thousands):

	Years Ended December 31,		
	2024	2023	2022
Net operating loss	$ (175,850)	$ (38,988)	$ (24,067)
Less total other income, net	11,821	2,396	330
Operating loss	(187,671)	(41,384)	(24,397)
Total operating expenses	187,671	41,384	24,397
Less non-cash expenses			
Depreciation and amortization	(1,987)	(1,958)	(1,964)
Noncash lease expense	(444)	(321)	(290)
Change in fair value of contingent consideration	(3,242)	(2,714)	712
Stock-based compensation	(99,958)	(5,945)	(2,530)
Cash operating expenses	$ 82,040	$ 30,446	$ 20,325

Note 14. Subsequent Events

The Company has evaluated its subsequent events from December 31, 2024 through the date these condensed consolidated financial statements were issued and has determined that there are no subsequent events disclosure required.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURES

None.

ITEM 9A. CONTROLS AND PROCEDURES

Management's Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) that are designed to provide reasonable assurance that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to management, including our Chief Executive Officer (principal executive officer) and Chief Financial Officer (principal financial officer), as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As required by Rule 13a-15(b) under the Exchange Act, our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Exchange Act) as of December 31, 2024. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were not effective as of December 31, 2024 because of the material weakness in internal controls discussed below. Notwithstanding the material weakness, our management, including our Chief Executive Officer and Chief Financial Officer, has concluded that our consolidated financial statements included in this Annual Report on Form 10-K fairly present, in all material respects, our financial condition, results of operations and cash flows for the periods presented in conformity with generally accepted accounting principles.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rule 13a-15(f) or 15d-15(f) of the Exchange Act). Our management assessed the effectiveness of the Company's internal control over financial reporting based on certain criteria established in the Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations (COSO) of the Treadway Commission in 2013. Based on this assessment, our management concluded that our internal control over financial reporting was not effective as of December 31, 2024, due to the material weakness described below. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. Specifically:

- The Company had ineffective design and operation of controls over certain information technology general controls (ITGCs), including segregation of incompatible duties, program change management, and user access controls to ensure: (i) that access to applications and data, and the ability to perform program changes, were adequately restricted to appropriate personnel and (ii) that the activities of individuals with access to modify data and make program changes were appropriately monitored and restricted. Automated process-level and manual controls that are dependent upon the information derived from such financially relevant systems were also determined to be ineffective as a result of such deficiency.

The material weakness described above did not result in a material misstatement to the Company's previously issued consolidated financial statements, nor in the consolidated financial statements included in this Annual Report.

The registered public accounting firm that audited our consolidated financial statements within this Annual Report has issued an attestation report on our internal control over financial reporting.

Remediation Plans

Our management is committed to maintaining a strong internal control environment. Management intends to take comprehensive actions to remediate the material weakness in internal control over financial reporting, which include the following:

- Hire additional personnel in the accounting and financial reporting function that would allow for appropriate segregation of duties, both systematically and operationally. We will continue to reassess staffing and add additional resources, as required, with the requisite experience and training, to support our system of internal control;
- Implement a training program for all personnel responsible for internal controls over financial reporting, including educating control owners regarding the requirements of each control. For control owners with IT responsibilities, develop and implement additional training and awareness programs addressing ITGC policy and requirements, with a specific focus on user access and change management processes and controls;
- Continue to enhance, standardize and monitor the ongoing improvements in design and operating effectiveness of our controls and the adherence of our personnel to any enhancements in controls, policies, and procedures. Moreover, within our IT environment, increase the extent of oversight and verification checks included in the operation of user access and program change management controls and processes;
- We will continue to report regularly to the audit committee on the progress and results of the remediation plan, including the identification, status and resolution of internal control deficiencies.

We believe the foregoing efforts will effectively remediate the identified material weakness in internal controls over financial reporting. Because the reliability of the internal control process requires repeatable execution, the successful remediation will require review and evidence of effectiveness prior to management concluding that the Company's internal controls over financial reporting are effective. We may also conclude that the additional measures may be required to remediate the material weakness which may necessitate additional implementation and evaluation time. We will continue to assess the effectiveness of our internal control over financial reporting and take steps to remediate the material weakness expeditiously.

Changes in Internal Control Over Financial Reporting

Except as described above, there were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d 15(f) under the Exchange Act) that occurred during the quarter ended December 31, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM ON INTERNAL CONTROL OVER FINANCIAL REPORTING

To the Stockholders and Board of Directors of
Soleno Therapeutics, Inc.

Adverse Opinion on Internal Control over Financial Reporting

We have audited Soleno Therapeutics Inc.'s (the Company) internal control over financial reporting as of December 31, 2024, based on criteria established in *Internal Control-Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission. In our opinion, because of the effect of the material weakness described in the following paragraph on the achievement of the objectives of the control criteria, the Company has not maintained effective internal control over financial reporting as of December 31, 2024, based on criteria established in *Internal Control-Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

A material weakness is a control deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis. The following material weakness have been identified and included in Management's Annual Report on Internal Control Over Financial Reporting:

- The Company did not design and maintain formal and effective controls over certain information technology general controls (ITGCs) for IT systems that are relevant to the preparation of the financial statements. Specifically, (a) user access controls to ensure appropriate segregation of duties and adequate restriction of user and privileged access to financial applications, programs, and data (b) program change management controls to ensure that IT program and data changes affecting financially significant IT applications and underlying accounting records are identified, tested, authorized and implemented appropriately. Automated process-level and manual controls that are dependent upon the information derived from such financially relevant systems were also determined to be ineffective as a result of such deficiency.

This material weakness was considered in determining the nature, timing and extent of audit tests applied in our audit of the fiscal December 31, 2024 consolidated financial statements, and this report does not affect our report dated February 28, 2025 on those financial statements.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets as of December 31, 2024 and 2023 and the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2024 of the Company and our report dated February 28, 2025 expressed an unqualified opinion on those financial statements.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management Annual Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of the inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that degree of compliance with the policies or procedures may deteriorate.

/s/ Marcum LLP

Marcum LLP
San Francisco, CA
February 28, 2025

ITEM 9B. OTHER INFORMATION

We have social media posts at Twitter (X) - @SolenoTX and LinkedIn - Soleno Therapeutics, Inc. It is possible that information we post on social media channels could be deemed to be material information. The information on, or that may be accessed through, our website and social media channels is not incorporated by reference into this Annual Report on Form 10-K and should not be considered a part of this Annual Report on Form 10-K.

Securities Trading Plans of Directors and Executive Officers

During the three months ended December 31, 2024, the Company did not adopt, modify or terminate and no directors or officers, as defined in Rule 16a-1(f), adopted, modified or terminated a Rule 10b5-1 trading arrangement or a non-Rule 10b5-1 trading arrangement, each as defined in Regulation S-K Item 408.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this item is incorporated by reference to our Definitive Proxy Statement for our 2025 Annual Meeting of Stockholders. The Definitive Proxy Statement will be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

Our Board of Directors has adopted a Code of Business Conduct and Ethics that applies to all of our employees, officers and directors, including our Chief Executive Officer, Chief Financial Officer, and other executive and senior financial officers. The full text of our Code of Business Conduct and Ethics is posted on the Corporate Governance portion of our website at https://investors.soleno.life/. We will post amendments to our Code of Business Conduct and Ethics or waivers of our Code of Business Conduct and Ethics for directors and executive officers on the same website.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated by reference to our Definitive Proxy Statement for our 2025 Annual Meeting of Stockholders. The Definitive Proxy Statement will be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this item is incorporated by reference to our Definitive Proxy Statement for our 2025 Annual Meeting of Stockholders. The Definitive Proxy Statement will be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS,AND DIRECTOR INDEPENDENCE

The information required by this item is incorporated by reference to our Definitive Proxy Statement for our 2025 Annual Meeting of Stockholders. The Definitive Proxy Statement will be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this item is incorporated by reference to our Definitive Proxy Statement for our 2025 Annual Meeting of Stockholders. The Definitive Proxy Statement will be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

1. Financial Statements: See “Index to Financial Statements” in Part II, Item 8 of this Annual Report on Form 10-K
2. Financial Schedules: All schedules have been omitted because the information called for is not required or is shown either in the financial statements or in the notes thereto.
3. Exhibits: The exhibits listed in the accompanying index to exhibits are filed or incorporated by reference as part of this Annual Report on Form 10-K.

EXHIBIT INDEX

Exhibit Number	Description of Document	Incorporated by Reference from			Filed Herewith
		Registrant's Form	Date Filed with the SEC	Exhibit Number	
2.1	Agreement and Plan of Merger and Reorganization, dated as of December 22, 2016, by and among Soleno Therapeutics, Inc., Essentialis, Inc., Company E Merger Sub, Inc., a wholly-owned subsidiary of Soleno Therapeutics, and Neil Cowen as the stockholders' representative.	8-K	December 27, 2016	2.1	
3.1	Amended and Restated Certificate of Incorporation of Soleno Therapeutics, Inc.	S-1/A	August 7, 2014	3.2	
3.2	Amended and Restated Bylaws of Soleno Therapeutics, Inc.	S-1/A	July 1, 2014	3.4	
3.3	Certificate of Amendment	8-K	May 11, 2017	3.1	
3.4	Certificate of Amendment to the Certificate of Incorporation	8-K	October 6, 2017	3.1	
3.5	Certificate of Amendment to the Certificate of Incorporation	8-K	August 25, 2022	3.1	
4.1	Form of the Registrant's common stock certificate.	S-1/A	August 5, 2014	4.1	
4.2	Description of the Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934	10-K	March 4, 2020	4.29	
4.3	Form of Common Warrant To Purchase Common Stock.	8-K	March 30, 2022	4.2	
4.4	Form of Tranche B Warrant to Purchase Common Stock	8-K	December 19, 2022	10.3	
4.5	Form of Pre-Funded Warrant to Purchase Common Stock	8-K	September 28, 2023	10.2	
10.1†	Form of Indemnification Agreement between the Registrant and each of its directors and executive officers.	S-1/A	June 10, 2014	10.1	
10.2†	1999 Incentive Stock Plan and forms of agreements thereunder.	S-1/A	June 10, 2014	10.2	
10.3†	2010 Equity Incentive Plan and forms of agreements thereunder.	S-1/A	June 10, 2014	10.3	
10.4†	2014 Equity Incentive Plan and forms of agreements thereunder.	S-1/A	July 1, 2014	10.4	

Exhibit Number	Description of Document	Incorporated by Reference from			Filed Herewith
		Registrant's Form	Date Filed with the SEC	Exhibit Number	
10.5†	2014 Employee Stock Purchase Plan and forms of agreements thereunder.	S-1/A	July 1, 2014	10.5	
10.6†	2020 Inducement Equity Incentive Plan, as amended on January 24, 2024	8-K	January 30, 2024	10.1	
10.7†	Employment Agreement, dated April 6, 2010, by and between Soleno Therapeutics, Inc. and Anish Bhatnagar.	S-1	June 10, 2014	10.7	
10.8†	Employment Agreement by and between the Company and James Mackaness, dated as of November 11, 2020	8-K	November 13, 2020	10.1	
10.9†	Amendment to Employment Agreement by and between the Company and James Mackaness, dated as of January 8, 2021	8-K	January 13, 2021	10.1	
10.10†	Employment Agreement by and between the Company and Patricia Hirano, dated January 1, 2019				X
10.11†	Amendment to Employment Agreement by and between the Company and Patricia Hirano, dated as of January 8, 2021	8-K	January 13, 2021	10.3	
10.12†	Employment Agreement by and between the Company and Meredith Manning, dated January 23, 2024				X
10.13	License Agreement for Space and Services, dated February 8, 2024, by and between Soleno Therapeutics, Inc. and Hudson Towers at Shore Center, LLC	10-K	March 7, 2024	10.58	
10.14	Lease agreement between the Company and 1 Twin Property Owner, LLC dated June 13, 2024 Owner, LLC dated June 13, 2024	10-Q	August 7, 2024	10.1	
10.15	Open Market Sale Agreement℠, dated July 19, 2024, by and between Soleno Therapeutics, Inc. and Jefferies LLC	8-K	July 19, 2024	10.1	
10.16#	Loan and Security Agreement by and between Soleno Therapeutics, Inc. and Oxford Finance LLC, dated December 17, 2024				X
10.17†	Amended and Restated Outside Director Compensation Policy				X
19.1	Insider Trading Policy				X
21.1	Subsidiaries				X

Exhibit Number	Description of Document	Incorporated by Reference from			Filed Herewith
		Registrant's Form	Date Filed with the SEC	Exhibit Number	
23.1	Consent of Marcum LLP				X
31.1	Certification of Principal Executive Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended				X
31.2	Certification of Principal Financial and Accounting Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended				X
32.1*	Certification of Principal Executive Officer Required Under Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. §1350				X
32.2*	Certification of Principal Financial and Accounting Officer Required Under Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. §1350				X
97.1†	Compensation Recovery Policy	10-K	March 7, 2024	97.1	
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data file because XBRL tags are embedded within the Inline XBRL document.				X
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents.				X
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).				

* Furnished and not filed herewith.
† Indicates management contract or compensatory plan.
# Confidential treatment has been requested for portions of this exhibit. These portions have been omitted and have been filed separately with the Securities and Exchange Commission.

SIGNATURES

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

Soleno Therapeutics, Inc.

Date: February 28, 2025

By: /S/ ANISH BHATNAGAR
President and Chief Executive Officer

POWER OF ATTORNEY

Each person whose individual signature appears below hereby authorizes and appoints Anish Bhatnagar and James Mackaness, with full power of substitution and resubstitution and full power to act, as his or her true and lawful attorney-in-fact and agent to act in his or her name, place and stead and to execute in the name and on behalf of each person, individually and in each capacity stated below, and to file any and all amendments to this annual report on Form 10-K and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing, ratifying and confirming all that said attorneys-in-fact and agents or any of them or their or his substitute or substitutes may lawfully do or cause to be done by virtue thereof.

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

Signature	Title	Date
/S/ ANISH BHATNAGAR Anish Bhatnagar	President, Chief Executive Officer and Director (Principal Executive Officer)	February 28, 2025
/S/ JAMES MACKANESS James Mackaness	Chief Financial Officer (Principal Financial and Accounting Officer)	February 28, 2025
/S/ MATTHEW PAULS Matthew Pauls	Lead Independent Director	February 28, 2025
/S/ ANDREW SINCLAIR Andrew Sinclair	Director	February 28, 2025
/S/ WILLIAM G. HARRIS William G. Harris	Director	February 28, 2025
/S/ DAWN BIR Dawn Bir	Director	February 28, 2025
/S/ BIRGITTE VOLCK Birgitte Volck	Director	February 28, 2025