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, 2025

☐ **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 **(State or other Jurisdiction of Incorporation or Organization)**	**77-0523891** **(I.R.S. Employer Identification No.)**
100 Marine Parkway, Suite 400 **Redwood City, California** **(Address of principal executive offices)**	**94065** **(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 30, 2025, based on the closing price of $83.78 for shares of the registrant's Common Stock as reported by the Nasdaq Capital Market, was approximately $4.1 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 19, 2026, there were 51,624,384 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 2026 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, 2025. 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: CBIZ CPAs P.C. Auditor Location: San Francisco, CA Auditor Firm ID: 199

Soleno Therapeutics, Inc.
Annual Report on Form 10-K
For the Year Ended December 31, 2025

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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 marketing and commercialization of VYKAT™ XR (diazoxide choline) extended-release tablets (formerly known as DCCR), any statements regarding the timing of any regulatory process or ultimate approvals and determining a path forward for DCCR for the treatment of Prader-Willi syndrome outside of the United States; any plans or projections regarding the commercialization of DCCR outside of the United States; any projections of financial information; any statements about our research and development pipeline; 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 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. On March 26, 2025, we announced that our lead product candidate, VYKAT™ XR (diazoxide choline) extended-release tablets, formerly known as DCCR, had been approved by the U.S. Food and Drug Administration (FDA). VYKAT XR is indicated to treat hyperphagia in adults and pediatric patients four years of age and older with Prader-Willi syndrome (PWS). On April 14, 2025, we announced that prescriptions of VYKAT XR had been delivered to the first individuals living with PWS who had been prescribed the medication and began recognizing revenue from the sales of VYKAT XR during the three months ended June 30, 2025. We are incorporated in the State of Delaware and headquartered in Redwood City, California.

VYKAT XR 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.

VYKAT XR (Diazoxide Choline) Extended-Release Tablets

VYKAT XR 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 -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.

VYKAT XR 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 VYKAT XR, making it suitable for once-a-day dosing. The gradual release and absorption of diazoxide achieved using VYKAT XR 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

On March 26, 2025, VYKAT XR was approved by the FDA for the treatment of patients with PWS ages 4 years and older who have hyperphagia. Currently, the only other approved treatment in the U.S. related to PWS is growth hormone which addresses the growth failure 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.

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 ICD10 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. VYKAT XR is 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. 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 have positioned ourselves to launch VYKAT XR through our commercial organization in a targeted and efficient manner. We have a field force of approximately 65 individuals, including approximately 28 rare disease specialists, 16 clinical nurse educators, 6 regional access directors and 15 remote or hybrid lead generation specialists.

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

Pricing

VYKAT XR is sold based on weight-based pricing, with a list price of $6.0976 per milligram. It is our philosophy that those in need of VYKAT XR have access to VYKAT XR. We offer several programs through SOLENO ONE™ to provide patients and caregivers education and resources including financial assistance in certain situations, consequently any actual out-of-pocket costs vary significantly with insurance.

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 other approved products for patients with PWS in the U.S. are forms of somatropin, which are approved only for growth failure due to PWS. There are no other 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 Aardvark Therapeutics, Bright Minds Biosciences, Consynance, Harmony Biosciences, Neuren Pharmaceuticals, OT4B, Palobiofarma and Rhythm Pharmaceuticals.

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

- the perceived efficacy and safety of VYKAT XR;
- our ability to obtain product acceptance by physicians and other healthcare providers and secure coverage and adequate reimbursement for VYKAT XR;
- our ability, and the ability of our collaborators, to manufacture and sell commercial quantities of VYKAT XR;
- the timing and scope of regulatory approvals of VYKAT XR outside of the United States;
- 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 VYKAT XR 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 production and distribution of VYKAT XR. Instead, we have multiple contractual agreements in place with third-party organizations who, on our behalf, manufacture, store and distribute commercial supplies of VYKAT XR. We have selected well-established and reputable global contract manufacturing organizations (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 VYKAT XR 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 VYKAT XR for the foreseeable future.

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.

We utilize a third party logistics provider (3PL) with multiple locations to provide shipping and warehousing services for our commercial supply of VYKAT XR. We have also entered into a non-exclusive agreement with a specialty pharmacy who purchases and dispenses VYKAT XR to patients pursuant to prescriptions provided by health care providers.

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 2026 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. Our portfolio covers various aspects of our core technologies including 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 drug products and product

candidates 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. Further, FDA's "real-time" release of newly issued Complete Response Letters associated with withdrawn or abandoned applications, if applicable to any of our product candidates, can materially impact our business and competitive advantage.

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 review and priority approval.

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. The Consolidated Appropriations Act of 2026, signed into law in February 2026, codified this longstanding FDA interpretation of the Orphan Drug Act, allowing the FDA to approve multiple versions of the same orphan drug for different subindications and subpopulations. 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

Pharmaceutical companies are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business, which may constrain the financial arrangements and relationships through which we conduct research, as well as sell, market and distribute any products for which we obtain marketing approval. Such laws include, without limitation, federal and state anti-kickback, fraud and abuse, false claims, data privacy and security and physician and other health care provider transparency laws and regulations. If our significant operations are found to be in violation of any of such laws or any other governmental regulations that apply, they may be subject to penalties, including, without limitation, administrative, civil and criminal penalties, damages, fines, disgorgement, the curtailment or restructuring of operations, integrity oversight and reporting obligations, exclusion from participation in federal and state healthcare programs and imprisonment.

Coverage and Reimbursement

Sales of any approved products depend, in part, on the extent to which such product will be covered by third-party payors, such as federal, state, and foreign government healthcare programs, commercial insurance and managed healthcare organizations, and the level of reimbursement for such product by third-party payors. Decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a country-by-country and a plan-by-plan basis. These third-party payors are increasingly reducing reimbursements for drugs. In addition, the U.S. government, state legislatures, and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit sales of any product. Decreases in third-party reimbursement for any product or a decision by a third-party payor not to cover a product could reduce physician usage and patient demand for the product and also have a material adverse effect on sales.

Healthcare Reform

The United States government and other governments have shown significant interest in pursuing health care reform. Any government-adopted reform measures could adversely impact the pricing of health care products and services in the United States or internationally and the amount of reimbursement available from governmental agencies or other third-party payors. For example, the Patient Protection and Affordable Care Act (the ACA) which was enacted in the United States in 2010, substantially changed the way healthcare is financed by both governmental and private insurers, and significantly affected the pharmaceutical industry. The ACA contains a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement adjustments and changes to fraud and abuse laws. Since its enactment, there have been judicial, executive, and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the United States Supreme Court dismissed the most

recent judicial challenge to the ACA without specifically ruling on the constitutionality of the ACA. Thus, the ACA will remain in force in its current form.

Other legislative changes have been proposed and adopted since the ACA was enacted, including reductions of Medicare payments to providers through 2032. The American Rescue Plan Act of 2021 eliminated the statutory Medicaid drug rebate cap. Elimination of this cap may require pharmaceutical manufacturers to pay more in rebates than they receive from the sale of products, which could have a material impact on our business. Under the Inflation Reduction Act of 2022 (IRA), among other things, the law requires manufacturers of certain drugs to engage in price negotiations with Medicare, with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation; and replaces the Part D coverage gap discount program with a new discounting program. The IRA permits the Secretary of the Department of Health and Human Services to implement many of these provisions through guidance, as opposed to regulation, for the initial years. Only high-expenditure single-source drugs that have been approved for at least seven years (11 years for single-source biologics) can qualify for negotiation, with the negotiated price taking effect two years after the selection year. Various industry stakeholders have initiated lawsuits against the federal government asserting that the price negotiation provisions of the IRA are unconstitutional. Further, the current administration has issued executive orders focused on decreasing prescription drug prices, including directing the Secretary of HHS to establish a mechanism through which American patients can buy drugs directly from manufacturers who sell at a most-favored-nation price and directing the U.S. Trade Representative and Secretary of Commerce to take action to ensure foreign countries are not engaged in practices that purposefully and unfairly undercut market prices and drive price hikes in the U.S. In November 2025, CMS announced a voluntary initiative called the GENEROUS Model (GENErating cost Reductions fOr U.S. Medicaid Model) to introduce the option of most-favored-nation pricing to the Medicaid program, whereby a drug manufacturer may voluntarily offer supplemental rebates to participating state Medicaid programs for a manufacturer's covered outpatient drugs. Government agreements with pharmaceutical companies and other measures that use most-favored-nation pricing targets for prescription drugs or that increase generic and biosimilar drug entry sooner than expected can have a material adverse effect on our industry, ability to set adequate pricing for new drugs to recover R&D costs, ability to attract potential investors and potential buyers in the future, or the pricing of our approved product in the U.S. and in foreign countries. The impact of any future healthcare measures and agency rules, including those implemented by the current administration, 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.

Moreover, there has been recent heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which is likely to continue. Individual states in the United States 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, designed to encourage importation from other countries and bulk purchasing. For example, the FDA has authorized the state of Florida to develop a drug importation program to import certain prescription drugs from Canada for a limited period 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. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates, if approved, or additional pricing pressures.

Similar political, economic, and regulatory developments are occurring in the European Union (E.U.) and may affect the ability of pharmaceutical companies to profitably commercialize their products. In addition to continuing pressure on prices and cost containment measures, legislative developments at the E.U. or member state level may result in significant additional requirements or obstacles. The delivery of healthcare in the E.U., including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than E.U., law and policy. National governments and health service providers have different priorities and approaches to the delivery of healthcare and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most E.U. member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing E.U. and national regulatory burdens on those wishing to develop and market products, this

could restrict or regulate post-approval activities and affect the ability of pharmaceutical companies to commercialize their products. In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies.

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. Violations under the Anti-Kickback Statute, discussed further below, can implicate violations under the False Claims Act. Liability under the False Claims Act can result in treble damages and imposition of penalties. For example, civil penalties of up to $25,595 may be imposed per violation, 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 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 Anti-Kickback Laws and the Sunshine Act

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" has been broadly interpreted to include anything of 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. 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.

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.

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.

Drug manufacturers are also subject to the Physician Payment Sunshine Act, or the Open Payments Act, which was enacted as part of the Affordable Care Act, requires all applicable manufacturers that participate in Medicare, Medicaid or the Children's Health Insurance Program to report annually to the Secretary of the Department of Health and Human Services payments and other transfers of value made in the previous year by that entity, or by a third party as directed by that entity, to covered recipients, including physicians, certain non-physician healthcare professionals, and teaching hospitals, as defined by law, or to third parties on behalf of such covered recipients, as well as ownership and investment interests held by physicians and their immediate family members. Failure to comply with the reporting requirements can result in significant civil monetary penalties. Additionally, there are criminal penalties if an entity intentionally makes false statements in such reports. We are subject to the Sunshine Act and the information we disclose may lead to greater scrutiny. Additionally, similar reporting requirements have also been enacted on the state level domestically, and an increasing number of countries worldwide either have adopted or are considering adopting similar laws requiring transparency of interactions with health care professionals.

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, 2025, we had 182 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 have limited commercialization history as a company and, until recently, have incurred significant losses since our inception;
- we have just begun to generate product revenue and are dependent upon the success of VYKAT XR;
- VYKAT XR 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;
- we recently have been and may be in the future become subject to short-selling campaigns, activist investors and securities litigation, which are expensive and could divert management attention; 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 have limited commercialization history as a company and, until recently, have incurred significant losses since our inception.

We have historically been a clinical-stage company with no approved therapeutic products or revenues from the sale of therapeutic products. Following FDA approval on March 26, 2025, we have begun to commercialize our first product, VYKAT XR, to treat hyperphagia in patients four years and older who have Prader-Willi syndrome (PWS). Evaluating our performance, viability or future success will be more difficult than if we had a longer operating history or prior approved products for sale on the market. Following approval of VYKAT XR, we will continue to incur significant research and development, 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 our sole commercial product, VYKAT XR. This will require us to be successful in a range of activities, including manufacturing, marketing and selling VYKAT XR. We are only in the preliminary stages of some of these activities and may not succeed in the long-term. We may not be able to sustain growth 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 have just begun to generate product revenue and are dependent upon the success of VYKAT XR.

To date, we have invested substantially all of our efforts and financial resources in the development and commercialization of VYKAT XR for the treatment of PWS, a rare complex genetic neurobehavioral/metabolic disease. We began to generate revenue from the commercialization of VYKAT XR in the three months ended June 30, 2025. Our ability to generate revenue from product sales from VYKAT XR depends on a number of additional factors, including our ability to:

- build and maintain an infrastructure capable of supporting product sales, marketing, and distribution of VYKAT XR in the U.S. and territories where we pursue commercialization directly;
- achieve market acceptance of VYKAT XR by patients, caregivers and the medical community;
- maintain a continued acceptable safety and efficacy profile of VYKAT XR;
- sustain a commercially viable price for VYKAT XR;
- 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 VYKAT XR in other markets;
- complete and submit applications to, obtain regulatory approval from, and complete any post-marketing requirements of, foreign regulatory authorities;
- establish, maintain and enforce our intellectual property rights, obtain and maintain regulatory exclusivity and avoid third-party patent interference, intellectual property challenges, including any potential challenges to our Orange Book patent listings in the U.S., or intellectual property infringement claims; and
- attract, hire and retain qualified personnel.

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

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

Our quarterly and annual operating results may fluctuate significantly in the future, which makes it difficult for us to predict our future operating results. 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.

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:

- the cost and risk of initiating sales and marketing activities;
- 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 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 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;
- 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 acquire and 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.

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 are in the early stages of commercializing VYKAT XR, our current sole novel therapeutic product, and accordingly, have just begun to generate revenue from operations during 2025. We had a net income of $20.9 million during the year ended December 31, 2025 and an accumulated deficit of $431.4 million at December 31, 2025 as a result of losses incurred prior to 2025.

Although we are currently cash flow positive, we may not be able to sustain profitability, and therefore we may need to raise additional capital, either through debt or equity financings to achieve our business plan objectives, including ongoing expenses related to scaling of a sales and marketing organization to support the launch of VYKAT XR and our ongoing regulatory activities necessary to obtain marketing approvals outside of the United

States. Our ability to obtain additional financing will depend on a number of factors, including, among others, 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.

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 assets that we would not otherwise relinquish. If we issue equity or convertible debt securities to raise additional funds, our existing stockholders will experience further dilution, and the new equity or debt securities may have rights, preferences and privileges senior to those of our existing stockholders. If we incur debt, our fixed payment obligations, liabilities and leverage relative to our equity capitalization would increase, which could increase the cost of future capital. Further, the terms of any debt securities we issue or borrowings we incur, if available, could impose significant restrictions on our operations, such as limitations on our ability to incur additional debt or issue additional equity or other operating restrictions that could adversely affect our ability to conduct our business, and any such debt could be secured by any or all of our assets pledged as collateral. Additionally, we may incur substantial costs in pursuing future capital, including investment banking, legal and accounting fees, printing and distribution expenses and other costs.

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

As of December 31, 2025, 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, following FDA approval of VYKAT XR, an additional $50 million became available through September 30, 2025, but was not drawn. Following the amendment of our loan and security agreement in November 2025, the final three tranches of an aggregate of $100 million may be made available upon mutual consent with Oxford. As a result of a milestone achieved in 2025, the loan carries an interest-only period of 60 months and a total term of 72 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.

Risks related to the commercialization of VYKAT XR

VYKAT XR may fail to achieve the degree of market acceptance by physicians, patients, caregivers, healthcare payers and others in the medical community necessary for sustained commercial success.

VYKAT XR may fail to gain sufficient market acceptance by physicians, hospital administrators, patients, caregivers, healthcare payers and others in the medical community. The degree of market acceptance of VYKAT XR 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 VYKAT XR;
- our ability to educate the physician community;
- 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' or caregivers' perception of the efficacy of VYKAT XR 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 VYKAT XR 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 could be prescribed VYKAT XR, are estimates based on data analysis of the reported patient population. If our estimates of the prevalence of PWS, the number of patients who may benefit from treatment with VYKAT XR, or the number of patients willing to stay on treatment indefinitely prove to be incorrect, the market opportunity for VYKAT XR 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 VYKAT XR 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 VYKAT XR represents a promising commercial opportunity, VYKAT XR may never gain significant acceptance in the marketplace and therefore may never generate substantial revenue or sustainable profits for us. We will need to establish a market for VYKAT XR 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 VYKAT XR, and word-of-mouth between physicians. The process of publication in leading medical journals is subject to a peer review process and peer reviewers may not consider the results of our studies sufficiently novel or worthy of publication. Failure to have our 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 VYKAT XR provides clinical utility which outweighs potential side effects; and
- whether health insurers, government health programs and other payers will cover and pay for VYKAT XR and, if so, whether they will adequately reimburse us.

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

If we are unable to build our sales, marketing, distribution, training and support functions or enter into agreements with third parties to perform these functions, we will not be able to effectively commercialize VYKAT XR and may not sustain profitability.

To achieve commercial success for VYKAT XR, we will need to establish and maintain a robust sales and marketing organization. We have built a targeted sales, marketing, training and support infrastructure to market VYKAT XR in the U.S. and to establish relationships with collaborations to market, distribute and support VYKAT XR 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 impact 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, removal of our promotional materials from the market, or the removal of our approved products from the marketplace by regulatory authorities.

Factors that may inhibit our efforts to commercialize VYKAT XR 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 VYKAT XR 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 successfully 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 VYKAT XR ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell, market and distribute VYKAT XR 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 VYKAT XR 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 VYKAT XR and achieving sustainable profitability, and our business would be harmed.

If physicians decide not to prescribe VYKAT XR, we may be unable to generate sufficient revenue to sustain our business.

To generate demand for VYKAT XR, we will need to educate physicians and other health care professionals on the clinical utility and benefits that VYKAT XR provides 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 VYKAT XR justifies payment at adequate pricing levels. We will also need to continue to train physicians on how to appropriately on how to treat and monitor patients with VYKAT XR in accordance with its approved label, and may find that some physicians are unwilling or unable to dedicate the necessary time or resources to appropriately treat patients with VYKAT XR. We may need to hire additional commercial, scientific, technical and other personnel to support this process.

We may attempt to form partnerships with respect to VYKAT XR, 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 VYKAT XR.

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 VYKAT XR could negatively impact the development or commercialization of VYKAT XR, particularly in geographic regions like Europe, where we have limited 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.

VYKAT XR may cause serious adverse events or side effects or have other properties that could limit the commercial desirability or result in significant negative consequences following commercialization.

Undesirable side effects caused by VYKAT XR could result in a number of potentially significant negative consequences could result, including:

- patients and caregivers could discontinue use of VYKAT XR after starting treatment;
- physicians may be reluctant to continue prescribing VYKAT XR if they have had a negative experience with a patient on VYKAT XR;
- regulatory authorities may withdraw their approvals of VYKAT XR and we may be forced to recall VYKAT XR and suspend the marketing of VYKAT XR;
- regulatory authorities may require additional warnings on the label that could diminish the usage or otherwise limit the commercial success of VYKAT XR;
- the FDA or other regulatory bodies may issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings about VYKAT XR;
- the FDA may require more intensive monitoring or the establishment of Risk Evaluation Mitigation Strategy or a comparable foreign regulatory authority may require 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 VYKAT XR is administered or conduct additional clinical trials;
- third parties may submit a Citizen Petition to the FDA asking for the FDA to request that we voluntarily recall VYKAT XR;
- we could be sued and held liable for harm caused to subjects or patients;
- we may be subject to litigation or product liability claims; or
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of VYKAT XR. 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.

Additionally, in August 2025, the FDA began daily publication of adverse event data from the FDA's Adverse Event Reporting System (FAERS). The FAERS database includes spontaneous and voluntary reports from patients, caregivers and doctors, as well as mandatory manufacturer reports that companies are required to submit to the FDA, including expedited (15-day) alerts and periodic safety updates. A report in FAERS does not establish that a drug caused an adverse event and the adverse event could have been caused by the patient's underlying disease, other medications, or other factors. Reports frequently lack crucial clinical details like a patient's full medical history, the exact drug dosage, and the case narrative. Because of these limitations, FAERS data cannot be used to determine the frequency or likelihood of adverse events. It is difficult for external researchers and the public to interpret the significance of new reports, which can lead to a misinterpretation of the safety signals reported and a decrease in public confidence in a drug.

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

Alternative 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, 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 the symptoms of PWS. We are aware of several 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 VYKAT XR, 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, establish "most-favored-nation" policies, and the amount of reimbursement for particular medications. We cannot be sure that reimbursement will be available for any product that we commercialize in a particular geography 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 our products in specific geographies.

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, manufacturing, sales 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 longer than twelve months after the receipt of regulatory marketing approval for a product in many cases. 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.

If we fail to obtain regulatory approval for our products in the E.U. or other jurisdictions our business would be harmed.

We are required to obtain regulatory approval for each indication we are seeking before we can market and sell our products in a particular jurisdiction, for such indication. Our ability to obtain regulatory approval of our products 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 European Medicines Agency (EMA) or other regulatory agencies' requirements to approve our products 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 our products outside of the United States would be delayed and our business would be harmed.

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 VYKAT XR and other planned products outside the U.S. In May 2025, we announced that our E.U. marketing authorization application (MAA) for diazoxide choline prolonged-release tablets (which we market in the U.S. as VYKAT XR) for the treatment of adults and children four years and older with PWS who have hyperphagia had been validated by the European Medicines Agency (EMA). We are currently in the process of addressing the EMA's written comments regarding our MAA and there is no guarantee that the EMA will approve our MAA. Even if we are successful in obtaining E.U. marketing authorization, the expansion of our commercial activities in the E.U. will increase our compliance costs and exposure to potential liabilities under E.U. laws. Additionally, 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, including hiring and maintaining a foreign employee base;
- 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;

- third parties might illegally distribute and sell counterfeit or unfit versions of our products, which do not meet our rigorous manufacturing, distribution and testing standards;
- inventory that is stolen from warehouses or while in-transit, and that is subsequently improperly stored and sold through unauthorized channels, could adversely impact patient safety, our reputation and our business;
- 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, 2025, we had 182 employees, up from 92 and 33 full-time employees as of December 31, 2024 and December 31, 2023, respectively. We have experienced significant growth in the number of our employees and the scope of our operations, particularly in the areas of sales and marketing, quality assurance, product development, regulatory affairs and drug development. 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:

- 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, distributors, licensors, suppliers and other third parties;
- improving our managerial, development, operational and finance reporting systems and procedures;
- managing our clinical trials effectively, which we anticipate being conducted at numerous clinical sites; 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 commercial, financial, business development and research and development functions. 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. 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 trial 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 wars, 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, outbreaks of disease, 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 VYKAT XR 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 qualified as a smaller reporting company and the reduced compliance requirements to smaller reporting companies no longer apply to us. As such, our auditor was required to attest to the effectiveness of our internal control over financial reporting beginning with our annual report on Form 10-K for the year ended December 31, 2024. 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. 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, 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 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.

In the past, our management has concluded that our disclosure controls and procedures and our internal control over financial reporting were not effective at the reasonable assurance level. While these material weaknesses have been remediated, 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 VYKAT XR. We are currently dependent on sole source suppliers to produce raw materials, active pharmaceutical ingredients (APIs), the finished drug product and the associated packaging for VYKAT XR. If there

is an interruption in supply 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 VYKAT XR, which in turn could adversely affect the commercialization of VYKAT XR.

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 VYKAT XR, 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 VYKAT XR. 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 rely on one specialty pharmacy to dispense VYKAT XR, 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.

Our VYKAT XR sales in the United States have initially been through a single specialty pharmacy and therefore our sales of VYKAT XR are highly dependent on the performance of this specialty pharmacy. 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 VYKAT XR;
- 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 VYKAT XR;
- fails to provide timely and accurate information regarding product adverse events or product complaints;
- does not devote the resources necessary to dispense VYKAT XR in a manner that meets patient needs;
- is unable to satisfy financial obligations to us or others;
- loses the required licenses to distribute VYKAT XR; or
- ceases operations.

If a specialty pharmacy partner does not fulfill its contractual obligations to us or fails to adequately dispense VYKAT XR 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 contract research organizations, 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 and other regulatory agencies require 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.

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 industry. 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 VYKAT XR or other business activities may be subject to claims of infringement of the patent and other proprietary rights of third parties or requests for inter partes review and post-grant review. 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 VYKAT XR. 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 VYKAT XR, 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 continue to commercialize VYKAT XR 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 VYKAT XR.

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 VYKAT XR, we may be open to competition from generic versions of VYKAT XR. 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, and there can be no assurance that such efforts will be successful. Our ability to enforce our patents and other intellectual property rights also depends on the laws of individual countries and each country's practices regarding the enforcement of intellectual property rights and may also be impacted by regulatory actions taken by governmental authorities that affect our ability to use and maintain our intellectual property rights. The loss of patent protection or regulatory exclusivity on VYKAT XR or future products, including potential challenges to our Orange Book patent listings in the U.S., could materially impact our business, results of operations, financial condition and prospects. 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.

Additionally, the U.S. Congress and certain state legislatures in the U.S. have also passed, or have proposed passing, legislation that could adversely impact our ability to settle patent litigations. For example, the State of California has enacted legislation that creates a presumption, with certain exceptions and safe harbors, that various types of patent litigation settlements are anti-competitive, and imposes substantial monetary penalties on companies and individuals who do not comply. The enforcement of this law has been preliminarily enjoined on constitutional grounds, but such legislation still creates a risk of significant potential exposure for settling patent litigations and, in turn, makes it more difficult to settle in the first place, which could have a material adverse effect on our business. VYKAT XR is listed in the Orange Book and can be cited by potential generic competitors in support of approval of an abbreviated new drug application (ANDA). An ANDA provides for the marketing of a drug product that has the same active ingredients in the same strengths and dosage form as the listed drug and has been shown to be bioequivalent to the listed drug. Other than the requirement for bioequivalence testing, ANDA applicants are not required to conduct, or submit results of, pre-clinical or clinical tests to prove the safety or effectiveness of their drug product. Drugs approved in this way are commonly referred to as “generic equivalents” to the listed drug and can often be substituted by pharmacists under prescriptions written for the original listed drug.

The ANDA applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA’s Orange Book. Specifically, the applicant must certify that: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. The ANDA applicant may also elect to submit a section viii statement certifying that its proposed ANDA label does not contain (or carves out) any language regarding the patented method-of-use rather than certify to a listed method-of-use patent. If the ANDA applicant does not challenge the listed patents, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired.

We may receive a Paragraph IV certification asserting that the new product will not infringe our listed patents for VYKAT XR, or that such patents are invalid. Upon receipt of such a Paragraph IV certification, we would have 45 days from the receipt of such a certification to initiate a patent infringement lawsuit. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit, or a decision in the infringement case that is favorable to the ANDA applicant.

The ANDA application also will not be approved until any applicable non-patent exclusivity, such as Orphan Exclusivity, listed in the Orange Book for the referenced product has expired.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims, including potential challenges to our Orange Book patent listings in the U.S., 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, unenforceable or not properly listable in the Orange Book in the U.S., 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 has significantly impacted 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). 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.

Additionally, recent reforms and changes at government agencies of the U.S. and those of non-U.S. jurisdictions could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications, and the maintenance, enforcement, or defense of our issued patents. For example, the ability of the USPTO and other applicable patent authorities to properly administer their functions is highly dependent on the levels of funding available to the agency and their ability to retain key personnel and fill key leadership appointments, among various factors. Termination of employees or delays in replacing or hiring for key positions could significantly impact the ability of the USPTO and other applicable patent authorities to fulfill their functions and could greatly impact our ability to timely and adequately prosecute or maintain our patent applications, and our ability to timely and adequately maintain, enforce, or defend our issued patents.

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, and these regulations differ from country to country. We are not permitted to market our planned products until we have received the requisite approval or clearance from the appropriate authorities. In March 2025, we announced that the FDA has approved VYKAT XR in the U.S. for the treatment of hyperphagia in adults and pediatric patients 4 years of age and older with PWS. In May 2025, we announced that our MAA for diazoxide choline prolonged-release tablets (which we market in the U.S. as VYKAT XR) for the treatment of adults and children four years and older with PWS who have hyperphagia had been validated by the EMA. We are currently in the process of addressing the EMA's written comments regarding our MAA and there is no guarantee that the EMA will approve our MAA.

Obtaining approvals from regulatory authorities 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, EMA or a comparable foreign regulatory authority is not guaranteed, and the approval process is expensive and may take several years. The FDA, EMA and comparable regulatory authorities also have 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, EMA approval or approval from comparable regulatory authorities 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, EMA and comparable regulatory authorities 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;
- regulatory officials may not find the data from preclinical studies and clinical trials sufficient;
- regulatory authorities might not approve our or our third-party manufacturer’s processes or facilities; or

- regulatory authorities may change its approval policies or adopt new regulations.

If any current or 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, EMA 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:

- regulatory authorities may disagree with the design, implementation or results of our clinical trials;
- regulatory authorities 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;
- regulatory authorities may not accept data pooled from different studies, especially if the studies features are not sufficiently similar;
- regulatory authorities finds that our data are not adequate to support the safety and efficacy of our product candidate for the proposed indication;
- regulatory authorities may disagree with our statistical analysis plans;
- 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;
- 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;
- 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 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 regulatory authorities could hinder those agencies from performing normal business functions and increase the time necessary for regulatory submissions to be reviewed and approved, or decrease the likelihood of an approval;
- 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 regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval or resulting in delays in our regulatory approval.

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

Further, under the current administration and new leadership at the U.S. Department of Health and Human Services (HHS) and the FDA, executive orders and layoffs due to the reduction in force initiative, government

shutdowns and other measures implemented by the U.S. government may impact the normal operations of the FDA as well as other federal agencies. The FDA may lack adequate staff and resources to meet current review, approval, and inspection schedules, which could delay our anticipated timelines. In January 2025, an executive order entitled "Unleashing Prosperity Through Deregulation", was issued which calls for at least 10 existing regulations to be repealed whenever an executive department or agency publicly proposes for notice and comment or otherwise promulgates a new regulation. Recent developments at the FDA include announcement of a new Commissioner's National Priority Voucher program for companies supporting certain U.S. national health priorities and interests. To the extent our competitors are selected for this new voucher pilot program and obtain faster approvals, our competitive position may be harmed. Further, the FDA's "real-time" release of newly issued Complete Response Letters associated with withdrawn or abandoned applications, if applicable to any of our product candidates, can materially impact our business and competitive advantage. It is unclear how our industry and our clinical programs and operations will be impacted by policies and regulations implemented under the current administration and FDA leadership, or other executive orders. There is significant uncertainty in the industry and how federal agencies like the FDA will change in the coming years under the current administration. To the extent new policies and other agency changes lead to disruptions in the FDA's operations, our correspondence and regulatory review processes with the FDA may be materially delayed.

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.

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, 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, and may not be the same in all geographies, which may cause confusion.

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, EMA 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 and foreign 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, EMA and other regulatory authorities for compliance with cGMP and foreign 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. 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. 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 future marketing applications.

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.

For example, 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, and potentially benefit from 10 years of market exclusivity (which period of market exclusivity may be extended by two years for orphan medicinal products that have also complied with an agreed pediatric investigation plan), during which time the EMA is generally precluded from approving a MAA for a similar medicinal product. Applicants must first satisfy the orphan designation criteria and apply for orphan designation before making the application for marketing authorization. The applicant must then successfully maintain the orphan designation at the time of the MAA in order to qualify for 10 years of orphan market exclusivity. It is important to note that the regulatory protection afforded to medicinal products such as data exclusivity, marketing protection, market exclusivity for orphan indications and pediatric extension are currently under review at the E.U. level. The protection currently afforded in the E.U. could be reduced in the future.

While the Catalyst Pharms., Inc. v. Becerra, 14 F.4th 1299 (11th Cir. 2021) decision created uncertainty in the application of the orphan drug exclusivity, on January 24, 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. The Consolidated Appropriations Act of 2026, signed into law in February 2026, codified this longstanding FDA interpretation of the Orphan Drug Act, allowing the FDA to approve multiple versions of the same orphan drug for different subindications and subpopulations.

Further, orphan exclusivity in the U.S. and other jurisdictions may be lost if the FDA or comparable foreign regulatory authorities later determines that the request for designation was materially defective or if we are unable to ensure that we will be able to manufacture sufficient quantities of the product to meet the needs of patients with the rare disease or condition. In the U.S. and other jurisdictions, orphan drug exclusivity may not effectively protect an approved product from competition because different drugs with different active moieties may be approved for the same condition. Even after an orphan drug is approved, regulatory authorities can subsequently approve the same drug with the same active moiety for the same condition if the applicable regulatory authorities conclude that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care or the manufacturer of the product with orphan exclusivity is unable to maintain sufficient product quantity.

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

We may seek distribution and marketing partners for our current products outside the U.S. and may market planned products in international markets. In May 2025, we announced that our MAA for diazoxide choline prolonged-release tablets (which we market in the U.S. as VYKAT XR) for the treatment of adults and children four years and older with PWS who have hyperphagia had been validated by the EMA. We are currently in the process of addressing the EMA's written comments regarding our MAA and there is no guarantee that the EMA will approve our MAA. If we obtain E.U. marketing authorization, the expansion of our commercial activities in the E.U. will increase our compliance costs and exposure to potential liabilities under E.U. laws.

After receiving regulatory approval through any of the E.U. registration procedures, separate pricing and reimbursement approvals are also required in each Member State. During the time of MAA assessment and following approval of an MAA by the EMA, the applicant is subject to oversight and inspection in pharmacovigilance (Good Vigilance Practice - GVP), clinical trials (Good Clinical Practice - GCP), manufacturing and distribution (Good Manufacturing and Good Distribution Practices- GMP & GDP) and as a Marketing Authorisation Holder.

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 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 American Taxpayer Relief Act of 2012 (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, which will remain in effect through 2032, unless Congress takes further action. 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 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. Only high-expenditure single-source drugs that have been approved for at least 7 years (11 years for single-source biologics) can qualify for negotiation, with the negotiated price taking effect two years after the selection year. For 2026, the first year in which negotiated prices become effective, CMS selected 10 high-cost Medicare Part D drugs in 2023, negotiations began in 2024, and the negotiated maximum fair price for each drug has been announced. CMS has selected 15 additional Medicare Part D drugs for negotiated maximum fair pricing in 2027. For 2028, up to an additional 15 drugs, which may be covered under either Medicare Part B or Part D, will be selected, and for 2029 and subsequent years, up to 20 additional Part B or Part D drugs will be selected. Various industry stakeholders have initiated lawsuits against the federal government asserting that the price negotiation provisions of the IRA are unconstitutional. The current administration has issued executive orders focused on decreasing prescription drug prices, including directing the Secretary of HHS to establish a mechanism through which American patients can buy drugs directly from manufacturers who sell at a most-favored-nation price and directing the U.S. Trade Representative and Secretary of Commerce to take action to ensure foreign countries are not engaged in practices that purposefully and unfairly undercut market prices and drive price hikes in the U.S. In November 2025, CMS

announced a voluntary initiative called the GENEROUS Model (GENErating cost Reductions fOr U.S. Medicaid Model) to introduce the option of most-favored-nation pricing to the Medicaid program, whereby a drug manufacturer may voluntarily offer supplemental rebates to participating state Medicaid programs for a manufacturer's covered outpatient drugs. Government agreements with pharmaceutical companies and other measures that use most-favored-nation pricing targets for prescription drugs, including the use of international pricing reference to set drug prices in the U.S., or that increase generic and biosimilar drug entry sooner than expected, can have a material adverse effect on our industry, the ability to set adequate pricing for new drugs to recover R&D costs, and the ability to attract potential investors and potential buyers in the future. We cannot predict the full impact of the executive orders focused on reducing prescription drug prices or increasing domestic drug manufacturing capacity, or other measures that may be implemented by the current administration related to drug pricing, drug supply chain and manufacturing in the U.S. Such cost containment policies and executive orders could substantially and negatively impact the prices we may charge for any approved products, which could harm our valuation, ability to generate revenue and sustain profitability. In addition, the One Big Beautiful Bill Act (OBBBA), which was signed into law in July 2025, includes provisions that will impact the United States healthcare system in various ways, including budget cuts to Medicaid and introducing new participant work and eligibility requirements for Medicaid coverage, which are expected to significantly change the administration and applicability of Medicaid coverage. The OBBBA also expanded exemptions for orphan designated drugs for Medicare drug price negotiations, which is expected to incentivize development of orphan designated drugs or increase competition for drug development in orphan diseases or conditions. Although the full impact of the OBBBA on the healthcare system and our business is uncertain, the resulting changes may increase the cost and complexity of completing clinical development of and launching any product candidates for which we may receive regulatory approval or increase our competition in the marketplace, any of which could adversely affect our business and prospects. The impact of ongoing and future judicial challenges, as well as future legislative, executive, and administrative actions and healthcare measures and agency rules implemented by the government on us and the pharmaceutical industry as a whole is unclear. To the extent changes lead to disruptions in federal agencies, greater uncertainty in the industry, or impose more constraints on drug pricing, such as the introduction of the most-favored nation pricing or international reference pricing, our business may be materially impacted. The implementation of cost containment measures or other healthcare reforms may negatively impact the valuation of our company or prevent us from being able to generate revenue, sustain 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. Further, the FDA has authorized the State of Florida to develop a program to import certain prescription drugs from Canada for a limited time-period 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, sustain profitability or commercialize our products or product candidates.

Further, changes in regulatory requirements and guidance may occur and we may need to amend clinical trial protocols of ongoing studies 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.

If we fail to comply with U.S. 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 U.S. 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 are 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.

Now that we have begun commercializing VYKAT XR, we are 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 play a primary role in the recommendation and prescription of VYKAT XR. Our 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 VYKAT XR. 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 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 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. Our 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. Since the approval of VYKAT XR in March 2025, our stock price has closed as high as $88.49 and as low as $37.24. 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:

- our ability to successfully commercialize and sustain profitability from sales of VYKAT XR;
- 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;
- our ability to obtain regulatory approvals in foreign jurisdictions;
- 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 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, 2024 through June 30, 2025 and determined that a change in ownership has occurred on June 30, 2024. As a result, the net operating loss carryforwards and tax credit carryforwards may be subject to annual limitations before being applied to reduce future income tax liabilities. For years ended after June 30, 2025, 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 raised capital in May 2024 and July 2025 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.

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.

We recently have been and may be in the future become subject to short-selling campaigns, activist investors and securities litigation, which are expensive and could divert management attention.

We have recently experienced volatility in the market price of our common stock caused by a short-selling campaign, which may lead to securities class action litigation or additional short-selling or activist investor activities. This has resulted and may continue to result in substantial costs and divert management's attention from other business concerns, any of which could seriously harm our business.

There has recently been a concerted effort by an activist short seller to spread negative information about us and VYKAT XR in order to gain a market advantage. Short selling is the practice of selling securities that the seller does not own, but rather has borrowed or intends to borrow from a third party with the intention of buying identical securities at a later date to return to the lender. A short seller hopes to profit from a decline in the value of the securities between the sale of the borrowed securities and the purchase of the replacement shares, as the short seller expects to pay less in that purchase than it received in the sale. It is therefore in the short seller's interest for the price of the stock to decline, and some short sellers publish, or arrange for the publication of, opinions or characterizations regarding the relevant issuer, often involving misrepresentations of the issuer's business prospects and similar matters calculated to create negative market momentum, which may permit them to obtain profits for themselves as a result of selling the stock short.

The publication of this type of commentary regarding the Company and VYKAT XR by a short seller in August 2025 resulted in a decline in the market price of our common stock. Publication of incomplete or misleading information about the Company and VYKAT XR may also result in provider concerns, patient discontinuations, payer questions, increased insurance premiums and shareholder lawsuits, the uncertainty and expense of which could adversely impact our reputation, business, financial condition, and operating results. No assurance can be made that we will not continue to be the target of such commentary or that declines in the market price of our common stock will not occur in the future in connection with such commentary by this short seller or otherwise.

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 company policies may require us to pay severance benefits to our executive officers who are terminated in connection with a change in control of us, which could harm our financial condition or results.

We have implemented policies with change in control and severance provisions providing for aggregate cash payments for severance and other benefits to our executive officers and acceleration of equity vesting in the event of a termination of employment in connection with a change in control of our company. The accelerated vesting of equity awards 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 our risk factor "*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 around the world 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 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.
- Sensitivity labeling and data loss prevention controls: These controls enable the identification and labeling of confidential and highly sensitive data, including intellectual property, clinical trial data, regulatory submissions, financial information, and protected health information. These controls also support our responsible AI adoption strategy by limiting exposure of highly sensitive information in generative AI tools and enforcing identity-based and policy-driven safeguards around the use of such data.
- 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. These plans include defined escalation pathways, containment and remediation procedures, and recovery testing for critical business systems and data.
- 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. Our approach includes security reviews, contractual safeguards, and monitoring controls designed to manage third-party access to sensitive data and 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. We are also implementing governance measures related to emerging technologies, including artificial intelligence, to ensure appropriate oversight, responsible usage, and protection of sensitive information.

ITEM 2. PROPERTIES

Facilities

Our principal facilities primarily consist of one office space 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. On November 25, 2025, we executed an amendment to our operating lease which gives us access to another 17,779 square feet of office space, but we had not yet taken possession of such space as of December 31, 2025. We also lease a small office space in Dublin, Ireland that houses our European operations that expires in October 2026.

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 and October 2023 pre-funded warrants are not traded on a national securities exchange.

As of February 19, 2026, there were 31 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.

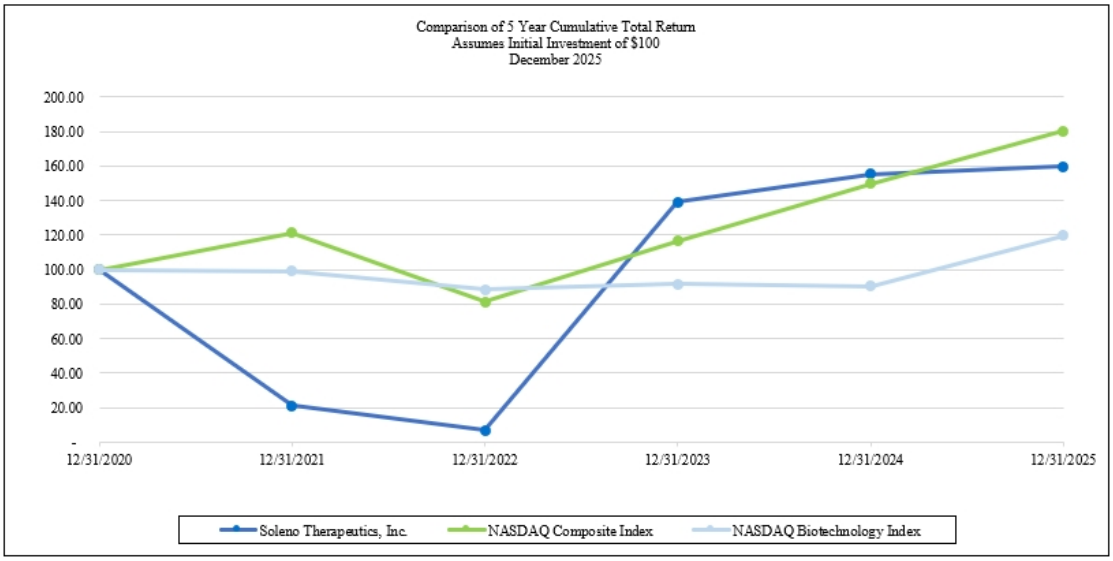
Securities Authorized for Issuance under Equity Compensation Plan

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, 2020, through December 31, 2025 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.



	12/31/2020	12/31/2021	12/31/2022	12/31/2023	12/31/2024	12/31/2025
Soleno Therapeutics, Inc.	100.00	21.24	6.84	139.04	155.28	159.94
NASDAQ Composite Index	100.00	121.39	81.21	116.47	149.83	180.33
NASDAQ Biotechnology Index	100.00	99.37	88.53	91.84	90.58	119.92

Unregistered Sales of Equity Securities and Use of Proceeds

N/A.

Purchases of Equity Securities by the Issuer

On November 10, 2025, we entered into a confirmation and a supplemental confirmation (together, the "ASR Agreement") of an accelerated share repurchase transaction with Jefferies LLC ("Jefferies"). Under the terms of the ASR Agreement, we prepaid the $100.0 million purchase price to Jefferies and received an aggregate initial share delivery of 1,511,553 shares of our common stock in November 2025, with the remaining shares of common stock, if any, to be delivered by the end of our first fiscal quarter of 2026.

The following table summarizes the stock repurchase activity for the three months ended December 31, 2025:

	Total number of shares purchased	Average price paid per share	Total number of shares purchased as part of publicly announced plans or programs	Approximate dollar value of shares that may yet be purchased under the plans or programs
October 1, 2025 - October 31, 2025	—	$ —	—	$ —
November 1, 2025 - November 30, 2025	1,511,553[1]	$ 46.00 [2]	1,511,553	$ — [3]
December 1, 2025 - December 31, 2025	—	$ -	—	$ —

(1) The specific number of shares of our common Stock that we ultimately repurchased under the ASR Agreement was determined based on the volume-weighted average price of our common stock during the term of the transaction, less an agreed discount and subject to adjustments pursuant to the terms and conditions of the ASR Agreement. Upon final settlement in January 2026, Jefferies was required to deliver an aggregate of 662,497 additional shares of our common stock to us.

(2) Based upon our aggregate repurchase of 2,174,050 shares of our common stock pursuant to the ASR Agreement, we paid an average of $46.00 per share.

(3) The transactions contemplated by the ASR Agreement are now complete and the company did not make any payments beyond the initial $100 million prepayment.

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. On March 26, 2025, we announced that our lead product candidate, VYKAT XR (diazoxide choline) extended-release tablets, formerly known as DCCR, had been approved by the U.S. Food and Drug Administration (FDA). VYKAT XR is indicated to treat hyperphagia in adults and pediatric patients four years of age and older with Prader-Willi syndrome (PWS).

Financial overview

Summary

Following FDA approval of VYKAT XR in March 2025, we began to generate revenue during the three months ended June 30, 2025. We became profitable during the three months ended September 30, 2025 and ended the year with a net income of $20.1 million. Our ability to sustain operating profitability is dependent upon continued successful commercialization of VYKAT XR. As of December 31, 2025, we had an accumulated deficit of $431.4 million and we had cash and cash equivalents of $70.1 million and marketable securities of $436.0 million.

Product Revenue, Net

We began commercial marketing and sales and recognizing revenue during the three months ended June 30, 2025. The transaction price that we recognize as revenue for VYKAT XR sales includes an estimate of variable consideration, which includes rebates, discounts, returns, and copay assistance that are offered within our contract with our specialty pharmacy distribution partner. For additional information, refer to Note 3 of our audited financial statements contained herein.

Cost of Goods Sold

Cost of goods sold consists of manufacturing costs, transportation and freight, amortization of capitalized intangibles, royalty payments and indirect overhead costs associated with the manufacturing and distribution of VYKAT XR. Cost of goods sold may also include periodic costs related to certain manufacturing services and inventory adjustment charges. Finally, cost of goods sold may also include costs related to excess or obsolete inventory adjustment charges, abnormal costs, unabsorbed manufacturing and overhead costs, and manufacturing variances.

Research and development expenses

Research and development expenses are charged to operations as incurred and consist primarily of salaries, benefits, bonus, stock-based compensation, consultant fees, certain facility costs and other costs associated with

clinical trials and certain manufacture costs associated with our drug product that are not included in cost of goods sold. 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. These expenses will vary with the cadence and success of our drug candidates progressing from clinical to commercial stage.

Selling, general and administrative expenses

Selling, 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, commercial activities such as disease state education, analytics, other marketing costs, medical affair and patient advocacy costs, and other general operating expenses not otherwise included in research and development. We anticipate selling, general and administrative expenses will increase in future periods, reflecting an expanding infrastructure, an increase in commercial activities and 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 million in revenue and $200 million in revenue related to VYKAT XR in future years.

Other income (expense), net

Other income (expense), net is comprised of interest income, interest expense from our loan and security agreement with 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. Significant estimates made by management include valuation of marketable securities, stock-based compensation, valuation of contingent liabilities for the purchase price of assets obtained through acquisition, provisions for sales rebates, returns and other incentives, valuation of financial instruments, and income taxes. 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.

Revenue Recognition

After FDA approval of VYKAT XR in March 2025, we began commercial marketing and made our first product sales during the three months ended June 30, 2025. ASC Topic 606, *Revenue from Contracts with Customers*, requires us to make estimates of variable consideration included in contracts with customers, to be included in the transaction price. The transaction price that is recognized as revenue for products upon delivery and transfer of title to the customer includes an estimate of variable consideration for reserves which result from rebates, discounts, returns, and co-pay assistance that are offered within the contract between us and our customer.

Government rebates: We are subject to discount obligations under several government programs, including Medicaid programs, Medicare and TRICARE in the United States. We estimate these rebates based upon a range of possible outcomes that are weighted for the estimated payer mix. These reserves are recorded in the same period that the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a liability that is included in accrued expenses and other current liabilities on our consolidated balance sheets. On a quarterly basis, we update our estimates and record any adjustments in the period that we identify the adjustments.

Trade discounts and allowances: We provide discounts on VYKAT XR sales to our customer for prompt payment. This discount is recorded as a reduction of revenue in the period the related product revenue is recognized. In addition, we receive and pay for various distribution services from our customer in the distribution channel.

Product returns: Our customer has limited return rights related to unexpected instances in which the product is found to be damaged or defective. We estimate the amount of product sales that may be returned and record the estimate as a reduction of revenue and a refund liability in the period in which the related product revenue is recognized. Based on the distribution model for VYKAT XR, we believe there will be minimal returns as such returns have not been material to date.

Other incentives: Other incentives include co-payment assistance we provide to patients with commercial insurance that have coverage and reside in states that allow co-payment assistance. The calculation of the accrual for co-pay assistance is based on an estimate of claims and the cost per claim that we expect to receive associated with product that has been recognized as revenue. The estimate is recorded as a reduction of revenue in the same period the related revenue is recognized.

Variable consideration is estimated and reduces the transaction price to reflect our best estimate of the amount of consideration to which we are entitled based on the terms of the contract and are recorded in the same period the related product revenue is recognized. The amount of variable consideration that is included in the transaction price may be constrained and is included in the net sales price only to the extent that it is considered probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. Actual amounts of consideration ultimately received may differ from our estimates. If actual results in the future vary from our estimates, we will adjust these estimates in the period these variances become known.

Marketable Securities

We classify our marketable securities as available-for-sale and record 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 income (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. 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 years ended December 31, 2025 and 2024, we did not recognize any credit losses related to our available-for-sale debt securities. Further, as of December 31, 2025 and 2024, we did not record an allowance for credit losses related to our available-for-sale debt securities. During 2023, we did not hold any marketable securities.

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 income (loss) and net income (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 income (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 income (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 income (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, 2025 and 2024 (in thousands)

	Years Ended December 31,		Increase (decrease)	
	2025	2024	Amount	Percentage
Product revenue, net	$ 190,405	$ -	$ 190,405	100%
Operating expenses				
Cost of goods sold	2,700	-	2,700	100%
Research and development	40,627	78,568	(37,941)	(48%)
Selling, general and administrative	132,128	105,861	26,267	25%
Change in fair value of contingent consideration	5,536	3,242	2,294	71%
Total operating expenses	180,991	187,671	(6,680)	(4%)
Operating income (loss)	9,414	(187,671)	197,085	(105%)
Other income (expense), net				
Interest income, net	16,952	12,052	4,900	41%
Interest expense	(5,476)	(231)	(5,245)	2271%
Total other income (expense), net	11,476	11,821	(345)	(3%)
Net income (loss)	$ 20,890	$ (175,850)	$ 196,740	(112%)

Revenue

Product revenue, net was $190.4 million for the year ended December 31, 2025, due to sales of VYKAT XR after FDA approval was obtained in March 2025, compared to zero for the year ended December 31, 2024.

Research and development expenses

Research and development expenses were $40.6 million for the year ended December 31, 2025, which includes $11.7 million of non-cash stock-based compensation expense, a decrease of $38.0 million from $78.6 million in 2024, which included $33.7 million of non-cash stock-based compensation. Pre-commercial launch research and development costs in support of our 2024 NDA submission, supply chain activities, and clinical activities decreased $7.5 million, $6.0 million, and $3.8 million, respectively, in 2025. The reduction in costs was offset by the Company incurring an additional $1.4 million of expense towards our MAA submission in Europe, which was submitted in the second quarter of 2025. 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 our regulatory filings and research activities.

Selling, general and administrative expenses

Selling, general and administrative expenses were $132.1 million for the year ended December 31, 2025, which includes $34.1 million of non-cash stock-based compensation, an increase of $26.2 million from $105.9 million in 2024, which included $66.2 million of non-cash stock-based compensation. Personnel costs including hiring expense and other associated headcount costs increased $31.3 million as we have hired additional employees in support of our commercial launch and increased business activities. New program costs associated with commercial launch activities, including disease state education, analytics, other marketing programs, medical affairs and patient advocacy activities, increased $23.4 million. Costs for international expansion increased $3.5 million. Selling, general and administrative expenses are anticipated to increase as we continue commercialization of VYKAT XR.

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 VYKAT XR 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 $20.3 million as of December 31, 2025, a $5.5 million increase from the estimate as of December 31, 2024, primarily due to the approval of our NDA for VYKAT XR by the FDA in March 2025 and recording product revenue from sales of VYKAT XR following the approval. The first commercial milestone was achieved in the fourth quarter of 2025 and $7.0 million will be paid in the first quarter of 2026.

Other income (expense), net

We had other income (expense), net of $11.5 million, a decrease of $0.3 million from $11.8 million in 2024. The decrease was primarily due to interest expense associated with the long-term debt, partially offset by an increase in interest income driven by higher cash and cash equivalents and marketable securities during the year ended December 31, 2025, compared to the year ended December 31, 2024.

Comparison of the Years Ended December 31, 2024 and 2023 (in thousands)

	Years Ended December 31,		Increase (decrease)	
	2024	2023	Amount	Percentage
Product revenue, net	$ -	$ -	$ -	0%
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 had not commenced commercialization of VYKAT XR, our current sole novel therapeutic drug candidate, and accordingly, through December 31, 2024, had 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 preparation 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 in 2024 and fully vested upon the approval of our NDA by the FDA in March 2025.

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 in 2024 and fully vested upon approval of our NDA by the FDA in March 2025.

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.

Liquidity and Capital Resources

We had net income of $20.9 million, generated $46.8 million of net cash provided by operating activities during 2025 and had an accumulated deficit of $431.4 million at December 31, 2025 as a result of losses incurred prior to 2025. We had $70.1 million in cash and cash equivalents, $436.0 million of marketable securities and $294.5 million of working capital on December 31, 2025. We had a lease obligation totaling $2.7 million to be paid through August 2029, consisting of one operating lease for office space in Redwood City, California.

As of December 31, 2025, we had $50.0 million outstanding under our loan and security agreement with Oxford. Under the terms of the loan agreement with Oxford, following FDA approval of VYKAT XR, an additional $50 million became available through September 30, 2025, but was not drawn down. Following the amendment of our loan and security agreement in November 2025, the final three tranches of an aggregate of $100 million may be made available upon mutual consent with Oxford. As a result of a milestone achieved in 2025, the loan carries an interest-only period of 60 months and a total term of 72 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%.

In July 2025, we closed an underwritten public offering of 2,705,882 shares of our common stock at a public offering price of $85.00 per share, which included the exercise in full by the underwriters of their option to purchase additional shares of our common stock. The gross proceeds of the public offering were $230.0 million, before deducting the underwriter discount and other offering expenses, totaling approximately $14.3 million.

In July 2024, we entered into an Open Market Sale Agreement[SM] 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.

We believe that our existing cash, cash equivalents and marketable securities and cash flows from operations will be sufficient to meet the company's working capital needs for the next twelve months. Our long-term capital requirements will depend on several factors, most notably the timing and degree of success of our continued commercialization of VYKAT XR. 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.

Cash Flows

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

	Years Ended December 31,		
	2025	2024	2023
Net cash provided by (used in) operating activities	$ 46,798	$ (69,096)	$ (24,940)
Net cash used in investing activities	(201,781)	(225,682)	-
Net cash provided by financing activities	137,161	213,025	180,019
Net increase (decrease) in cash and cash equivalents	$ (17,822)	$ (81,753)	$ 155,079

Cash provided by (used in) operating activities

During 2025, operating activities provided net cash of $46.8 million, which was primarily due to net income of $20.9 million which included $45.8 million of stock-based compensation expense, $2.0 million of depreciation and amortization, $0.6 million of non-cash lease expense, non-cash expense of $5.5 million for the change in fair value of contingent consideration, and $3.5 million added back for accretion of premium/discount on marketable securities. Additionally, there was a $24.6 million net increase in cash used during 2025 due to changes in operating assets and liabilities.

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 in cash used during 2024 due to changes in operating assets and liabilities.

Cash used in investing activities

During 2025, we used $455.8 million for purchases of marketable securities and $0.1 million for purchases of property and equipment. We received proceeds of $254.1 million from maturities of marketable securities.

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.

Cash provided by financing activities

During 2025, we received $215.7 million from the sale of common stock, net of issuance costs, $5.2 million from the exercise of common stock warrants, and $17.2 million from the exercise of stock options. We paid $100.1 million for repurchase of common stock including costs, $0.7 million of tax withholding for net share-settled equity awards, and $0.1 million of debt issuance costs.

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.

Off-Balance Sheet Arrangements

As of December 31, 2025 and December 31, 2024, 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. Refer to Note 3 in Part II, Item 8 of this Annual Report on Form 10-K regarding the effect of recently adopted and issued accounting pronouncements on our financial statements.

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, 2025, we had unrestricted cash and cash equivalents totaling $70.1 million and $436.0 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.

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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 sheet of Soleno Therapeutics, Inc. (the "Company") as of December 31, 2025, the related consolidated statements of operations and comprehensive income (loss), stockholders' equity and cash flows for the year ended December 31, 2025, 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, 2025, and the results of its operations and its cash flows for the year ended December 31, 2025, 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, 2025, 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 25, 2026, expressed an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

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.

Initial Implementation of ASC 606 for Revenue Recognition

Description of the Matter

As described in Note 3, the Company implemented ASC 606, Revenue from Contracts with Customers, related to the launch of its first commercial product offering. The implementation of ASC 606 involved significant judgment in evaluating the Company's revenue arrangements, identifying distinct performance obligations, determining the appropriate timing of revenue recognition, estimating variable consideration, and assessing disclosures in accordance

with ASC 606. The implementation of the standard required the Company to update its systems, processes, and internal controls to comply with the newly applicable guidance.

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:

- Reviewing management's adoption and application of the new accounting policy, including changes to systems and internal controls.
- Evaluating management's process for identifying and assessing revenue contracts and performance obligations.
- Assessing management's estimates of variable consideration, including rebates, discounts, and returns, and evaluating constraints applied to variable consideration.
- Evaluating the adequacy and completeness of the Company's ASC 606 disclosures in the financial statements.

/s/ CBIZ CPAs P.C.

CBIZ CPAs P.C.

We have served as the Company's auditor since 2014 (such date takes into account the acquisition of the attest business of Marcum LLP by CBIZ CPAs P.C. effective November 1, 2024).

San Francisco, CA
February 25, 2026

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

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.

/s/ Marcum LLP

Marcum LLP

We served as the Company's auditor from 2014 to 2025.

San Francisco, CA
February 28, 2025

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

	December 31, 2025	December 31, 2024
Assets		
Current assets		
Cash and cash equivalents	$ 70,106	$ 87,928
Marketable securities	235,366	203,509
Accounts receivable, net	28,208	—
Inventory, net	15,024	—
Prepaid expenses and other current assets	7,110	2,452
Total current assets	355,814	293,889
Long-term assets		
Property and equipment, net	185	186
Operating lease right-of-use assets	2,191	2,798
Intangible assets, net	4,861	6,805
Long-term marketable securities	200,616	27,211
Other long-term assets	163	83
Total assets	$ 563,830	$ 330,972
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 12,435	$ 8,882
Accrued compensation	9,677	4,776
Operating lease liabilities	726	526
Contingent liability for Essentialis purchase price	20,327	—
Other current liabilities	18,198	4,563
Total current liabilities	61,363	18,747
Long-term liabilities		
Contingent liability for Essentialis purchase price	—	14,791
Long-term debt, net	49,863	49,828
Long-term lease liabilities	1,964	2,472
Other long-term liabilities	525	21
Total liabilities	113,715	85,859
Commitments and contingencies (Note 6)		
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, 52,286,881 and 45,703,811 shares issued and outstanding at December 31, 2025 and 2024, respectively	52	46
Additional paid-in-capital	881,018	696,966
Accumulated other comprehensive income	415	361
Accumulated deficit	(431,370)	(452,260)
Total stockholders' equity	450,115	245,113
Total liabilities and stockholders' equity	$ 563,830	$ 330,972

See accompanying notes to consolidated financial statements

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

	For the Years Ended December 31,		
	2025	2024	2023
Product revenue, net	$ 190,405	$ -	$ -
Operating expenses			
Cost of goods sold	2,700	-	-
Research and development	40,627	78,568	25,189
Selling, general and administrative	132,128	105,861	13,481
Change in fair value of contingent consideration	5,536	3,242	2,714
Total operating expenses	180,991	187,671	41,384
Operating income (loss)	9,414	(187,671)	(41,384)
Other income (expense), net			
Change in fair value of warrant liabilities	—	—	(182)
Interest income, net	16,952	12,052	2,578
Interest expense	(5,476)	(231)	—
Total other income (expense), net	11,476	11,821	2,396
Net income (loss)	$ 20,890	$ (175,850)	$ (38,988)
Other comprehensive income (loss)			
Net unrealized gain on marketable securities	37	361	—
Foreign currency translation adjustment	17	—	—
Total comprehensive income (loss)	$ 20,944	$ (175,489)	$ (38,988)
Net income (loss)	20,890	(175,850)	(38,988)
Less: Undistributed earnings attributable to participating securities	(415)	—	—
Net income (loss) attributable to common stockholders - basic and diluted	$ 20,475	$ (175,850)	$ (38,988)
Net income (loss) per share - basic	$ 0.40	$ (4.38)	$ (2.36)
Net income (loss) per share - diluted	$ 0.39	$ (4.38)	$ (2.36)
Weighted-average common shares outstanding - basic	50,817,586	40,175,926	16,492,132
Weighted-average common shares outstanding - diluted	52,384,886	40,175,926	16,492,132

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, 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
Net 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
Stock-based compensation	—	—	46,839	—	—	46,839
Sales of common stock, net of issuance costs of $14,300	2,705,882	3	215,718	—	—	215,721
Repurchase of common stock	(1,511,553)	(2)	(100,148)	—	—	(100,150)
Issuance of common stock in connection with exercise of stock options and vesting of restricted stock units	2,166,501	2	17,200			17,202
Tax withholding payments for net share-settled equity awards	(14,608)	—	(741)	—	—	(741)
Exercise of common stock warrants	3,236,848	3	5,184	—	—	5,187
Net unrealized gain on marketable securities	—	—	—	37	—	37
Foreign currency translation adjustment	—	—	—	17	—	17
Net income	—	—	—		20,890	20,890
Balances at December 31, 2025	52,286,881	$ 52	$ 881,018	$ 415	$ (431,370)	$ 450,115

See accompanying notes to consolidated financial statements

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

	For the Years Ended December 31,		
	2025	**2024**	**2023**
Cash flows from operating activities:			
Net income (loss)	$ 20,890	$ (175,850)	$ (38,988)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:			
Depreciation and amortization	2,017	1,987	1,958
Accretion of premium/discount on marketable securities	(3,517)	(4,895)	—
Non-cash lease expense	607	444	321
Amortization of debt issuance costs	35	—	—
Stock-based compensation expense	45,846	99,958	5,945
Change in fair value of stock warrants	—	—	182
Change in fair value of contingent consideration	5,536	3,242	2,714
Other non-cash reconciling items	17	—	—
Change in operating assets and liabilities:			
Accounts receivable	(28,208)	—	—
Inventory	(14,031)	—	—
Prepaid expenses, other current assets and other assets	(4,738)	(750)	(837)
Accounts payable	3,612	5,672	1,372
Accrued compensation	4,901	1,641	1,460
Operating lease liabilities	(308)	(183)	(309)
Other liabilities	14,139	(362)	1,242
Net cash provided by (used in) operating activities	46,798	(69,096)	(24,940)
Cash flows from investing activities:			
Purchases of property and equipment	(73)	(218)	—
Purchases of marketable securities	(455,776)	(356,464)	—
Maturities of marketable securities	254,068	131,000	—
Net cash used in investing activities	(201,781)	(225,682)	—
Cash flows from financing activities:			
Proceeds from issuance of debt, net of issuance costs	—	49,888	—
Payment of debt issuance costs	(62)	—	—
Proceeds from the sale of common stock, net of issuance costs	215,721	148,955	—
Proceeds from the sale of common stock, common stock warrants and pre-funded stock warrants, net of issuance costs	—	—	137,857
Payment for repurchase of common stock	(100,146)	—	—
Proceeds from exercise of common stock and pre-funded stock warrants	5,187	12,866	41,815
Proceeds from exercise of stock options	17,202	1,316	347
Tax withholding payments for net share-settled equity awards	(741)	—	—
Net cash provided by financing activities	137,161	213,025	180,019
Net increase (decrease) in cash and cash equivalents	(17,822)	(81,753)	155,079
Cash and cash equivalents, beginning of period	87,928	169,681	14,602
Cash and cash equivalents, end of period	$ 70,106	$ 87,928	$ 169,681
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
Cash paid for interest	$ 4,534	$ 209	$ —
Common stock repurchase costs included in accounts payable	$ 4	$ —	$ —
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, 2025

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. On March 26, 2025, the Company announced that its lead product candidate, VYKAT™ XR (diazoxide choline) extended-release tablets, formerly known as DCCR, had been approved by the FDA. VYKAT XR is indicated to treat hyperphagia in adults and pediatric patients four years of age and older with Prader-Willi syndrome (PWS). On April 14, 2025, the Company announced that prescriptions of VYKAT XR had been delivered to the first individuals living with PWS who had been prescribed the medication and began recognizing revenue from the sales of VYKAT XR during the three months ended June 30, 2025.

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, Inc., 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 received $46.8 million of net cash provided by its operating activities, had a net income of $20.9 million during 2025 and had an accumulated deficit of $431.4 million at December 31, 2025 resulting from losses incurred prior to 2025. The Company had $70.1 million of cash and cash equivalents and $436.0 million of marketable securities on December 31, 2025. With FDA approval of VYKAT XR and first prescriptions being delivered in April 2025, the Company began recognizing revenue and became profitable during 2025. The Company's ability to sustain operating profitability is dependent upon continued successful commercialization of VYKAT XR.

As of December 31, 2025, 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, following FDA approval of VYKAT XR, an additional $50 million became available through September 30, 2025, but was not drawn down. Following the amendment of the Company's loan and security agreement in November 2025, the final three tranches of an aggregate of $100 million may be made available upon mutual consent with Oxford. As a result of a milestone achieved in 2025, the loan carries an interest-only period of 60 months and a total term of 72 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%.

In addition to the Oxford loan and security agreement, the Company has historically financed its operations through issuance of equity securities. In July 2025, the Company closed an underwritten public offering of 2,705,882 shares of its common stock at an offering price of $85.00 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 $230.0 million, before deducting the underwriter discount and other offering expenses, totaling approximately $14.3 million.

On July 19, 2024, the Company entered into an Open Market Sale 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 May 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.

The Company expects that its current cash, cash equivalents and marketable securities balances and cash flows from operations 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).

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. Significant estimates made by management include valuation of marketable securities, stock-based compensation, valuation of contingent liabilities for the purchase price of assets obtained through acquisition, provisions for sales rebates, returns and other incentives, valuation of financial instruments, and income taxes.

Accounts Receivable, net

Accounts receivable, net consists of amounts due from customers, net of customer allowances for cash discounts and any estimated expected credit losses. The Company's measurement of expected credit losses is based on relevant information about past events, including historical experience, current conditions, and reasonable and supportable forecasts that affect the collectability of the reported amount. To date, the Company has not experienced any credit losses. The Company's contract with its customer has customary payment terms that require payment within 45 days. The Company analyzes amounts that are past due for collectability, and periodically evaluates the creditworthiness of its customer. Based on its assessment, as of December 31, 2025, the Company determined that an allowance for credit loss was not required.

Concentration of Major Customers and Off-Balance Sheet Risk

The Company contracts with one customer, its specialty pharmacy, to market and distribute VYKAT XR to patients in the United States. As of December 31, 2025, its accounts receivable, net are solely from sales of VYKAT XR, and are from this sole customer.

The Company's dependency on one customer exposes it to several risks, including the potential for disruptions in its distribution network, changes in this customer's business strategies, or financial difficulties faced by this customer. Any significant disruption or change in the Company's relationship with this customer could materially and adversely affect its ability to effectively reach other potential end users and maintain its market position.

While the Company believes its relationship with this customer is strong and mutually beneficial, there can be no assurance that it will be able to maintain this relationship or that it will be able to replace this specialty pharmacy with alternative specialty pharmacies, if necessary.

The Company relies on sole source suppliers and third-party manufacturers to supply raw materials and manufacture its product. The inability of these suppliers or manufacturers to fulfill supply requirements of the Company could materially impact future operating results. A change in the relationship with these suppliers or manufacturers, or an adverse change in their business, could materially impact future operating results.

Revenue Recognition

The Company recognizes revenue in accordance with ASC Topic 606, *Revenue from Contracts with Customers*, or ASC 606. Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services.

Product Revenue, net

The Company sells its product to one customer, a specialty pharmacy. The product is distributed through a third-party logistics distribution agent (3PL) that does not take title to the product. In the Company's agreement with the 3PL, the Company acts as principal because it retains control of the product. Once the product is delivered to the Company’s specialty pharmacy, the specialty pharmacy takes title to the product. The specialty pharmacy then distributes the product to patients. The Company offers returns of product sold to the customer on a limited basis; however, no material returns have been recognized to date.

Revenue from product sales is recognized when the customer obtains control of the Company's product, which occurs at the point in time that there is a transfer of title to the customer. The Company has no other performance obligations besides the sale of product, and because the Company's payment terms are 45 days or less, the Company concluded there is not a significant financing component. The Company classifies payments to its customer or other parties in the distribution channel for services that are distinct and priced at fair value as selling, general and administrative expenses in its consolidated statements of operations and comprehensive income (loss). Otherwise, payments to customer or other parties in the distribution channel that do not meet those criteria are classified as a reduction of revenue, as discussed further below. The Company expenses incremental costs of obtaining a contract as and when incurred since the expected amortization period of the asset that the Company would have recognized is one year or less.

Reserves for Variable Consideration

Revenues from product sales are recorded at the net sales price, or the transaction price, which includes estimates of variable consideration for which reserves are established and which result from rebates, discounts, returns, and co-pay assistance that are offered within the contract between the Company and its customer relating to the sale of VYKAT XR. These reserves are based on the amounts earned or to be claimed on the related sales and are classified as reductions of accounts receivable (if the amount is payable to the customer) or a current liability (if the amount is payable to a party other than the customer). Where appropriate, these estimates take into consideration a range of possible outcomes that are weighted for relevant factors such as the Company's historical experience, current contractual and statutory requirements, specific known market events and trends, industry data and forecasted customer buying and payment patterns. Overall, these reserves reflect the Company's best estimates of the amount of consideration to which it is entitled based on the terms of the contract. The amount of variable consideration that is included in the transaction price may be constrained and is included in the net sales price only to the extent that it is considered probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. Actual amounts of consideration ultimately received may differ from the Company's estimates. If actual results in the future vary from the Company's estimates, it will adjust these estimates, which would affect net product revenue and earnings in the period such variances become known.

The following are the components of variable consideration related to product revenue:

Government rebates: The Company is subject to discount obligations under several government programs, including Medicaid programs, Medicare and TRICARE in the United States. The Company estimates these rebates based upon a range of possible outcomes that are weighted for the estimated payer mix. These reserves are recorded in the same period that the related revenue is recognized, resulting in a reduction

of product revenue and the establishment of a liability that is included in other current liabilities on the Company's consolidated balance sheets. On a quarterly basis, the Company updates its estimates and records any adjustments in the period that it identifies the adjustments.

Trade discounts and allowances: The Company provides discounts on VYKAT XR sales to its customer for prompt payment. This discount is recorded as a reduction of revenue in the period the related product revenue is recognized. In addition, the Company receives and pays for various distribution services from its customer in the distribution channel.

Product returns: The Company's customer has limited return rights related to unexpected instances in which the product is found to be damaged or defective. The Company estimates the amount of product sales that may be returned and records the estimate as a reduction of revenue and a refund liability in the period in which the related product revenue is recognized. Based on the distribution model for VYKAT XR, the Company believes there will be minimal returns as such returns have not been material to date.

Other incentives: Other incentives include co-payment assistance the Company provides to patients with commercial insurance that have coverage and reside in states that allow co-payment assistance. The calculation of the accrual for co-pay assistance is based on an estimate of claims and the cost per claim that the Company expects to receive associated with product that has been recognized as revenue. The estimate is recorded as a reduction of revenue in the same period the related revenue is recognized.

Provisions for trade discounts and allowances are recorded as reductions to accounts receivable, and returns, government rebates, and other incentives are recorded as a component of accrued expenses.

The table below summarizes balances and activity in each of the product revenue allowance and reserve categories as follows (in thousands):

	Rebates	Discounts and Chargebacks	Copay Assistance and Returns	Total
Balance as of December 31, 2024	$ -	$ -	$ -	$ -
Provisions	21,396	5,397	981	27,774
Credits/payments	(7,711)	(4,674)	(634)	(13,019)
Balance as of December 31, 2025	$ 13,685	$ 723	$ 347	$ 14,755

Inventory

The Company capitalizes inventory costs associated with products when future economic benefit is expected to be realized. These costs consist of raw materials, manufacturing-related costs, personnel costs including stock-based compensation, facility costs, and other indirect overhead costs. Prior to receiving FDA approval for VYKAT XR in March 2025, the Company expensed costs related to inventory for clinical and pre-commercial purposes directly to research and development expense. Following the FDA’s approval of VYKAT XR, the Company began capitalizing inventory related to commercialized products held for sale, in-process of production for sale, and raw materials to be used in the manufacturing of inventory.

The Company values inventory at the lower of cost or estimated net realizable value. The Company determines the cost of inventory, which includes amounts related to materials and manufacturing overhead, on a first-in, first-out basis. Raw materials and work in process includes all inventory costs prior to packaging and labeling, including raw materials, active pharmaceutical ingredient, and drug product. Finished goods include packaged and labeled products. Raw materials and work in process that may be used for either research and development or commercial sale are classified as inventory until the material is consumed or otherwise allocated for research and development. If the material is intended to be used for research and development, it is expensed as research and development once that determination is made. On a quarterly basis, the Company

analyzes its inventory levels for excess quantities and obsolescence (expiration), taking into account factors such as historical and anticipated future sales compared to quantities on hand and the remaining shelf life.

Cost of Goods Sold

Cost of goods sold consists of manufacturing costs, transportation and freight, amortization of capitalized intangibles, royalty payments and indirect overhead costs associated with the manufacturing and distribution of VYKAT XR. Cost of goods sold may also include periodic costs related to certain manufacturing services and inventory adjustment charges. Finally, cost of goods sold may also include costs related to excess or obsolete inventory adjustment charges, abnormal costs, unabsorbed manufacturing and overhead costs, and manufacturing variances.

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.

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 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 income (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. 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 years ended December 31, 2025 and 2024, the Company did not recognize any credit losses related to its available-for-sale debt securities. Further, as of December 31, 2025 and 2024, the Company did not record an allowance for credit losses related to its available-for-sale debt securities. During 2023, 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 associated 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 income (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, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*. The amendments in ASU 2023-09 address investor requests for enhanced income tax information primarily through changes to the rate reconciliation and income taxes paid information. Early adoption is permitted. A public entity should apply the amendments in ASU 2023-09 prospectively to all annual periods beginning after December 15, 2024. The Company adopted this standard effective January 1, 2025 using a retrospective approach.

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, accounts receivable 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, 2025 (in thousands):

	December 31, 2025			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
U.S. treasury securities	$ 274,524	$ 388	$ (80)	$ 274,832
Other government agency securities	23,202	14	-	23,216
Corporate debt securities and commercial paper	137,859	133	(58)	137,934
Total	$ 435,585	$ 535	$ (138)	$ 435,982

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, 2025			
	Total	Level 1	Level 2	Level 3
Assets				
Cash equivalents:				
Money market funds	$ 63,613	$ 63,613	$ -	$ -
Total cash equivalents	$ 63,613	$ 63,613	$ -	$ -
Marketable securities:				
U.S. treasury securities	$ 274,832	$ -	$ 274,832	$ -
Other government agency securities	23,216	-	23,216	-
Corporate debt securities and commercial paper	137,934	-	137,934	-
Total marketable securities	435,982	-	435,982	-
Total assets	$ 499,595	$ 63,613	$ 435,982	$ -
Liabilities				
Essentialis purchase price contingency liability	$ 20,327	$ -	$ -	$ 20,327
Total liabilities	$ 20,327	$ -	$ -	$ 20,327

	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

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. As of December 31, 2025, following the receipt of FDA approval for VYKAT XR, the Company no longer considers FDA approval as a variable and determined a 100% probability of achieving the remaining two milestones. Prior to receiving FDA approval, management relied on published research relating to clinical development success rates to determine the likelihood of FDA approval occurring. Based on this 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, other than as discussed above regarding the

receipt of FDA approval for VYKAT XR, 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 for the years ended December 31, 2025 and 2024 (in thousands):

	Purchase Price Contingent Liability
Balance at January 1, 2025	$ 14,791
Change in value of contingent liability	5,536
Balance at December 31, 2025	$ 20,327

	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

Note 5. Balance Sheet Components

Inventory, Net

Inventory consisted of the following (in thousands):

	December 31, 2025	December 31, 2024
Raw materials	$ 6,449	$ -
Work in process	2,710	-
Finished goods	6,022	-
Less: Reserve for excess and obsolete inventory	(157)	-
Total inventory, net	$ 15,024	$ -

Property and Equipment, Net

Property and equipment consisted of the following (in thousands):

	December 31, 2025	December 31, 2024
Computer hardware	$ 42	$ 24
Leasehold improvements	93	52
Furniture and fixtures	173	180
	308	256
Less accumulated depreciation and amortization	(123)	(70)
Total	$ 185	$ 186

Depreciation expense was approximately $73 thousand, $43 thousand, and $14 thousand for the years ended December 31, 2025, 2024, and 2023, respectively.

Intangible Assets, Net

Intangible assets consisted of the following (in thousands):

	December 31, 2025			December 31, 2024		
	Amount	Accumulated Amortization	Net Amount	Amount	Accumulated Amortization	Net Amount
Patents and merger costs	$ 22,003	$ (17,142)	$ 4,861	$ 22,003	$ (15,198)	$ 6,805

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

Year ending December 31	Patents and trademarks
2026	$ 1,944
2027	1,944
2028	973
Total	$ 4,861

Amortization expense was $1.9 million for the years ended December 31, 2025, 2024 and 2023.

Other Current Liabilities

Other current liabilities consisted of the following (in thousands):

	December 31, 2025	December 31, 2024
Product revenue reserve for rebates, returns, and other incentives	$ 14,031	$ -
Accrued consulting and professional fees	1,902	1,259
Accrued research and development costs	679	1,478
Accrued clinical trial site costs	1,130	1,826
Accrued interest payable	403	-
Other	53	-
Total other current liabilities	$ 18,198	$ 4,563

Note 6. 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, 2025. The Company's operating lease for its predecessor headquarters facility office space in Redwood City, California began on June 1, 2023 and expired in May 2025.

On November 25, 2025, the Company executed an amendment to its office lease in Redwood City, California for additional office space for its headquarters facility. The amendment provides additional office

space of approximately 17,779 square feet and for base monthly rent payments beginning at $32,747 that increase annually to $79,650 in the final year of the lease in 2029. In addition to base rent, the Company has agreed to reimburse the landlord for certain operating expenses under the terms of the lease. As of the date of this filing, the premises is not available for occupancy and therefore as the office lease has not commenced, the related operating lease ROU assets and liabilities are not recorded in the Company's consolidated balance sheet as of December 31, 2025.

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, 2025 and December 31, 2024, the Company's short-term liabilities were equal to $0.7 million and $0.5 million, respectively, and the long-term operating lease liabilities were equal to $2.0 million and $2.5 million, respectively.

The weighted average discount rate related to the Company’s lease liabilities was 8.5% as of December 31, 2025 over a remaining term of 3.7 years, and 8.5% as of December 31, 2024 over the remaining term of 4.7 years. 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,		
	2025	2024	2023
Operating lease cost:			
Operating lease cost	$ 853	$ 548	$ 312
Variable lease cost	6	16	-
Short-term lease cost	87	157	44
Total operating lease cost	$ 946	$ 721	$ 356

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

	Years Ended December 31,		
	2025	2024	2023
Cash paid for amounts included in the measurement of lease liabilities:			
Operating cash flows from operating leases	$ 552	$ 344	$ 341

The following is a schedule by year of future maturities of the Company’s operating lease liabilities as of December 31, 2025 (in thousands):

2026	$ 692
2027	861
2028	942
2029	665
Total lease payments	3,160
Less interest	(470)
Total	$ 2,690

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, 2025, the Company's non-cancelable other commitments aggregated $15.3 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 7. 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, 2025, the Company had $50.0 million outstanding under the loan and security agreement with Oxford. Under the terms of the loan agreement with Oxford, following FDA approval of VYKAT XR, an additional $50 million became available through September 30, 2025, but was not drawn down. Following the amendment of the loan and security agreement in November 2025, the final three tranches of an aggregate of $100 million may be made available upon mutual consent with Oxford. As a result of a milestone achieved in 2025, the loan carries an interest-only period of 60 months and a total term of 72 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%. As a result of a milestone achieved in 2025, the term loan will begin to amortize in equal monthly installments beginning on February 1, 2030, through the maturity date of December 1, 2030. As a result of a milestone achieved in 2025, the final principal payment at maturity will include a fee of 6.5% of the total principal borrowed. The $3.3 million final interest payment related to the $50 million borrowed as of December 31, 2025 is accrued over the term of loan as long-term accrued interest payable. $525 thousand and $21 thousand were accrued as part of other long-term liabilities on the consolidated balance sheet as of December 31, 2025 and 2024, respectively. 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, 2025, the Company recorded $5.5 million in interest expense and $4.5 million of interest was paid. For the year ended December 31, 2024, the Company recorded $231 thousand in interest expense and $209 thousand of interest was paid.

The outstanding long-term debt consisted of the following (in thousands):

	December 31, 2025	December 31, 2024
Long-term debt	$ 50,000	$ 50,000
Unamortized debt issuance costs	(137)	(172)
Total long-term debt, net	$ 49,863	$ 49,828

The following table provides the components of interest expense related to the long-term debt (in thousands):

	Years Ended December 31,		
	2025	2024	2023
Interest expense based on contractual loan rate	$ 4,937	$ 209	$ -
Amortization of debt issuance costs and accretion of final interest payment	539	22	-
Total interest expense	$ 5,476	$ 231	$ -

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 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. The Company was in compliance with all applicable debt covenants as of December 31, 2025.

Note 8. Stockholders' Equity

Preferred Stock

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

November 2025 Accelerated Share Repurchase Agreement

On November 10, 2025, the Company entered into an accelerated share repurchase agreement (the ASR Agreement) with Jefferies LLC (Jefferies) to repurchase an aggregate amount of $100.0 million of its common stock. Under the ASR agreement, the Company made an aggregate upfront payment of $100.0 million to Jefferies and received an initial delivery of 1,511,553 shares of its common stock on November 12, 2025, based on the closing price of the Company's common stock on November 10, 2025.

The final number of shares that the Company will ultimately repurchase pursuant to the ASR Agreement will be based on the average of the daily volume-weighted average price per share of the Company's common stock during the repurchase period less a discount, subject to adjustments pursuant to the terms and conditions of the ASR Agreement. The accelerated share repurchase was completed in the first quarter of 2026. Refer to Note 13. Subsequent Events for additional information.

Shares of common stock repurchased under the ASR Agreement are immediately retired upon receipt and returned to authorized and unissued status. Repurchased common stock is reflected as a reduction of stockholders' equity. Any excess of cost over par value is charged to additional paid-in capital to the extent that

a balance is present. If additional paid-in capital is fully depleted, any remaining excess of cost over par value is charged to accumulated deficit.

July 2025 Public Offering of Common Stock

In July 2025, the Company closed an underwritten public offering of 2,705,882 shares of its common stock at a public offering price of $85.00 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 $230.0 million, before deducting the underwriter discount and other offering expenses, totaling approximately $14.3 million.

May 2024 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.

October 2023 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.

December 2022 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 following the FDA's approval of VYKAT XR, the remainder of these warrants were exercised. The Company received an aggregate of $35.0 million from the exercise of the Tranche B warrants. As of December 31, 2025, there were no remaining warrants outstanding under the Securities Purchase Agreement.

March 2022 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 2025, 5,333 of the March 2022 common warrants were exercised for gross proceeds of $24 thousand and 1,248,414 warrants were exercised using the cashless exercise option with no proceeds to the Company. In 2024, 254,664 March 2022 warrants were exercised for gross proceeds of $1.1 million and 419,056 warrants were exercised using the cashless exercise option with no proceeds received by the Company. As of December 31, 2025, 1,599 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.

Common Stock Warrants

As of December 31, 2025, 2024 and 2023, the following table summarizes the Company's outstanding common stock warrants:

	As of December 31, 2025		As of December 31, 2024		As of December 31, 2023		
	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	November 2024
March 2022 Common warrants	1,599	$ 4.50	1,255,346	$ 4.50	1,929,066	$ 4.50	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
May 2023 Tranche B Pre-funded warrants	—	$ —	—	$ —	451,632	$ 0.01	November 2026
October 2023 Pre-funded warrants	250,000	$ 0.01	250,000	$ 0.01	1,175,000	$ 0.01	N/A
Total	251,599		3,570,651		13,071,883		

Equity Incentive Plans

2014 Plan

The Company maintains the Amended and Restated 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.

As of December 31, 2025, a total of 358,527 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 2014 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.

As of December 31, 2025, a total of 23,068 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. The compensation expense is allocated on a departmental basis, based on the classification of the stock award holder. For the years ended December 31, 2025, 2024 and 2023, the total income tax benefit related to stock-based compensation was $6.9 million, $5.7 million and $1.9 million, respectively, however, due to net operating income (loss) 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 income (loss) as follows (in thousands):

	Years Ended December 31,		
	2025	2024	2023
Research and development	$ 11,722	$ 33,743	$ 2,434
Selling, general and administrative	34,124	66,215	3,511
Total	$ 45,846	$ 99,958	$ 5,945

After the FDA approval of VYKAT XR in March 2025, the Company began capitalizing stock-based compensation associated with the allocation of labor costs related to work performed to manufacture VYKAT XR. For the year ended December 31, 2025, the Company capitalized into inventory $1.0 million.

Stock Options

The Company granted options to purchase 1,404,516 of the Company's common stock to employees and a consultant during year ended December 31, 2025, and 1,819,324 and 1,821,784 to employees during year ended December 31, 2024 and 2023, respectively. There were no performance-based options granted in 2025, 2024 and 2023. 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,		
	2025	2024	2023
Expected life (years)	5.9-6.3	5.8-6.1	5.3-6.1
Risk-free interest rate	3.7%-4.7%	3.7%-4.6%	3.5%-4.5%
Volatility	115%-120%	121%-124%	98%-122%
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, 2025 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, 2024	3,971,798	$ 26.75	8.48	
Options granted	1,404,516	54.88		
Options exercised	(1,141,597)	15.07		
Options canceled/forfeited	(202,608)	52.49		
Balance at December 31, 2025	4,032,109	$ 38.56	8.26	$ 47,415
Options exercisable at December 31, 2025	1,529,334	$ 26.45	7.27	$ 32,501
Options vested and expected to vest at December 31, 2025	4,032,109	$ 38.56	8.26	$ 47,415

The weighted-average grant date fair value of employee options granted was $47.81, $40.13 and $5.04 per share for the years ended December 31, 2025, 2024 and 2023, respectively. The intrinsic value of the stock

options exercised was $60.1 million, $6.7 million and $2.2 million for the years ended December 31, 2025, 2024 and 2023, respectively. At December 31, 2025, total unrecognized employee stock-based compensation for options that are expected to vest was $95.6 million, which is expected to be recognized over the weighted-average remaining vesting period of 3.1 years.

Restricted Stock Units

There were 409,984 restricted stock units granted to employees by the Company during the year ended December 31, 2025. During the year ended December 31, 2024, the Company granted 1,249,375 performance-based restricted stock units and 763,270 restricted stock units were granted to employees and directors. The shares were valued based on the Company's common stock price on the grant date.

The following table summarizes restricted stock unit transactions for the year ended December 31, 2025 under the 2014 Plan:

	Number of Restricted Stock Units	Weighted-Average Grant-Date Fair Value per Share
Outstanding at December 31, 2024	939,865	$ 48.55
Restricted stock units granted	409,984	57.68
Restricted stock units vested	(887,124)	48.59
Restricted stock units cancelled/forfeited	(19,434)	58.75
Outstanding at December 31, 2025	443,291	$ 56.47

The weighted-average grant-date fair value of all restricted stock units granted was $57.68, $46.47, and $5.49 per share during the year ended December 31, 2025, 2024 and 2023, respectively. The fair value of all restricted stock units vested during the year ended December 31, 2025, 2024 and 2023, was $44.1 million, $50.9 million and $12.0 million, respectively. At December 31, 2025, total unrecognized employee stock-based compensation related to restricted stock units was $14.7 million, which is expected to be recognized over the weighted-average remaining vesting period of 2.5 years.

Certain directors have elected to delay the issuance of their vested restricted stock units granted under the 2014 Plan. A portion of these RSUs have vested as of December 31, 2025 based on the applicable service periods, but the issuance of common stock has been deferred until a future date when the directors' service to the Company terminates, or there is a change in control of the Company. The grant-date fair value of these 6,500 shares is $0.3 million, which has been recognized as stock-based compensation expense over the requisite service period in the consolidated statements of operations and comprehensive income (loss).

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, 2025, there were no purchases by employees under this plan.

Note 9. Income Taxes

For financial reporting purposes, income (loss) before provision for income taxes, includes the following components (in thousands):

	Years Ended December 31,		
	2025	2024	2023
United States	$ 20,253	$ (175,921)	$ (39,180)
Foreign	637	71	192
Income (loss) before income taxes	$ 20,890	$ (175,850)	$ (38,988)

Income Taxes Paid

Income taxes paid, net of refunds received consists of the following (in thousands):

	Years Ended December 31,		
	2025	2024	2023
U.S. Federal	$ -	$ -	$ -
U.S. State and Local			
California	2	2	2
New Jersey	2	2	2
Massachusetts	-	8	1
Other	1	-	-
Total U.S. State and Local	5	12	5
Foreign			
United Kingdom	1	27	-
Ireland	8	-	-
Total Foreign	9	27	-
Total income taxes paid	$ 14	$ 39	$ 5

Provision (Benefit) for Income Taxes

The Company recorded no provision for income taxes for the years ended December 31, 2025, 2024 and 2023.

Income tax provision (benefit) differs from the amounts computed by applying the statutory income tax rate of 21% to pretax income (loss) as follows (in thousands):

	Years Ended December 31,					
	2025		2024		2023	
	Amount	Percent	Amount	Percent	Amount	Percent
Tax at U.S. statutory rate on income before income taxes	$ 4,387	21.0%	$ (36,928)	21.0%	$ (8,187)	20.5%
State income taxes, net of federal effect [1]	(435)	-2.1%	(458)	0.3%	(273)	0.7%
Change in valuation allowance	(7,026)	-33.6%	16,880	-9.6%	8,701	-21.8%
Nontaxable or nondeductible items:						
Stock-based compensation	(1,625)	-7.8%	9,652	-5.5%	(600)	1.5%
Contingent consideration remeasurement	1,163	5.6%	681	-0.4%	570	-1.4%
Section 162(m) limitation	8,127	38.9%	(958)	0.5%	589	-1.5%
Net operating loss expiration	804	3.9%	734	-0.4%	464	-1.2%
Section 382 limitation	-	0.0%	16,531	-9.4%	-	0.0%
Other nontaxable or nondeductible items	72	0.3%	25	0.0%	48	-0.1%
Change in tax laws or rates	-	0.0%	-	0.0%	-	0.0%
Tax credits:						
Federal research and development credits	87	0.4%	2,429	-1.4%	(2,362)	5.9%
Orphan Drug Credit	(8,414)	-40.3%	(12,404)	7.1%	-	0.0%
Cross-border tax laws	61	0.3%	(74)	0.0%	74	-0.2%
Worldwide changes in UTB	2,933	14.0%	3,428	-1.9%	1,003	-2.5%
Other	-	0.0%	477	-0.3%	13	0.0%
Foreign tax effects						
Foreign jurisdictions	(134)	-0.6%	(15)	0.0%	(40)	0.1%
Provision for income taxes	$ -	0.0%	$ -	0.0%	$ -	0.0%

[1] The states that contribute to the majority (greater than 50%) of the tax effect in this category include Mississippi, New Jersey, and California for 2025, Massachusetts, New Jersey, and California for 2024, and New Jersey and California for 2023.

Deferred Tax Assets and Liabilities

Deferred income taxes reflect the net tax effects of loss and credit carryforwards and 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 for federal and state income taxes are as follows (in thousands):

	December 31,		
	2025	2024	2023
Deferred tax assets:			
Federal and state net operating loss carryforwards	$ 45,942	$ 44,319	$ 51,481
Research and other credits	20,758	14,127	6,352
Capitalized research and development	1,037	17,200	6,778
Reserves and accruals	1,435	555	655
Fixed assets	139	23	29
Capital loss carryforward	-	-	432
Stock-based compensation	11,640	8,628	2,013
Lease liability	701	636	85
Other deferred tax assets	91	57	54
Gross deferred tax assets	81,743	85,545	67,879
Deferred tax liabilities:			
Intangible assets	(1,267)	(1,445)	(1,837)
Right-of-use assets	(571)	(594)	(86)
Total deferred tax liabilities	(1,838)	(2,039)	(1,923)
Total deferred tax assets	79,905	83,506	65,956
Valuation allowance	(79,905)	(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 decreased by $3.6 million from December 31, 2024 to December 31, 2025 primarily due to expensing of unamortized basis of capitalized research and development expenses.

As required under ASU 2023-09, the Company has included only the portion of the valuation allowance related to federal deferred tax assets in the "change in valuation allowance" line of the rate reconciliation. The following table presents a reconciliation of the total change in the valuation allowance (in thousands):

	Years Ended December 31,		
	2025	2024	2023
Beginning balance	$ 83,506	$ 65,956	$ 57,017
Change charged to income tax expense	(3,591)	17,627	8,939
Change charged to other comprehensive income	(10)	(77)	-
Ending balance	$ 79,905	$ 83,506	$ 65,956

As of December 31, 2025, the Company had $179.7 million of federal and $122.1 million of state 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 $162.5 million may be carried forward indefinitely. The state net operating loss carryforwards will begin to expire in 2028. As of December 31, 2025, the Company also had $24.6 million of federal orphan drug and research and development credits and $6.4 million of state research and development credit carryforwards. The federal research and development credit carryforward begin to expire in 2025 and the state research and development credit can be carried forward indefinitely.

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 June 30, 2025 and determined that a change in ownership has occurred on March 7, 2017, December 21, 2018, June 30, 2020, September 26, 2023, and June 30, 2024. As a result, the net operating loss carryforwards and tax credit carryforwards may be subject to annual limitations before being applied to reduce future income tax liabilities. For years ended after December 31, 2025, the utilization of net operating losses and tax credit carryforwards may be 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, 2025, 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,		
	2025	2024	2023
Beginning balance	$ 6,367	$ 2,938	$ 1,936
Increase related to current year tax positions	2,921	2,884	1,002
Increase related to prior year tax positions	68	1,332	-
Decrease related to prior year tax positions	(56)	(787)	-
Ending balance	$ 9,300	$ 6,367	$ 2,938

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 $9.3 million of unrecognized assets and liabilities related to uncertain tax positions as of December 31, 2025. 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, 2025 and December 31, 2024. As of December 31, 2025, unrecognized tax benefits of $9.3 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. 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 2006 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 10. Net Income (Loss) per Share

Basic net income (loss) per share is computed by dividing net income (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 income (loss) per share is computed by dividing net income (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 using the treasury stock method which would result in the issuance of incremental shares of common stock. The Company applies the two-class method to calculate basic and diluted earnings per share as its warrants issued in March 2022 and May 2023 are

participating securities. However, the two-class method does not impact the net loss per share of common stock as the March 2022 and May 2023 common warrants issued do not participate in losses. For the years ended December 31, 2024 and 2023, 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 income (loss) per common share:

	Years Ended December 31,		
	2025	2024	2023
Numerator:			
Net income (loss)	$ 20,890	$ (175,850)	$ (38,988)
Less: Earnings attributable to participating securities	(415)	—	—
Net income (loss) attributable to common stockholders - basic and diluted	$ 20,475	$ (175,850)	$ (38,988)
Denominator:			
Common stock	50,567,586	37,689,804	15,040,036
March 2022 pre-funded warrants	—	—	290,665
May 2023 Tranche A pre-funded warrants	—	1,685,181	778,904
May 2023 Tranche B pre-funded warrants	—	373,892	92,801
October 2023 pre-funded warrants	250,000	427,049	289,726
Weighted-average shares - basic	50,817,586	40,175,926	16,492,132
Effect of dilutive securities:			
Stock options	1,228,032	—	—
Restricted stock units	339,268	—	—
Weighted-average shares - diluted	52,384,886	40,175,926	16,492,132
Net income (loss) per share - basic	$ 0.40	$ (4.38)	$ (2.36)
Net income (loss) per share - diluted	$ 0.39	$ (4.38)	$ (2.36)

The following potentially dilutive securities outstanding have been excluded from the computation of diluted net income (loss) per share because their effect would have been anti-dilutive for the periods presented:

	Years Ended December 31,		
	2025	2024	2023
Warrants issued to 2010/2012 convertible note holders to purchase common stock	-	-	6,804
Warrants issued to underwriter to purchase common stock	-	-	1,100
March 2022 common warrants	-	1,255,346	1,929,066
May 2023 Tranche B warrants	-	2,065,305	6,750,000
Options to purchase common stock	1,869,149	3,971,798	2,369,665
Outstanding restricted stock units	8,307	939,865	15,534
Total	1,877,456	8,232,314	11,072,169

Note 11. 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. The Company made matching contributions of $0.6 million and $0.2 million in 2025 and 2024, respectively, and no matching contributions in 2023.

Note 12. Segment Reporting

The Company has one operating and reporting segment focused on the development and commercialization of its sole therapeutic product, VYKAT XR. The Company's chief operating decision maker (CODM) is the chief executive officer who reviews product revenue, net and 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.

The following table presents selected financial information with respect to the Company's single operating segment for the years ended December 31, 2025, 2024 and 2023 (in thousands):

	Years Ended December 31,		
	2025	2024	2023
Product revenue, net	$ 190,405	$ -	$ -
Net income (loss)	20,890	(175,850)	(38,988)
Less total other income, net	11,476	11,821	2,396
Operating income (loss)	9,414	(187,671)	(41,384)
Total operating expenses	180,991	187,671	41,384
Less non-cash expenses			
Depreciation and amortization	(2,017)	(1,987)	(1,958)
Non-cash lease expense	(607)	(444)	(321)
Change in fair value of contingent consideration	(5,536)	(3,242)	(2,714)
Stock-based compensation	(45,846)	(99,958)	(5,945)
Cash operating expenses	$ 126,985	$ 82,040	$ 30,446

Note 13. Subsequent Events

The Company has evaluated its subsequent events from December 31, 2025 through the date these consolidated financial statements were issued and has determined that there are no subsequent events disclosure required, with the exception of the following:

November 2025 Accelerated Share Repurchase Agreement

Pursuant to the terms of the ASR Agreement, Jefferies delivered 662,497 additional shares of the Company's common stock to the Company in January 2026, bringing the aggregate number of shares repurchased under the ASR Agreement to 2,174,050 shares. The transactions contemplated by the ASR Agreement are now complete and the Company did not make any payments beyond the initial $100 million prepayment.

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

Inherent Limitations on Effectiveness of Controls

In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, even if determined effective and no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives to prevent or detect misstatements. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs. 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 the degree of compliance with the policies or procedures may deteriorate.

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, 2025. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of December 31, 2025.

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 effective as of December 31, 2025.

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 of Previously Identified Material Weakness in Internal Control

As disclosed in "Part II, Item 9A - Controls and Procedures" in our 2024 Annual Report, management previously concluded that a material weakness existed in our internal control over financial reporting related to ineffective design and operation of controls over certain information technology general controls (ITGCs), including segregation of incompatible duties, program change management, user access controls, and automated and manual process-level controls that relied on information produced by financially relevant IT systems.

During fiscal year 2025, we evaluated, designed, and implemented controls and procedures to address this material weakness in our internal control over financial reporting. These measures included: (i) hiring additional

accounting and financial reporting personnel to enable appropriate segregation of duties; (ii) implementing or enhancing ITGCs to strengthen oversight, review, and verification procedures related to user access, program change management, and segregation of duties controls within key systems; (iii) providing targeted training to control owners on IT control requirements and policies, with a particular focus on user access and change-management controls affecting financial reporting; and (iv) establishing ongoing monitoring protocols to assess the design and operating effectiveness of the enhanced controls and to ensure adherence to related policies and procedures.

We completed testing of these controls during the fourth quarter of fiscal year 2025, and we have concluded that the previously identified material weakness has been remediated as of December 31, 2025.

Changes in Internal Control Over Financial Reporting

During the year ended December 31, 2025, we implemented new processes and controls in relation to the commercialization of VYKAT XR in the United States, including processes and controls relating to revenue recognition and inventory in which we have documented and evaluated the design and tested the effectiveness of such controls. Except as described above, there were no further 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 year ended December 31, 2025 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.

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, 2025, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in 2013. In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2025, based on criteria established in COSO.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the consolidated balance sheet as of December 31, 2025 and the related consolidated statements of operations and comprehensive income (loss), stockholders' equity, and cash flows and the related notes (collectively referred to as the "financial statements") for the year ended December 31, 2025 of the Company, and our report dated February 25, 2026 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's 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/ CBIZ CPAs P.C.

CBIZ CPAs P.C.
San Francisco, CA
February 25, 2026

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, 2025, the Company did not adopt, modify or terminate a Rule 10b5-1 trading arrangement or a non-Rule 10b5-1 trading arrangement, each as defined in Regulation S-K Item 408.

On November 24, 2025, James Mackaness, our Chief Financial Officer, terminated the Rule 10b5-1 trading plan announced in the Company's Quarterly Report on Form 10-Q for the three months ended September 30, 2025, prior to any trades being made thereunder.

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 2026 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 2026 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 2026 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 2026 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 2026 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.	8-K	June 6, 2024	10.1	

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 May 15, 2015, by and between Capnia, Inc. and Anish Bhatnagar.				X
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	10-K	February 28, 2025	10.10	
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	10-K	February 28, 2025	10.12	
10.13	License Agreement for Space and Services, dated February 8, 2024, by and between the Company 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	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 the Company and Oxford Finance LLC, dated December 17, 2024	10-K	February 28, 2025	10.16	
10.17†	Amended and Restated Outside Director Compensation Policy				X
10.18	First Amendment to Loan and Security Agreement between the Company and Oxford Finance LLC dated November 10, 2025	8-K	November 12, 2025	10.2	

Exhibit Number	Description of Document	Incorporated by Reference from			Filed Herewith
		Registrant's Form	Date Filed with the SEC	Exhibit Number	
10.19	First Amendment to Office Lease between the Company and 1 Twin Property Owner, LLC dated November 25, 2025				X
10.20	Executive Change in Control and Severance Plan, and related Participation Agreement	8-K	January 23, 2026	10.1	
19.1	Insider Trading Policy	10-K	February 28, 2025	19.1	
21.1	Subsidiaries				X
23.1	Consent of CBIZ CPAs P.C.				X
23.2	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 25, 2026

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 Chairman of the Board (Principal Executive Officer)	February 25, 2026
/S/ JAMES MACKANESS James Mackaness	Chief Financial Officer (Principal Financial and Accounting Officer)	February 25, 2026
/S/ MATTHEW PAULS Matthew Pauls	Lead Independent Director	February 25, 2026
/S/ ANDREW SINCLAIR Andrew Sinclair	Director	February 25, 2026
/S/ MARK HAHN Mark Hahn	Director	February 25, 2026
/S/ DAWN BIR Dawn Bir	Director	February 25, 2026
/S/ BIRGITTE VOLCK Birgitte Volck	Director	February 25, 2026

Exhibit 10.7

CAPNIA, INC.

EMPLOYMENT AGREEMENT

This Employment Agreement (the "**Agreement**") is entered into as of May 15, 2015, (the **"Effective Date")** by and between Capnia, Inc. (the "**Company**"), and Anish Bhatnagar **("Executive").**

1. Duties and Scope of Employment.

(a) Positions and Duties. Executive's employment agreement with the Company will commence on May 15, 2015 (the "**Start Date**"). Executive will serve as President and Chief Executive Officer of the Company. Executive will render such business and professional services in the performance of him duties, consistent with Executive's position within the Company, as will reasonably be assigned to him by the Company's Board of Directors (the **"Board").** The Board may modify Executive's job title and duties as it deems necessary and appropriate in light of the Company's needs and interests from time to time. The period of Executive's employment under this Agreement is referred to herein as the **"Employment Term."**

(b) Obligations. During the Employment Term, Executive will perform him duties faithfully and to the best of him ability and will devote substantially all of him business efforts and time to the Company. For the duration of the Employment Term, Executive agrees not to actively engage in any other employment, occupation or consulting activity for any direct or indirect remuneration that would impact in any material respect him ability to perform him duties and obligations hereunder.

2. At-Will Employment. The parties agree that Executive's employment with the Company will be "at-will" employment and may be terminated at any time with or without Cause or notice. Executive understands and agrees that neither him job performance nor promotions, commendations, bonuses or the like from the Company give rise to or in any way serve as the basis for modification, amendment, or extension, by implication or otherwise, of him employment with the Company. However, as described in this Agreement, Executive may be entitled to severance benefits depending on the circumstances of Executive's termination of employment with the Company. •

3. Term of Agreement. This Agreement will have an initial term running from the Effective Date through the first anniversary of the Start Date (the **"Initial Term").** On the first anniversary of the Start Date, this Agreement will renew automatically for additional one (1) year terms (each an **"Additional Term"),** unless either party provides the other party with written notice of non-renewal at least thirty (30) days prior to the date of automatic renewal. If Executive becomes entitled to benefits under Section 8 during the term of this Agreement, the Agreement will not terminate until all of the obligations of the parties hereto with respect to this Agreement have been satisfied.

4. Compensation.

(a) Base Salary. During the Employment Term, the Company will pay Executive an annual salary of $460,000.00 as compensation for his services (the **"Base Salary").** The Base Salary will be paid periodically in accordance with the Company's normal payroll practices and be subject to the usual, required withholding. Executive's Base Salary will be subject to review and adjustments will be made based upon the Company's normal performance review practices.

(b) Annual Bonus. Executive will be eligible to participate in any bonus plans or programs maintained from time to time by the Company on such terms and conditions as determined by the Board or its compensation committee (the **"Committee"),** including eligibility for a bonus of up to fifty percent (50%) of Executive's Base Salary, upon achievement of performance objectives to be determined by the Board in its sole discretion (the **"Target Bonus").** Any earned bonus will be paid in the next regular payroll period after the Board or the Committee determines that it has been earned, but in no event shall the bonus be paid after the later of (i) the fifteenth (15th) day of the third (3rd) month following the close of the Company's fiscal year in which the bonus is earned, or (ii) March 15 following the calendar year in which the bonus is earned.

(c) Stock Option. Executive will be granted an option to purchase 150,000 of the Company's common stock, at an exercise price equal to the fair market value of Company common stock per share on the date of grant (the **"Option").** Subject to the accelerated vesting provisions set forth herein, the Option will vest as to 25% of the shares subject to the Option on the first anniversary of the Start Date, and as to 1148th of the shares subject to the Option monthly thereafter on the same day of the month as the Start Date, so that the Option will be fully vested and exercisable four (4) years from the Start Date, subject to Executive continuing to provide services to the Company through the relevant vesting dates. The Option will be subject to the terms, definitions and provisions of the 2014 Equity Incentive Plan (the **"2014 Plan")** and the stock option agreement by and between Executive and the Company (the **"Option Agreement"),** both of which documents are incorporated herein by reference.

(d) Equity. Executive will be eligible to receive awards of stock options, restricted stock units or other equity awards pursuant to any plans or arrangements the Company may have in effect from time to time. The Board or the Committee will determine in its discretion whether Executive will be granted any such equity awards and the terms of any such award in accordance with the terms of any applicable plan or arrangement that may be in effect from time to time.

5. Employee Benefits. During the Employment Term, Executive will be entitled to participate in the employee benefit plans currently and hereafter maintained by the Company of general applicability to other senior executives of the Company, including, without limitation, the Company's group medical, dental, vision, disability, life insurance, and flexible-spending account plans. The Company reserves the right to cancel or change the benefit plans and programs it offers to its employees at any time.

6. Vacation. Executive will be entitled to receive paid annual vacation in accordance with Company policy for other senior executive officers.

7. Expenses. The Company will reimburse Executive for reasonable travel, entertainment or other expenses incurred by Executive in the furthermore of or in connection with the performance of Executive's duties hereunder, in accordance with the Company's expense reimbursement policy as in effect from time to time.

8. Severance. If the Company terminates Executive's employment with the Company without Cause (excluding death or Disability) or if Executive resigns from such employment for Good Reason, and, in each case, Executive signs and does not revoke a standard release of claims with the Company in a form acceptable to the Company and subject to Section 9 below, then Executive will receive, in addition to Executive's salary payable through the date of termination of employment and any other employee benefits earned and owed through the date of termination, the following benefits from the Company:

(a) continuing payments of severance pay in accordance with the Company's normal payroll policies at a rate equal to Executive's Base Salary rate, as then in effect, for: (x) fifteen (15) months from the date of such termination without Cause or resignation for Good Reason, if such termination or resignation occurs prior to six (6) months before a Change in Control of the Company, or (y) eighteen (18) months from the date of such termination without Cause or resignation for Good Reason, if such termination or resignation occurs within six (6) months prior to, or twelve (12) months following, a Change in Control of the Company;

(b) if such termination or resignation occurs six (6) months prior to, a Change in Control of the Company, then twenty five percent (25%) of any Equity Awards held by Executive as of the date of such termination without Cause or resignation for Good Reason shall immediately vest and become fully exercisable (to the extent applicable), if such termination or resignation occurs within six (6) months prior to, or twelve (12) months following, a change in control of the Company, then one hundred percent (100%) of any unvested equity awards as of the date of such termination without cause or resignation for good reason shall immediately vest and become fully exercisable (to the extent applicable). Following termination without cause or resignation for good reason at any time, the Executive has one year to exercise vested options.

(c) if such termination or resignation occurs within six (6) months prior to, or twelve (12) months following, a Change in Control of the Company, then Executive shall receive one hundred percent (100%), multiplied by (Y) 1.5, multiplied by (Z) of the Target Bonus for the year in which Executive was terminated without Cause or resigned for Good Reason; and

(a) if Executive elects continuation coverage pursuant to the Consolidated Budget Reconciliation Act of 1985 **("COBRA")** within the time period prescribed pursuant to COBRA for Executive and Executive's eligible dependents, then the Company will reimburse Executive on the last day of each month after his employment termination date for the COBRA premiums paid during such period for such coverage (at the coverage levels in effect immediately prior to Executive's termination) for a period ending (x) twelve (12) months, if such termination or resignation occurs from today to three (3) months before a Change in Control of the Company, or (y) eighteen (18) months from the date of such termination or resignation occurs within three (3) months prior to, or six (6) months following a Change of Control of the Company; provided, that such coverage shall end upon such earlier date that Executive and/or Executive's eligible dependents become covered under similar plans. Notwithstanding the foregoing, if the Company determines in its sole discretion that it cannot provide the benefit described in this Section 8(b) without potentially violating, or being subject to an excise tax under, applicable law (including, without limitation, Section 2716 of the Public Health Service Act), the Company will in lieu thereof provide to Executive a taxable monthly payment, payable on the last day of a given month, in an amount equal to the monthly COBRA premium that Executive would be required to pay to continue Executive's group health coverage in effect on the termination of employment date (which amount will be based on the premium for the first month of COBRA coverage), which payments will be made regardless

of whether Executive elects COBRA continuation coverage and will commence on the month following Executive's termination of employment and will end on the earlier of (A) the date upon which Executive obtains other employment or (B) the date the Company has paid an amount equal to fifteen (15) or eighteen (18) payments, per the terms of this agreement. For the avoidance of doubt, the taxable payments in lieu of COBRA reimbursements may be used for any purpose, including, but not limited to continuation coverage under COBRA, and will be subject to all applicable tax withholdings'"

9. Conditions to Receipt of Severance; No Duty to Mitigate.

(a) Separation Agreement and Release of Claims. The payment of any severance set forth in Section 8 above is contingent upon Executive signing and not revoking the Company's standard separation and release of claims agreement upon Executive's termination of employment and such agreement becoming effective no later than sixty (60) days following Executive's employment termination date (such deadline, the **"Release Deadline").** In no event will severance payments be paid or provided until the release actually becomes effective. Any severance payments or benefits under this Agreement will be paid on, or, in the case of installments, will not commence until, the sixtieth (60th) day following Executive's separation from service, or if later, such time as required by Section 9(c). Except as required by Section 9(c), any installment payments that would have been made to Executive during the sixty (60) day period immediately following him separation from service but for the preceding sentence will be paid to Executive on the sixtieth (60th) day following Executive's separation from service and the remaining payments will be made as provided in the Agreement.

(b) Confidential Information Agreement. Executive's receipt of any payments or benefits under Section 8 will be subject to Executive continuing to comply with the terms of him Confidential Information Agreement (as defined in Section 12).

(c) Section 409A.

(i) Notwithstanding anything to the contrary in this Agreement, no severance pay or benefits payable upon separation that is payable to Executive, if any, pursuant to this Agreement, when considered together with any other severance payments or separation benefits that are considered deferred compensation (together, the **"Deferred Payments")** under Section 409A of the Internal Revenue Code, as amended (the **"Code")** and the final regulations and official guidance thereunder **("Section 409A")** will be payable until Executive has a "separation from service" within the meaning of Section 409A.

(ii) Notwithstanding anything to the contrary in this Agreement, if Executive is a "specified employee" within the meaning of Section 409A at the time of him termination (other than due to death), then the Deferred Payments, if any, that are payable within the first six (6) months following him separation from service, will become payable on the first payroll date that occurs on or after the date six (6) months and one (1) day following the date of Executive's separation from service. All subsequent Deferred Payments, if any, will be payable in accordance with the payment schedule applicable to each payment or benefit. Notwithstanding anything herein to the contrary, if Executive dies following him separation from service, but prior to the six (6) month anniversary of the separation from service, then any payments delayed in accordance with this Section 9(c) will be payable in a lump sum as soon as administratively practicable after the date of Executive's death and all other Deferred Payments will be payable in accordance with the payment schedule applicable to each payment or benefit. Each payment, installment and benefit payable under this Agreement is intended to constitute a separate payment for purposes of Section l.409A-2(b)(2) of the Treasury Regulations.

(iii)Any severance payment that satisfies the requirements of the "short-term deferral" rule set forth in Section 1.409A-l(b)(4) of the Treasury Regulations shall not constitute Deferred Payments for purposes herein. Any amount paid under this Agreement that qualifies as a payment made as a result of an involuntary separation from service pursuant to Section 1.409A-l(b) (9)(iii) of the Treasury Regulations that does not exceed the Section 409A Limit (as defined below) will not constitute Deferred Payments for purposes herein.

(iv)For purposes of this Agreement, **"Section 409A Limit"** means the lesser of two (2) times: (x) Executive's annualized compensation based upon the annual rate of pay paid to Executive during Executive's taxable year preceding Executive's taxable year of Executive's termination of employment as determined under Treasury Regulation 1.409A-1(b)(9)(iii)(A)(l) and any Internal Revenue Service guidance issued with respect thereto, or (y) the maximum amount that may be taken into account under a qualified plan pursuant to Section 401(a)(l 7) of the Code for the year in which Executive's employment is terminated.

(v) The foregoing provisions are intended to comply with or be exempt from the requirements of Section 409A so that none of the severance payments and benefits to be provided hereunder will be subject to the additional tax imposed under Section 409A, and any ambiguities herein will be interpreted to so comply. Executive and the Company agree to work together in good faith to consider amendments to this Agreement and to take such reasonable actions which are necessary, appropriate or desirable to avoid imposition of any additional tax or income recognition prior to actual payment to Executive under Section 409A.

(d) No Duty to Mitigate. Executive will not be required to mitigate the amount of any payment contemplated by this Agreement, nor will any earnings that Executive may receive from any other source reduce any such payment.

10. Definitions.

(a) Cause. For purposes of this Agreement, **"Cause"** means: (i) Executive's act of personal dishonesty in connection with him responsibilities as an employee that is intended to result in Executive's substantial personal enrichment; (ii) Executive being convicted of, or pleading no contest or guilty to, (x) a misdemeanor that the Company reasonably believes has had or will have a material detrimental effect on the Company, or (y) any felony; (iii) Executive's gross misconduct; (iv) Executive's willful and continued failure to perform the duties and responsibilities of him position after thime has been delivered to Executive a written demand for performance from the Company that describes the basis for the Company's belief that Executive has not substantially performed him duties and Executive has not corrected such failure within thirty (30) days of such written demand; or (v) Executive's material violation of any written Company employment policy or standard of conduct, including a material breach of the Confidential Information Agreement.

(b) Change in Control. For purposes of this Agreement, **"Change in Control"** has the same meaning assigned to such term in the 2014 Plan.

(c) Disability. For purposes of this Agreement, **"Disability"** means Executive's inability to perform Executive's duties due to Executive's physical or mental incapacity, as reasonably determined by the Board or its designee, for an aggregate of 180 days in any 365 consecutive day period.

(d) Equity Awards. For purposes of this Agreement, **"Equity Awards"** means Executive's outstanding stock options, stock appreciation rights, restricted stock units, performance shares, performance stock units and any other Company equity compensation awards.

(e) Good Reason. For purposes of this Agreement, **"Good Reason"** means Executive's resignation within thirty (30) days following the expiration of any Company cure period (discussed below) following the occurrence of one or more of the following, without Executive's consent: (i) a material reduction in Executive's Base Salary, excluding the substitution of substantially equivalent compensation and benefits, that is not generally applicable to all Company senior management or employees of the Company generally; (ii) a material reduction of Executive's authority, duties or responsibilities, unless Executive is provided with a comparable position; provided, however, that a reduction in authority, duties, or responsibilities solely by virtue of the Company being acquired and made part of a larger entity whether as a subsidiary, business unit or otherwise (as, for example, when the Chief Executive Officer of the Company remains as such following an acquisition whether the Company becomes a wholly owned subsidiary of the acquirer, but is not made the Chief Executive Officer of the acquiring corporation) will not constitute "Good Reason"; or (iii) a material change in the geographic location of Executive's primary work facility or location; provided, that a relocation of fifty (50) miles or less from Executive's then present location or to Executive's home as him primary work location will not be considered a material change in geographic location. In order for an event to qualify as Good Reason, Executive must not terminate employment with the Company without first providing the Company with written notice of the acts or omissions constituting the grounds for "Good Reason" within ninety (90) days of the initial existence of the grounds for "Good Reason" and a reasonable cure period of not less than thirty (30) days following the date of such notice, and such grounds must not have been cured during such time.

11. Limitation on Payments. In the event that the severance benefits provided for in this Agreement or otherwise payable to Executive (i) constitute "parachute payments" within the meaning of Section 280G of the Code and (ii) but for this Section 11, would be subject to the excise tax imposed by Section 4999 of the Code, then Executive's severance benefits under Section 8 will be either:

(a) delivered in full, or

(b) delivered as to such lesser extent which would result in no portion of such severance benefits being subject to excise tax under Section 4999 of the Code,

whichever of the foregoing amounts, taking into account the applicable federal, state and local income taxes and the excise tax imposed by Section 4999, results in the receipt by Executive on an after-tax basis, of the greatest amount of severance benefits, notwithstanding that all or some portion of such severance benefits may be taxable under Section 4999 of the Code. If a reduction in severance and other benefits constituting "parachute payments" is necessary so that benefits are delivered to a lesser extent, reduction will occur in the following order: (i) reduction of cash payments, which shall occur in reverse chronological order such that the cash payment owed on the latest date following the occurrence of the event triggering such excise tax will be the first cash payment to be reduced; (ii) reduction of acceleration of vesting of equity awards, which shall occur in the reverse order of the date of grant for such stock awards (i.e., the vesting of the most recently granted stock awards will be reduced first); and (iii) reduction of other benefits paid or provided to the Executive, which shall occur in reverse chronological order such that the benefit owed on the latest date following the occurrence of the event triggering such excise tax will be the first benefit to be reduced. If more than one equity award was made to the Executive on the same date of grant, all such awards shall have their acceleration of vesting reduced pro rata. In no event shall the Executive have any discretion with respect to the ordering of payment reductions.

Unless the Company and Executive otherwise agree in writing, any determination required under this Section 11 will be made in writing by a nationally recognized firm of independent public accountants selected by the Company (the **"Accountants"),** whose determination will be conclusive and binding upon Executive and the Company for all

purposes. For purposes of making the calculations required by this Section 11, the Accountants may make reasonable assumptions and approximations concerning applicable taxes and may rely on reasonable, good faith interpretations concerning the application of Sections 280G and 4999 of the Code. The Company and Executive will furnish to the Accountants such information and documents as the Accountants may reasonably request in order to make a determination under this Section. The Company will bear all costs the Accountants may reasonably incur in connection with any calculations contemplated by this Section 11.

12. Confidential Information. Executive confirms his continuing obligations under the Company's standard At-Will Employment, Proprietary Information and Invention Assignment Agreement (the **"Confidential Information Agreement")** dated on or about the date hereof.

13. Assignment. This Agreement will be binding upon and inure to the benefit of (a) the heirs, executors and legal representatives of Executive upon Executive's death and (b) any successor of the Company. Any such successor of the Company will be deemed substituted for the Company under the terms of this Agreement for all purposes. For this purpose, **"successor"** means any person, firm, corporation or other business entity which at any time, whether by purchase, merger or otherwise, directly or indirectly acquires all or substantially all of the assets or business of the Company. None of the rights of Executive to receive any form of compensation payable pursuant to this Agreement may be assigned or transferred except by will or the laws of descent and distribution. Any other attempted assignment, transfer, conveyance or other disposition of Executive's right to compensation or other benefits will be null and void.

14. Notices. All notices, requests, demands and other communications called for hereunder will be in writing and will be deemed given (i) on the date of delivery if delivered personally; (ii) one (1) day after being sent by a well established commercial overnight service; or (iii) four (4) days after being mailed by registered or certified mail, return receipt requested, prepaid and addressed to the parties or their successors at the following addresses, or at such other addresses as the parties may later designate in writing:

If to the Company:
Capnia, Inc.
Attn: Chief Executive Officer
1235 Radio Rd, Suite 110
Redwood City, CA 94065

If to Executive:

at the last residential address known by the Company.

15. Severability. In the event that any provision hereof becomes or is declared by a court of competent jurisdiction to be illegal, unenforceable or void, this Agreement will continue in full force and effect without said provision.

16. Integration. This Agreement, together with the 2014 Plan, Option Agreement and the Confidential Information Agreement represents the entire agreement and understanding between the parties as to the subject matter herein and supersedes all prior or contemporaneous agreements whether written or oral. This Agreement may be modified only by agreement of the parties by a written instrument executed by the parties that is designated as an amendment to this Agreement.

17. Waiver of Breach. The waiver of a breach of any term or provision of this Agreement, which must be in writing, will not operate as or be construed to be a waiver of any other previous or subsequent breach of this Agreement.

18. Headings. All captions and section headings used in this Agreement are for convenient reference only and do not form a part of this Agreement.

19. Tax Withholding. All payments made pursuant to this Agreement will be subject to withholding of applicable taxes.

20. Governing Law. This Agreement will be governed by the laws of the State of California (with the exception of its conflict of laws provisions).

21. Acknowledgment. Executive acknowledges that she has had the opportunity to discuss this matter with and obtain advice from him private attorney, has had sufficient time to, and has carefully read and fully understands all the provisions of this Agreement, and is knowingly and voluntarily entering into this Agreement.

22. Counterparts. This Agreement may be executed in counterparts, and each counterpart will have the same force and effect as an original and will constitute an effective, binding agreement on the part of each of the undersigned.

[Remainder of Page Intentionally Left Blank]

IN WITNESS WHETHEROF, each of the parties has executed this Agreement, in the case of the Company by their duly authorized officers, as of the day and year first above written.

COMPANY:

CAPNIA, INC.

By: /s/ Ernest Mario Date: 12/8/16

Ernest Mario

Chairman of the Board

EXECUTIVE:

By: /s/ Anish Bhatnagar Date: 12/7/16

Anish Bhatnagar, MD

[SIGNATURE PAGE TO ANISH BHATNAGAR EMPLOYMENT AGREEMENT]

Exhibit 10.17

SOLENO THERAPEUTICS, INC.

OUTSIDE DIRECTOR COMPENSATION POLICY

(As most recently amended on January 21, 2026)

Soleno Therapeutics, Inc. (the "**Company**") believes that the granting of equity and cash compensation to its members of the Board of Directors (the "**Board**," and members of the Board, the "**Directors**") represents an effective tool to attract, retain, and reward Directors who are not employees of the Company (the "**Outside Directors**"). This Outside Director Compensation Policy (the "**Policy**") is intended to formalize the Company's policy regarding the compensation to its Outside Directors. Unless otherwise defined herein, capitalized terms used in this Policy will have the meaning given to such terms in the Company's 2014 Equity Incentive Plan (the "**Plan**"), or if the Plan is no longer in place, the meaning given to such terms or any similar terms in the equity plan then in place. Each Outside Director will be solely responsible for any tax obligations incurred by such Outside Director as a result of the equity and cash payments such Outside Director receives under this Policy.

1. Cash Compensation

Annual Cash Retainer

Each Outside Director will be paid an annual cash retainer of $50,000. There are no per-meeting attendance fees for attending Board meetings.

Non-Executive Chair / Committee Membership Annual Cash Retainer

Each Outside Director who serves as Non-Executive Chair, or chair or member of a committee of the Board will be paid additional annual fees as follows:

Non-Executive Chair:	$30,000
Lead Independent Director:	$30,000
Chair of Audit Committee:	$20,000
Member of Audit Committee (other than the Chair of the Audit Committee):	$10,000
Chair of Nominating and Corporate Governance Committee:	$10,000
Member of Nominating and Corporate Governance Committee (other than the Chair of the Nominating and Corporate Governance Committee):	$5,000
Chair of Compensation Committee:	$15,000
Member of Compensation Committee (other than the Chair of the Compensation Committee):	$7,500

Each annual cash retainer and additional annual fee will be paid quarterly in arrears on a prorated basis.

2. EQUITY COMPENSATION

Outside Directors will be eligible to receive all types of Awards (except Incentive Stock Options) under the Plan (or the applicable equity plan in place at the time of grant), including discretionary Awards not covered under this Policy. All grants of Awards to Outside Directors pursuant to Section 2 of this Policy will be automatic and nondiscretionary, except as otherwise provided herein, and will be made in accordance with the following provisions:

a. No Discretion. No person will have any discretion to select which Outside Directors will be granted any Awards under this Policy or to determine the number of Shares to be covered by such Awards.

b. Initial Award. Subject to Section 7 of this Policy, each individual who first becomes an Outside Director will be granted Restricted Stock Units ("**RSUs**") with an aggregate Value equal to $600,000 (an "**Initial Award**"). The Initial Award will be made on the first Trading Day on or after the date on which such individual first becomes an Outside Director, whether through election by the stockholders of the Company or appointment by the Board to fill a vacancy (such grant date, the "**Initial Award Grant Date**"). If an individual was a member of the Board and also an employee, becoming an Outside Director due to termination of employment will not entitle the Outside Director to an Initial Award.

Subject to Section 3 of this Policy, each Initial Award will be scheduled to vest as follows 1/3rd of the Shares subject to the Initial Award will be scheduled to vest on each annual anniversary of the Initial Award Grant Date.

c. Annual Award. Subject to Section 7 of this Policy, on the date of each annual meeting of the Company's stockholders (each, an "**Annual Meeting**"), each Outside Director will be automatically granted RSUs with an aggregate Value equal to $300,000 (an "**Annual Award**"). Notwithstanding the foregoing, any Outside Director who has not been a Director for at least six (6) months prior to the date of the applicable Annual Meeting will not receive an Annual Award.

Subject to Section 3 of this Policy, each Annual Award will be scheduled to vest on the earlier of (i) the one (1)-year anniversary of the date the Annual Award is granted, or (ii) the day prior to the date of the Annual Meeting next following the date the Annual Award is granted, in each case, subject to the Outside Director continuing to be a Service Provider through the applicable vesting date.

d. Value. For purposes of this Policy, "**Value**" means, with respect to each Initial Award and Annual Award (each, an "**RSU Award**"), the average of the closing prices of the Company's Common Stock in each trading day occurring during the consecutive, thirty (30) trailing calendar day period ending on (and inclusive of) the Friday immediately preceding the grant date of the RSU Award, or such other methodology the Board or its Compensation

Committee may determine prior to the grant of the RSU Award becoming effective; provided, however, that any RSU Award will cover only a whole number of Shares, such that any fractional Share that otherwise would result from a given Value will be rounded down and will not become subject to such RSU Award.

e. Additional Terms of Initial Awards and Annual Awards. Each Initial Award and Annual Award will be granted under and subject to the terms and conditions of the Plan and the applicable form of Award Agreement previously approved by the Board or its Compensation Committee, as applicable, for use thereunder.

3. Change in Control

In the event of a Change in Control, each Outside Director outstanding Company equity awards will be treated in accordance with the terms of the Plan.

4. Travel Expenses

Each Outside Director's reasonable, customary, and documented travel expenses to Board meetings will be reimbursed by the Company.

5. Additional Provisions

All provisions of the Plan not inconsistent with this Policy will apply to Awards granted to Outside Directors.

6. Adjustments

In the event that any dividend or other distribution (whether in the form of cash, Shares, other securities or other property), recapitalization, stock split, reverse stock split, reorganization, merger, consolidation, split-up, spin-off, combination, reclassification, repurchase, or exchange of Shares or other securities of the Company, or other change in the corporate structure of the Company affecting the Shares occurs, the Administrator, in order to prevent diminution or enlargement of the benefits or potential benefits intended to be made available under this Policy, will adjust the number of Shares issuable pursuant to Awards granted under this Policy.

7. Limitations

No Outside Director may be paid, issued or granted, in any Fiscal Year, cash payments (including the fees under Section 1 above) and Awards with an aggregate value greater than $750,000, increased to $1,000,000 in connection with his or her initial service (with the value of Awards based on its grant date fair value (determined in accordance with U.S. generally accepted accounting principles)). Any Awards or other compensation provided to an individual (a) for his or her services as an Employee, or for his or her services as a Consultant other than as an Outside Director, or (b) prior to the Effective Date, will be excluded for purposes of the foregoing limits.

8. SECTION 409A

In no event will cash compensation or expense reimbursement payments under this Policy be paid after the later of (a) the fifteenth (15th) day of the third (3rd) month following the end of the Company's fiscal year in which the compensation is earned or expenses are incurred, as applicable, or (b) the fifteenth (15th) day of the third (3rd) month following the end of the calendar year in which the compensation is earned or expenses are incurred, as applicable, in compliance with the "short-term deferral" exception under Section 409A of the Internal Revenue Code of 1986, as amended, and the final regulations and guidance thereunder, as may be amended from time to time (together, "**Section 409A**"). It is the intent of this Policy that this Policy and all payments hereunder be exempt from or otherwise comply with the requirements of Section 409A so that none of the compensation to be provided hereunder will be subject to the additional tax imposed under Section 409A, and any ambiguities or ambiguous terms herein will be interpreted to be so exempt or comply. In no event will the Company reimburse an Outside Director for any taxes imposed or other costs incurred as a result of Section 409A.

9. REVISIONS

The Board or any Committee designated by the Board may amend, alter, suspend, or terminate this Policy at any time and for any reason. No amendment, alteration, suspension, or termination of this Policy will materially impair the rights of an Outside Director with respect to compensation that already has been paid or awarded, unless otherwise mutually agreed between the Outside Director and the Company. Termination of this Policy will not affect the Board's or the Compensation Committee's ability to exercise the powers granted to it under the Plan with respect to Awards granted under the Plan pursuant to this Policy prior to the date of such termination.

Exhibit 10.19

FIRST AMENDMENT TO OFFICE LEASE

THIS FIRST AMENDMENT TO OFFICE LEASE (the "**Amendment**") is made and entered into as of November 25, 2025, by and between **1 Twin Property Owner LLC, a Delaware limited liability company** ("**Landlord**"), and **Soleno Therapeutics, Inc., a Delaware corporation** ("**Tenant**").

RECITALS

A. Landlord and Tenant are parties to that certain Office Lease dated June 13, 2024 (the "**Lease**"). Pursuant to the Lease, Landlord has leased to Tenant space currently containing approximately **18,026** rentable square feet (the "**Original Premises**") described as Suite No. 400 on the fourth (4th) floor of the building located at 100 Marine Parkway, Redwood City, California (the "**Building**").

B. Tenant has requested that additional space containing approximately **17,779** rentable square feet described as Suite No. 500 consisting of the entire fifth (5th) floor of the Building shown on **Exhibit A** hereto (the "**Expansion Space**") be added to the Original Premises and that the Lease be appropriately amended and Landlord is willing to do the same on the following terms and conditions.

C. The capitalized terms used in this Amendment shall have the same definitions as set forth in the Lease to the extent that such capitalized terms are defined therein and not redefined in this Amendment.

NOW, THEREFORE, in consideration of the mutual covenants and agreements herein contained and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Landlord and Tenant agree as follows:

1. **Expansion.** Effective as of the Expansion Effective Date (defined below), the Premises is increased from approximately 18,026 rentable square feet on the fourth (4th) floor of the Building to approximately **35,805** rentable square feet on the fourth (4th) and fifth (5th) floors of the Building by the addition of the Expansion Space, and from and after the Expansion Effective Date, the Original Premises and the Expansion Space, collectively, shall be deemed the "Premises", as defined in the Lease and as used herein. The Term for the Expansion Space shall commence on the Expansion Effective Date and end on the Lease Expiration Date. The Expansion Space is subject to all the terms and conditions of the Lease except as expressly modified herein and except that Tenant shall not be entitled to receive any allowances, abatements or other financial concessions granted with respect to the Expansion Space unless such concessions are expressly provided for herein with respect to the Expansion Space.

1.1 The "**Expansion Effective Date**" shall be the date that is thirty (30) days following the date Landlord delivers possession of the Expansion Space to Tenant with the Tenant Alterations (as defined in **Exhibit B** attached hereto) in the Expansion Space substantially complete. The date Landlord delivers possession of the Expansion Space to Tenant with the Tenant Alterations substantially complete shall be referred to herein as the "**Delivery Date**." The Delivery Date is estimated to occur on December 1, 2025 (the "**Target Delivery Date**"), and the Expansion Effective Date is estimated to occur on January 1, 2026 (the "**Target Expansion Effective Date**"); provided, however, that if Landlord shall be delayed in substantially completing the Tenant Alterations in the Expansion Space as a result of the occurrence of a Tenant Delay (defined below), then, for purposes of determining the Delivery Date, the date of substantial completion shall be deemed to be the day that said Tenant Alterations would have been substantially completed absent any such Tenant Delay(s). During the period commencing on the Delivery Date and ending on the day immediately preceding the Expansion Effective Date, Tenant's possession of the Expansion Space shall be subject to the terms and conditions of the

Lease, as amended hereby, and Tenant shall comply with all terms and provisions of the Lease, except those provisions requiring payment of Base Rent or Tenant's Share of Direct Expenses as to the Expansion Space. A "**Tenant Delay**" means any act or omission of Tenant or its agents, employees, vendors or contractors that actually delays substantial completion of the Tenant Alterations, including, without limitation, the following:

1.1.1 Tenant's failure to furnish information or approvals within any time period specified in this Amendment, including the failure to prepare or approve preliminary or final plans by any applicable due date;

1.1.2 Tenant's selection of equipment or materials that have long lead times after first being informed by Landlord that the selection may result in a delay;

1.1.3 Changes requested or made by Tenant to previously approved plans and specifications;

The Expansion Space shall be deemed to be substantially completed on the date that Landlord reasonably determines that all Tenant Alterations have been performed (or would have been performed absent any Tenant Delays), other than any details of construction, mechanical adjustment or any other matter, the noncompletion of which does not materially interfere with Tenant's use of the Expansion Space.

1.2 If the Delivery Date shall be delayed to the extent that Landlord fails to deliver possession of the Expansion Space for any other reason (other than Tenant Delays by Tenant) then there shall be an adjustment to the Delivery Date and the Expansion Effective Date and, accordingly, the postponement of Tenant's obligation to pay Base Rent and Tenant's Share of Direct Expenses on the Expansion Space. If the Expansion Effective Date is delayed, the Lease Expiration Date shall not be similarly extended. Notwithstanding anything contained herein to the contrary, if the Expansion Effective Date has not occurred by (i) February 15, 2026, then Tenant shall receive an additional day for day abatement of Base Rent for each day thereafter until the Expansion Effective Date occurs and (ii) March 15, 2026, then Tenant may terminate this Amendment upon notice to Landlord, and upon such termination, Landlord shall return the Security Deposit for the Expansion Space provided in Section 4 below. The parties acknowledge and agree that the foregoing dates are subject to Tenant Delays and Force Majeure.

2. **Tenant's Share.** For the period commencing with the Expansion Effective Date and ending on the Lease Expiration Date, Tenant's Share for the Expansion Space is 20.67% of the Building. Tenant's Share for the Expansion Space and the Original Premises is, collectively, 41.62% of the Building.

3. **Base Rent.** In addition to Tenant's obligation to pay Base Rent for the Original Premises, Tenant shall pay Landlord Base Rent for the Expansion Space as follows:

Period*	Rentable Square Feet**	Monthly Installment of Base Rent	Monthly Base Rent per RSF
1/1/26 – 12/31/26	7,987	$32,746.70***	$4.10
1/1/27 – 12/31/27	10,000	$42,200.00	$4.22
1/1/28 – 12/31/28	16,000	$69,600.00	$4.35
1/1/29 – 8/31/29	17,779	$79,649.92	$4.48

All such Base Rent shall be payable by Tenant in accordance with the terms of the Lease, as amended hereby.

* Landlord and Tenant acknowledge that the foregoing schedule is based on the assumption that the Expansion Effective Date is the Target Expansion Effective Date. If the Expansion Effective Date is not the Target Expansion Effective Date, (i) the schedule set forth above with respect to the payment of any installment(s) of Base Rent for the Expansion Space shall be appropriately adjusted on a per diem basis to reflect the actual Expansion Effective Date and Tenant shall, at Landlord's request, execute and deliver a memorandum agreement provided by Landlord setting forth the actual Expansion Effective Date and a revised Base Rent schedule. Should Tenant fail to do so within thirty (30) days after Landlord's request, the information set forth in such memorandum provided by Landlord shall be conclusively presumed to be agreed and correct.

** Solely for the purpose of calculating the Base Rent payable by Tenant for the Expansion Space, the Expansion Space shall be deemed to be: (i) approximately 7,987 rentable square feet during the first twelve (12) full calendar months following the Expansion Effective Date; (ii) approximately 10,000 rentable square feet during the thirteenth (13^{th}) through the twenty-fourth (24^{th}) full calendar months following the Expansion Effective Date; (iii) approximately 16,000 rentable square feet during the twenty-fifth (25^{th}) through the thirty-sixth (36^{th}) full calendar months following the Expansion Effective Date; and (iv) approximately 17,779 rentable square feet during the thirty-seventh (37^{th}) through the forty-fourth (44^{th}) full calendar months following the Expansion Effective Date. Notwithstanding the foregoing, Tenant shall be in possession of the entire 17,779rentable square feet of the Expansion Space during the period commencing on the Expansion Effective Date and ending on the Lease Expiration Date and shall be responsible for all of its obligations and liabilities with respect to the entire Expansion Space pursuant to the terms of the Lease, as amended hereby, during the Lease Term, including without limitation, Tenant's obligation to pay Tenant's Share of Direct Expenses for the entire Expansion Space.

*** Notwithstanding anything in the Lease, as amended hereby, to the contrary, so long as Tenant is not in default under the Lease, as amended hereby, beyond any applicable notice or cure period, Tenant shall be entitled to an abatement of Base Rent with respect to the Expansion Space in the amount of $32,746.70 per month for the first two (2) full calendar months following the Expansion Effective Date. The maximum total amount of Base Rent abated with respect to the Premises in accordance with the foregoing shall equal $65,493.40 (the "**Abated Base Rent**"). If Tenant shall be in monetary or non-monetary material default under the Lease, as amended hereby, and shall fail to cure such default within the notice and cure period, if any, permitted for cure pursuant to terms and conditions of the Lease, then the dollar amount of the unapplied portion of the Abated Base Rent as of the date of such default shall be converted to a credit to be applied to the Base Rent applicable at the end of the Lease Term and Tenant shall immediately be obligated to begin paying Base Rent for the Expansion Space in full. Only Base Rent shall be abated pursuant to this Section, as more particularly described herein, and all other rent and other costs and charges specified in the Lease, as amended hereby, shall remain as due and payable pursuant to the provisions of the Lease, as amended hereby.

4. **Additional Security Deposit.** Upon Tenant's execution hereof, Tenant shall pay Landlord the sum of $79,649.92 which is added to and becomes part of the Security Deposit held by Landlord as provided under Article 21 of the Lease as security for payment of Rent and the performance of the other terms and conditions of the Lease by Tenant. Accordingly, simultaneous with the execution hereof, the Security Deposit is increased from $83,099.86 to $162,749.78.

5. **Additional Rent.** For the period commencing with the Expansion Effective Date and ending on the Lease Expiration Date, Tenant shall pay all Additional Rent payable under the Lease, including Tenant's Share of Direct Expenses applicable to the Expansion Space, in accordance with the terms of the Lease, provided, however, during such period, the Base Year for the computation of Tenant's Share of Direct Expenses applicable to the Expansion Space is 2026.

6. **Improvements to Expansion Space.**

6.1 **Condition of Expansion Space.** Tenant has inspected the Expansion Space and agrees to accept the same "as is" without any agreements, representations, understandings or obligations on the part of Landlord to perform any alterations, repairs or improvements, except as may be expressly provided otherwise in this Amendment. However, notwithstanding the foregoing, Landlord agrees that the Building's base electrical, heating, ventilation and air conditioning, plumbing and fire life safety systems located in the Expansion Space shall be in good working order as of the date Landlord delivers possession of the Expansion Space to Tenant. Except to the extent caused by the acts or omissions of Tenant or any of its agents, contractors, employees, licensees or invitees or by any alterations or improvements performed by or on behalf of Tenant, if such Building's base electrical, heating, ventilation and air conditioning, plumbing and fire life safety systems are not in good working order as of the date possession of the Expansion Space is delivered to Tenant and Tenant provides Landlord with notice of the same within nine (9) months following the date Landlord delivers possession of the Expansion Space to Tenant, Landlord shall be responsible for repairing or restoring the same at Landlord's sole cost and expense.

6.2 **Responsibility for Improvements to Expansion Space.** Landlord shall perform improvements to the Expansion Space in accordance with the terms of **Exhibit B** attached hereto. Upon the expiration of the Lease Term, or upon any earlier termination of the Lease, Tenant shall surrender possession of the Expansion Space to Landlord in accordance with the terms of the Lease and in as good order and condition as when Tenant took possession, reasonable wear and tear, casualty, and repairs which are specifically made the responsibility of Landlord excepted. Tenant shall not be required to remove any portion of the Tenant Alterations described on **Exhibit B**.

6.3 **Responsibilities for Improvements to Premises.** Prior to the Expansion Effective Date, Landlord shall install security lighting within the parking lot and building entrance areas to Tenant's reasonable satisfaction.

7. **Other Pertinent Provisions.** Landlord and Tenant agree that, effective as of the date of this Amendment (unless different effective date(s) is/are specifically referenced in this Section), the Lease shall be amended in the following additional respects:

7.1 **Parking**. Commencing upon the Expansion Effective Date, Tenant shall have the right, at no additional charge, to use three (3) additional unreserved parking passes for every 1,000 rentable square feet of the Expansion Space, subject to the terms of Article 28 of the Lease. In addition, Tenant shall have the right to reserve up to seven (7) dedicated parking stalls adjacent to either entrance to the Building. Landlord shall have no obligation to enforce or monitor Tenant's parking spaces nor shall Landlord be responsible for enforcing Tenant's parking rights against

any third parties, except that Landlord shall install signage indicating that Tenant's reservation of such parking spaces.

7.2 **Right of First Offer**. Section 1.3 of the Lease is hereby deleted in its entirety. Landlord hereby grants to the originally named Tenant or any Permitted Transferee pursuant to a Permitted Transfer ("**Original Tenant**") an ongoing right of first offer (the "**Offer Right**") with respect to each of the following spaces located on the third (3rd) floor of the Building: (i) Suite 350 containing approximately 3,270 rentable square feet; (ii) Suite 300 containing approximately 10,829 rentable square feet; and (iii) Suite 310 containing approximately 4,169 rentable square feet (each, a "**First Offer Space**"). Landlord and Tenant acknowledge that as of the date of this Lease, each First Offer Space is currently leased. If Tenant, following its receipt of a First Offer Notice fails to exercise its right to lease all or any portion of a First Offer Space, then Landlord may lease the First Offer Space to any party on the terms set forth in the First Offer Notice. Notwithstanding anything to the contrary in this Section 7.2, if Tenant was entitled to exercise its right of first offer pursuant to this Section 7.2, but did not accept Landlord's offer set forth in Landlord's First Offer Notice, and Landlord proposes to lease the First Offer Space to a prospective tenant on material terms that are substantially more favorable to the tenant than those set forth in the First Offer Notice, then the terms of this Section 7.2 shall apply again as if Landlord had not provided the First Offer Notice to Tenant; provided, however, Tenant's Exercise Period with respect to such new First Offer Notice shall be amended to be a period of five (5) days. For purposes hereof, the material terms offered to another party (the "**Proposed Terms**") shall not be deemed to be substantially more favorable than those set forth in an First Offer Notice unless the annualized net present value of the rent for the First Offer Space as provided under the Proposed Terms is less than ninety-five percent (95%) of the annualized net present value of the rent for the First Offer Space as provided under the First Offer Notice, as reasonably determined in good faith by Landlord using a discount rate selected in good faith by Landlord and taking into account all proposed material terms relating to the First Offer Space, including the length of the term, the net rent, any base year, any tax or expense escalation or other financial escalation, and any allowances or other financial concessions, but excluding any right to extend the term or any right to expand the leased premises (whether in the form of an expansion option, a right of first offer or refusal, or any similar right).

7.2.1 Landlord shall notify Tenant (a "**First Offer Notice**") from time to time when a First Offer Space becomes "Available," as that term is defined hereinbelow. Pursuant to such First Offer Notice, Landlord shall offer to lease to Tenant the then available First Offer Space. A First Offer Notice shall describe the space so offered to Tenant and shall set forth the "First Offer Rent" and the other economic terms upon which Landlord is willing to lease such space to Tenant. For purposes of this Section 7.2, a First Offer Space shall be deemed "**Available**" on the date Landlord determines that the existing tenant of the applicable First Offer Space will not extend or renew the term of its lease or enter into a new lease for the First Offer Space and Landlord intends to offer the First offer Space for lease to the public.

7.2.2 If Tenant wishes to exercise Tenant's right of first offer with respect to the space described in a First Offer Notice, then within fifteen (15) business days of delivery of such First Offer Notice to Tenant ("**Tenant's Exercise Period**"), Tenant shall deliver notice to Landlord of Tenant's intention to exercise its right of first offer with respect to the First Offer Space described in such First Offer Notice on the terms contained therein. If Tenant does not so notify Landlord within the fifteen (15) business day period, then, subject to the terms of Section 7.2.1 above, Landlord shall be free to lease the space described in such First Offer Notice to anyone to whom Landlord desires on any terms Landlord desires. Notwithstanding anything to the contrary contained

herein, Tenant must elect to exercise its right of first offer, if at all, with respect to the First Offer Space offered by Landlord to Tenant at any particular time, and Tenant may not elect to lease only a portion thereof. If Tenant does not exercise its right of first offer with respect to the First Offer Space described in a First Offer Notice or if Tenant fails to respond to a First Offer Notice within fifteen (15) business days of delivery thereof, then Tenant's right of first offer as set forth in this Section 7.2 shall not apply for twelve (12) months thereafter to the extent of the space covered by the First Offer Notice and, subject to the terms of Section 7.2.1 above, Landlord shall be free to lease such space and/or otherwise grant options or rights to such space on any terms and conditions whatsoever free and clear of the First Offer Right.

7.2.3 The annual Rent payable by Tenant for the First Offer Space (the "**First Offer Rent**") shall be equal to the "Fair Rental Value," as that term is defined below, for the First Offer Space, pursuant to transactions consummated within the nine (9)-month period preceding the First Offer Commencement Date. The new Base Year with respect to the First Offer Space only shall be the calendar year in which the First Offer Commencement Date occurs (unless the First Offer Commencement Date occurs in the last quarter of a calendar year, in which event the Base Year shall be the following year). The Fair Rental Value shall take into account (a) rental abatement concessions, if any, being granted such tenants in connection with such comparable space; (b) tenant improvements or allowances provided or to be provided for such comparable space, and taking into account the value, if any, of the existing improvements in the subject space, such value to be based upon the age, condition, design, quality of finishes and layout of the improvements and the extent to which the same can be utilized by a general office user other than Tenant; and (c) other reasonable monetary concessions being granted such tenants in connection with such comparable space. The "**Fair Rental Value**," as used in this Amendment, shall be equal to the annual rent per rentable square foot (including additional rent and considering any "base year" or "expense stop" applicable thereto at which tenants, are leasing non-sublease, non-encumbered, non-equity space which is not significantly greater or smaller in size than the subject space for a comparable lease term, in an arm's length transaction, which comparable space is located in comparable buildings in Redwood City, California.

7.2.4 Tenant shall accept the First Offer Space in its then existing "as is" condition, except as set forth in the First Offer Notice. The construction of improvements in the First Offer Space shall comply with the terms of Article 8 of the Lease.

7.2.5 If Tenant timely exercises Tenant's right to lease First Offer Space as set forth herein, then, within fifteen (15) days thereafter, Landlord and Tenant shall execute an amendment (the "**First Offer Amendment**") adding such First Offer Space to the Premises upon the terms and conditions as set forth in the First Offer Notice therefor and this Section 7.2. Tenant shall commence payment of Rent for such First Offer Space, and the term of such First Offer Space shall commence on the commencement date set forth in the First Offer Notice (the "**First Offer Commencement Date**") and terminate on the date set forth in the First Offer Notice therefor.

7.2.6 The rights contained in this Section 7.2 shall be personal to Original Tenant and any Permitted Transferee pursuant to a Permitted Transfer, and may only be exercised by Original Tenant and any Permitted Transferee if Original Tenant or Permitted Transferee leases the entire Premises. Tenant shall not have the right to lease First Offer Space if, as of the date of the attempted exercise of any right of first offer by Tenant, as of the date Landlord and Tenant execute the First Offer Amendment, or as of the scheduled date of delivery of such First Offer Space to Tenant, Tenant is in default under this Lease beyond any applicable notice or cure period or Tenant has previously been in monetary default or material non-monetary default beyond any applicable notice and cure period under this Lease more than twice (the "**Option Conditions**"); provided Landlord shall have the right to waive the Option Conditions in Landlord's sole discretion.

8. **Miscellaneous.**

8.1 This Amendment, including **Exhibit A** (Outline and Location of Expansion Space) and **Exhibit B** (Tenant Alterations) attached hereto, sets forth the entire agreement between the parties with respect to the matters set forth herein. There have been no additional oral or written representations or agreements. Under no circumstances shall Tenant be entitled to any Rent abatement, improvement allowance, leasehold improvements, or other work to the Premises, or any similar economic incentives that may have been provided Tenant in connection with entering into the Lease, unless specifically set forth in this Amendment.

8.2 Except as herein modified or amended, the provisions, conditions and terms of the Lease shall remain unchanged and in full force and effect. In the case of any inconsistency between the provisions of the Lease and this Amendment, the provisions of this Amendment shall govern and control.

8.3 Submission of this Amendment by Landlord is not an offer to enter into this Amendment but rather is a solicitation for such an offer by Tenant. Landlord shall not be bound by this Amendment until Landlord has executed and delivered the same to Tenant.

8.4 Tenant hereby represents to Landlord that Tenant has dealt with no broker in connection with this Amendment, other than Jones Lang LaSalle. Tenant agrees to indemnify and hold Landlord and the Landlord Parties harmless from all claims of any other brokers claiming to have represented Tenant in connection with this Amendment.

8.5 Each signatory of this Amendment represents hereby that he or she has the authority to execute and deliver the same on behalf of the party hereto for which such signatory is acting. Tenant hereby represents and warrants that neither Tenant, nor any persons or entities holding any legal or beneficial interest whatsoever in Tenant, are (i) the target of any sanctions program that is established by Executive Order of the President or published by the Office of Foreign Assets Control, U.S. Department of the Treasury ("**OFAC**"); (ii) designated by the President or OFAC pursuant to the Trading with the Enemy Act, 50 U.S.C. App. § 5, the International Emergency Economic Powers Act, 50 U.S.C. §§ 1701-06, the Patriot Act, Public Law 107-56, Executive Order 13224 (September 23, 2001) or any Executive Order of the President issued pursuant to such statutes; or (iii) named on the following list that is published by OFAC: "List of Specially Designated Nationals and Blocked Persons." If the foregoing representation is untrue at any time during the Term, a default under the Lease will be deemed to have occurred, without the necessity of notice to Tenant.

8.6 Tenant shall not bring upon the Premises or any portion of the Building or use the Premises or permit the Premises or any portion thereof to be used for the growing, manufacturing, administration, distribution (including without limitation, any retail sales), possession, use or consumption of any cannabis, marijuana or cannabinoid product or compound, regardless of the legality or illegality of the same.

8.7 Signatures to this Amendment transmitted by telecopy or electronic signatures shall be valid and effective to bind the party so signing. This Amendment may be executed in two or more counterparts, each of which shall be deemed an original and all of which together shall constitute one and same agreement. **THE PARTIES HERETO CONSENT AND AGREE THAT THIS AMENDMENT MAY BE SIGNED USING ELECTRONIC SIGNATURE TECHNOLOGY (E.G., VIA DOCUSIGN OR SIMILAR ELECTRONIC SIGNATURE TECHNOLOGY), AND THAT SUCH SIGNED ELECTRONIC RECORD SHALL BE VALID AND AS EFFECTIVE TO BIND THE PARTY SO SIGNING AS A PAPER COPY BEARING SUCH PARTY'S HAND-WRITTEN SIGNATURE**..

8.8 For purposes of Section 1938 of the California Civil Code, Landlord hereby discloses to Tenant, and Tenant hereby acknowledges, that the Expansion Space has not undergone inspection by a Certified Access Specialists (CASp). As required by Section 1938(e) of the California Civil Code, Landlord hereby states as follows: "A Certified Access Specialist (CASp) can inspect the subject premises and determine whether the subject premises comply with all of the applicable construction-related accessibility standards under state law. Although state law does not require a CASp inspection of the subject premises, the commercial property owner or lessor may not prohibit the lessee or tenant from obtaining a CASp inspection of the subject premises for the occupancy or potential occupancy of the lessee or tenant, if requested by the lessee or tenant. The parties shall mutually agree on the arrangements for the time and manner of the CASp inspection, the payment of the fee for the CASp inspection, and the cost of making any repairs necessary to correct violations of construction-related accessibility standards within the premises." In furtherance of the foregoing, Landlord and Tenant hereby agree as follows: (a) any CASp inspection requested by Tenant shall be conducted, at Tenant's sole cost and expense, by a CASp approved in advance by Landlord; and (b) any repairs within the Expansion Space to correct violations of construction-related accessibility standards; and any repairs to the Building (outside the Premises) required to correct violations of construction-related accessibility standards, shall be governed by the terms of Article 24 of the Lease.

8.9 Redress for any claim against Landlord under the Lease and this Amendment shall be limited to and enforceable only against and to the extent of Landlord's interest in the Building. The obligations of Landlord under the Lease are not intended to and shall not be personally binding on, nor shall any resort be had to the private properties of, any of its trustees or board of directors and officers, as the case may be, its investment manager, the general partners thereof, or any beneficiaries, stockholders, employees, or agents of Landlord or the investment manager, and in no case shall Landlord be liable to Tenant hereunder for any lost profits, damage to business, or any form of special, indirect or consequential damages.

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IN WITNESS WHEREOF, Landlord and Tenant have duly executed this Amendment as of the day and year first above written.

LANDLORD:	**TENANT:**
1 TWIN PROPERTY OWNER, LLC, **a Delaware limited liability company**	**SOLENO THERAPEUTICS, INC.,** **a Delaware corporation**
By: /s/ Alex Valner	By: /s/ James Mackaness
Name: Alex Valner	Name: James Mackaness
Title: Managing Partner	Title: Chief FinancialOfficer
Dated: November 25, 2025	Dated: 11/10/2025

EXHIBIT A - OUTLINE AND LOCATION OF EXPANSION SPACE

**attached to and made a part of the Amendment dated as of November 5, 2025,
between 1 Twin Property Owner, LLC, a Delaware limited liability company, as Landlord and Soleno Therapeutics, Inc., a Delaware corporation, as Tenant**

Exhibit A is intended only to show the general layout of the Expansion Space as of the beginning of Expansion Effective Date. It does not in any way supersede any of Landlord's rights set forth in the Lease with respect to arrangements and/or locations of public parts of the Building and changes in such arrangements and/or locations. It is not to be scaled; any measurements or distances shown should be taken as approximate.

EXHIBIT B - TENANT ALTERATIONS

attached to and made a part of the Amendment dated as of November 5, 2025, between 1 Twin Property Owner, LLC, a Delaware limited liability company, as Landlord and Soleno Therapeutics, Inc., a Delaware corporation, as Tenant

1. Landlord, at its sole cost and expense (subject to the terms and provisions of Section 2 below) shall perform improvements to the Expansion Space in accordance with the following work list (the "**Work List**") and space plan attached hereto as Schedule 1 (the "**Space Plan**"), using Building standard methods, materials and finishes. The improvements to be performed in accordance with the Work List are hereinafter referred to as the "**Tenant Alterations**". Landlord shall enter into a direct contract for the Tenant Alterations with a general contractor selected by Landlord. In addition, Landlord shall have the right to select and/or approve of any subcontractors used in connection with the Tenant Alterations.

WORK LIST

- Removal of film and cleaning of exterior windows on the 5th floor.
- Paint 2-3 accent color walls that Tenant chooses (green or blue).
- Fill in any holes in walls + fresh paint throughout space.
- Match the red/gray carpet throughout space.
- Match the tile that is in the kitchen on the 4th floor to the 5th floor space near the kitchenette.
- Match the smaller kitchenette area cabinets to what is in the 4th floor breakroom.
- Remove dishwasher in small kitchenette.
- In the larger mailspace, replace the mailboxes with cabinets similar to the 4th floor.
- Match the overhead hanging lighting.
- Replace any open/damaged ceiling tiles.
- Install "bee hive" hexagon privacy shading on the conference room glass walls.
- Remove wall near main entrance, similar to the 4th floor.
- Combine offices (outlined in red on the Space Plan) to create three additional conference rooms.

2. All other work and upgrades, subject to Landlord's approval, not to be unreasonably withheld, shall be at Tenant's sole cost and expense, plus any applicable state sales or use tax thereon, payable upon demand as Additional Rent. Tenant shall be responsible for any Tenant Delay in completion of the Tenant Alterations resulting from any such other work and upgrades requested or performed by Tenant.

3. Landlord's supervision or performance of any work for or on behalf of Tenant shall not be deemed to be a representation by Landlord that such work complies with applicable insurance requirements,

building codes, ordinances, laws or regulations or that the improvements constructed will be adequate for Tenant's use.

4. Notwithstanding anything to the contrary contained in the Lease and in addition to, and without limitation of, Landlord's obligations under the Lease and this Exhibit B, Tenant shall have a period of nine (9) months after the Delivery Date during which to notify Landlord in writing of any repairs, replacements or restoration resulting from any defect or improper workmanship in the Tenant Alterations, or materials or equipment furnished by Landlord in connection with the construction of the Tenant Alterations. If Tenant determines there are required repairs, replacements or restoration resulting from any defect or improper workmanship in the Tenant Alterations, or materials or equipment furnished by Landlord in connection with the construction of the Tenant Alterations, and Tenant provides Landlord with notice of the same within nine (9) months following the Delivery Date, Landlord shall be responsible for repairing or restoring the same at Landlord's sole cost.

5. This **Exhibit B** shall not be deemed applicable to any additional space added to the Premises at any time or from time to time, whether by any options under the Lease or otherwise, or to any portion of the original Premises or any additions to the Premises in the event of a renewal or extension of the original Lease Term, whether by any options under the Lease or otherwise, unless expressly so provided in the Lease or any amendment or supplement to the Lease.

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Schedule 1 to Exhibit B

Exhibit 21.1

Subsidiaries of Soleno Therapeutics, Inc.

Subsidiary	Jurisdiction
Soleno Therapeutics U.K. Ltd.	United Kingdom
Soleno Therapeutics Europe Ltd.	Ireland
Essentialis, Inc.	Delaware

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statement of Soleno Therapeutics, Inc. (the "Company") on Form S-8 (File No.'s 333-200175, 333-210563, 333-220056, 333-224070, 333-230402, 333-235999, 333-239496, 333-252014, 333-264035, 333-270285, 333-273816, 333-276548, 333-276785, 333-281339 and 333-285435) and Form S-3 (File No.'s 333-275120 and 333-276344) of our reports dated February 25, 2026, with respect to our audit of the consolidated financial statements of the Company as of and for the year ended December 31, 2025 and the effectiveness of internal control over financial reporting of the Company of December 31, 2025, which reports are included in this Annual Report on Form 10-K for the year ended December 31, 2025.

/s/ CBIZ CPAs P.C.

San Francisco, CA
February 25, 2026

Exhibit 23.2

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements of Soleno Therapeutics, Inc. (the "Company") on Form S-8 (File No.'s 333-200175, 333-210563, 333-220056, 333-224070, 333-230402, 333-235999, 333-239496, 333-252014, 333-264035, 333-270285, 333-273816, 333-276548, 333-276785, 333-281339 and 333-285435) and Form S-3 (File No.'s 333-275120 and 333-276344) of our report dated February 28, 2025, with respect to the consolidated financial statements of Soleno Therapeutics, Inc. as of December 31, 2024 and for each of the two years in the period ended December 31, 2024 included in this Annual Report on Form 10-K.

We resigned as the Company's independent registered public accounting firm on April 17, 2025 and, accordingly we have not performed any audit or review procedures with respect to any financial statements for the periods after that date.

/s/ Marcum LLP .

San Francisco, CA
February 25, 2026

Exhibit 31.1

CERTIFICATION OF THE CHIEF EXECUTIVE OFFICER
PURSUANT TO
SECURITIES EXCHANGE ACT RULES 13A-14(A) AND 15D-14(A)

I, Anish Bhatnagar, M.D., certify that:

1. I have reviewed this annual report on Form 10-K of Soleno Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 25, 2026

/S/ ANISH BHATNAGAR
Anish Bhatnagar
President, Chief Executive Officer
(principal executive officer)

Exhibit 31.2

CERTIFICATION OF THE CHIEF FINANCIAL OFFICER
PURSUANT TO
SECURITIES EXCHANGE ACT RULES 13A-14(A) AND 15D-14(A)

I, James Mackaness, certify that:

1. I have reviewed this annual report on Form 10-K of Soleno Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 25, 2026

/S/ JAMES MACKANESS
James Mackaness
Chief Financial Officer
(principal financial and accounting officer)

Exhibit 32.1

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

In connection with the Annual Report of Soleno Therapeutics, Inc. (the "Company") on Form 10-K for the fiscal year ended December 31, 2025, as filed with the Securities and Exchange Commission (the "Report"), Anish Bhatnagar, President, Chief Executive Officer of the Company, do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

Date: February 25, 2026

/S/ ANISH BHATNAGAR
Anish Bhatnagar
President, Chief Executive Officer
(principal executive officer)

Exhibit 32.2

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

In connection with the Annual Report of Soleno Therapeutics, Inc. (the "Company") on Form 10-K for the fiscal year ended December 31, 2025, as filed with the Securities and Exchange Commission (the "Report"), James Mackaness, Chief Financial Officer of the Company, do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

Date: February 25, 2026

/S/ JAMES MACKANESS
James Mackaness
Chief Financial Officer
(principal financial and accounting officer)