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

Or

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

For the transition period from to

Commission File Number: 000-50768

ACADIA PHARMACEUTICALS INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**06-1376651**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification Number)**
12830 El Camino Real, Suite 400 San Diego, California	**92130**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's telephone number, including area code:

(858) 558-2871

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, par value $0.0001 per share	**ACAD**	**The Nasdaq Stock Market LLC**

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 15(d) of the Securities Exchange Act of 1934. 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 definitions of "large accelerated filer", "accelerated filer", "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Securities Exchange Act of 1934:

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 Securities Exchange Act of 1934). Yes ☐ No ☒

As of June 30, 2025, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the registrant's common stock held by non-affiliates of the registrant was approximately $2.3 billion, based on the closing price of the registrant's common stock on the Nasdaq Global Select Market on June 30, 2025 of $21.57 per share.

As of February 18, 2026, 170,494,613 shares of the registrant's common stock, $0.0001 par value, were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement to be filed with the Securities and Exchange Commission by April 30, 2026 are incorporated by reference into Part III of this report.

ACADIA PHARMACEUTICALS INC.

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PART I

FORWARD-LOOKING STATEMENTS

This report and the information incorporated herein by reference contain forward-looking statements that involve a number of risks and uncertainties, as well as assumptions that, if they never materialize or prove incorrect, could cause our results to differ materially from those expressed or implied by such forward-looking statements. Although our forward-looking statements reflect the good faith judgment of our management, these statements can only be based on facts and factors currently known by us. Consequently, forward-looking statements are inherently subject to risks and uncertainties, and actual results and outcomes may differ materially from results and outcomes discussed in the forward-looking statements. In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and you are cautioned not to unduly rely upon these statements.

Forward-looking statements can be identified by the use of forward-looking words such as "aims," "anticipates," "believes," "continue," "could," "estimates," "expects," "hopes," "intends," "may," "plans," "potential" "predicts," "pro forma," "projects," "seeks," "should," "will," "would," or other similar words (including their use in the negative), or by discussions of future matters such as the benefits to be derived from our products and our product candidates, the potential market opportunities for our products and our drug candidates, our strategy for the commercialization of our products, our plans for exploring and developing our products for additional indications, the commercialization of DAYBUE or trofinetide in jurisdictions other than the United States (U.S.), our plans and timing with respect to seeking regulatory approvals, the potential commercialization of any of our product candidates that receive regulatory approval, the progress, timing, results or implications of clinical trials and other development milestones and activities involving our products and our product candidates, our strategy for discovering, developing and, if approved, commercializing our product candidates, our existing and potential future collaborations, our estimates of future payments, revenues and profitability, our estimates regarding our capital requirements, future expenses and needs for additional financing, possible changes in legislation, and other statements that are not historical. These statements include but are not limited to statements under the captions "Business," "Risk Factors," and "Management's Discussion and Analysis of Financial Condition and Results of Operations" as well as other sections in this report. You should be aware that the occurrence of any of the events discussed under the caption "Risk Factors" and elsewhere in this report could substantially harm our business, results of operations and financial condition and cause our results to differ materially from those expressed or implied by our forward-looking statements. If any of these events occurs, the trading price of our common stock could decline and you could lose all or a part of the value of your shares of our common stock.

The cautionary statements made in this report are intended to be applicable to all forward-looking statements wherever they may appear in this report. We urge you not to place undue reliance on these forward-looking statements, which speak only as of the date of this report. We undertake no obligation to update any forward-looking statements made in this report to reflect events or circumstances after the date of this report or to reflect new information or the occurrence of unanticipated events, except as required by law.

Summary of Risk Factors

We face risks and uncertainties related to our business, many of which are beyond our control. In particular, risks associated with our products and business include:

- Our prospects are highly dependent on the successful commercialization of our products. To the extent we cannot establish, maintain or increase sales of our products, our business, financial condition and results of operations may be materially adversely affected and the price of our common stock may decline.
- Our products may not gain maximal acceptance among physicians, patients, caregivers and the medical community, thereby limiting our potential to generate revenues.
- Our ability to generate product revenues will be diminished if coverage for our products from commercial or government payors is not provided, is decreased or if patients have unacceptably high out-of-pocket requirements.

- Our products are subject to ongoing regulatory requirements that could cause us significant expense and delay or limit our ability to generate sales revenues.
- We rely on a limited network of third-party distributors and pharmacies to market and sell our products. If this approach ceases to be effective, commercialization of our products may be adversely affected, and our products may not be profitable.
- Drug development is a long, expensive and unpredictable process with a high risk of failure, and there is no guarantee that our products or product candidates will be successful in ongoing or future clinical trials or obtain regulatory approval.
- The regulatory approval processes in the EU and outside North America are lengthy, time consuming and inherently unpredictable, and, if we do not obtain regulatory approval of trofinetide outside North America, we will not be able to market trofinetide outside North America, which will limit our trofinetide commercial revenues.
- Expanded access or compassionate use programs could subject us to additional risks.
- Delays, suspensions, variations and terminations in our clinical trials for our product candidates could result in increased costs to us and delay our ability to generate product revenues.
- If we are unable to attract, retain, and motivate key management, research and development, and sales and marketing personnel, our drug development programs, our research and discovery efforts, and our commercialization plans may be delayed and we may be unable to successfully commercialize our products, or develop our product candidates.
- If we fail to develop, acquire or in-license other product candidates or products, our business and prospects would be limited. Even if we obtain rights to other product candidates or products, we will incur a variety of costs and may never realize the anticipated benefits.
- We may require additional financing in the future to fund our operations. If we cannot raise additional financing in the future, we may be unable to fund our business plan and our future research, development, commercial and manufacturing efforts.
- We expect that our results of operations will fluctuate, which may make it difficult to predict our future performance from period to period.
- Changes in tax laws or regulations that are applied adversely to us or our customers may have a material adverse effect on our business, cash flow, financial condition or results of operations.
- Our ability to use net operating loss carryforwards and certain other tax attributes to offset future taxable income or taxes may be limited.
- Tax authorities could reallocate our taxable income among our subsidiaries, which could increase our overall tax liability.
- Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations.
- International trade policies, including tariffs, sanctions and trade barriers may adversely affect our business, financial condition, results of operations and prospects.
- We or the third parties upon whom we depend may be adversely affected by catastrophic events, such as earthquakes, fires or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.
- We have incurred, and expect to continue to incur, significant costs as a result of laws, regulations and standards relating to various aspects of our business, including corporate governance, work force initiatives and other matters, and failure to comply with such laws, regulations and standards could adversely affect our business.
- Our business involves the use of hazardous materials, and we and our third-party manufacturers and suppliers must comply with environmental, health and safety laws and regulations, which can be expensive and restrict how we do, or interrupt our, business.

Item 1. ***Business.***

Company Overview

We are a biopharmaceutical company focused on turning scientific promise into meaningful innovation that makes the difference for underserved neurological and rare disease communities around the world.

We have two core franchises in neurological and rare diseases. Our neurological disease franchise is anchored by the commercial product NUPLAZID (pimavanserin), which is the first and only drug approved by the U.S. Food and Drug Administration (FDA) for the treatment of hallucinations and delusions associated with Parkinson's disease psychosis (PDP). Our rare disease franchise is anchored by the commercial product DAYBUE, which is the first and only drug approved for the treatment of Rett syndrome. Net product sales from these two commercial products totaled $1,071.5 million for 2025, compared with $957.8 million for 2024.

In addition to these commercial products, we have a portfolio of product candidates and research programs that are designed to address significant unmet medical needs in neurological and rare diseases. In order to achieve significant long-term growth, we plan to develop our current portfolio, expand our pipeline of early- and late-stage product candidates and expand into areas of rare disease that are adjacent to our existing franchises, including through strategic business development, and make use of our internal capabilities and knowledge.

Our most advanced current product candidate is remlifanserin (formerly ACP-204) for the treatment of Alzheimer's disease psychosis (ADP) and Lewy Body Dementia Psychosis (LBDP). In November 2023, we initiated a Phase 2 study evaluating the efficacy and safety of remlifanserin for the treatment of hallucinations and delusions associated with ADP. We initiated an additional Phase 2 study of remlifanserin in LBDP in September 2025. In the fourth quarter of 2025, we initiated a Phase 2 study of ACP-211 for the treatment of major depressive disorder (MDD).

We have several product candidates in earlier stages of development for the treatment of neurological and rare diseases. These include ACP-711 for the treatment of essential tremor, with a Phase 2 study expected to begin in the fourth quarter of 2026 or the first quarter of 2027; and ACP-271 for the treatment of tardive dyskinesia and Huntington's disease, for which a Phase 1 study is planned for the first quarter of 2026.

Until September 2025 we had been developing the product candidate ACP-101 (intranasal carbetocin) for the treatment of hyperphagia in Prader-Willi syndrome (PWS), a neuro-rare disease. In September 2025, we announced top-line results from our COMPASS PWS study, a Phase 3 study evaluating the efficacy and safety of ACP-101 for the treatment of hyperphagia in PWS. In the study, ACP-101 did not demonstrate a statistically significant improvement over placebo on the study's primary endpoint, change from baseline to Week 12 on the Hyperphagia Questionnaire for Clinical Trials (HQ-CT), nor was there separation from placebo on any secondary endpoint. As a result, we do not intend to investigate ACP-101 any further.

Corporate Information

We were originally incorporated in Vermont in 1993 as Receptor Technologies, Inc. We reincorporated in Delaware in 1997. Our global headquarters are in San Diego, California. We also have substantial operations in Princeton, New Jersey and European headquarters in Zug, Switzerland. We maintain a website at *www.acadia.com*, to which we regularly post copies of our press releases as well as additional information about us. Our filings with the Securities and Exchange Commission (SEC) are available free of charge through our website as soon as reasonably practicable after being electronically filed with or furnished to the SEC. Interested persons can subscribe on our website to email alerts that are sent automatically when we issue press releases, file or furnish our reports with the SEC or post certain other information to our website. Information contained in our website does not constitute a part of this report or our other filings with the SEC.

We own or have rights to various trademarks, copyrights and trade names used in our business, including Acadia®, NUPLAZID® and DAYBUE®. Our logos and trademarks are the property of Acadia Pharmaceuticals Inc. All other brand names or trademarks appearing in this report are the property of their respective holders. Use or display by us of other parties' trademarks, trade dress, or products in this report is not intended to, and does not, imply a relationship with, or endorsement or sponsorship of us, by the trademark or trade dress owners.

Our Strategy

Our strategy is to build a strong foundation for growth with multiple innovative commercial products and product candidates that address high unmet medical needs and have the potential to be impactful products in our core franchises of neurological and rare diseases, including adjacencies within rare disease. We plan to execute on this strategy by enhancing the growth of the commercial products in our core franchises while expanding our pipeline of product candidates through business development, partnerships and collaborations.

Key elements of our strategy are to:

- ***Maximize growth of our successful commercialization of NUPLAZID for Parkinson's disease psychosis in the United States.*** We intend to accelerate the growth of NUPLAZID by 1) increasing field force size and efficiency with greater use of information technology tools, 2) leveraging real world evidence, and 3) activating consumers with our direct-to-consumer campaigns. We believe that with an approximate 25% current market share of the 130,000 Parkinson's disease patients that are treated with an atypical antipsychotic annually in the United States, we have ample opportunity to grow sales of NUPLAZID while delivering increasing annual cash flow to reinvest in overall corporate growth. We have a stated goal of achieving $1.0 billion in NUPLAZID net sales in 2028.
- ***Drive new patient adoption of DAYBUE for the treatment of patients with Rett syndrome in the United States.*** Our strategy to drive sales growth for DAYBUE in the U.S. is to drive new patient adoption while optimizing the patient experience for those already on therapy thereby achieving and maintaining stable persistency rates. We plan to achieve this by 1) increasing field force size, 2) increasing field force efficiency with greater use of information technology tools following an increase in field force size in 2025, 3) continuing branded direct-to-consumer campaigns, and 4) deploying an omni-channel strategy to bring DAYBUE clinical data to life by leveraging the growing body of real world experience, including updated data from the ongoing LOTUS study. Additionally, we expect growth to be driven by the introduction of DAYBUE STIX powder for oral solution, launched in the first quarter of 2026. Based on the number of Rett syndrome patients in the U.S., we believe there remains a substantial opportunity for new patient adoption. We estimate a prevalent population of 6,000 to 9,000 people in the U.S.
- ***Advance our late-stage product candidates to drive further growth.*** We have ongoing Phase 2 studies of remlifanserin in ADP and LBDP. We initiated a Phase 2 study of ACP-211 for the treatment of MDD in the fourth quarter of 2025. In the fourth quarter of 2026, we plan to initiate a Phase 2 study of ACP-711 in essential tremor.
- ***Expand trofinetide to markets outside the U.S. for the treatment of patients with Rett syndrome.*** We intend to make trofinetide available in markets outside the U.S. where Rett syndrome remains a significant unmet medical need as DAYBUE is the only currently approved treatment for Rett syndrome worldwide, and is currently only approved in the United States, Canada and Israel. In the European Union, where we estimate a prevalent population of 9,000 to 12,000 Rett syndrome patients, we filed our marketing authorization application (MAA) with the European Medicines Agency (EMA) in January 2025. In January 2026 we were informed by the Committee for Medicinal Products for Human Use (CHMP) of the EMA of a negative trend vote on our MAA for trofinetide for the treatment of Rett syndrome, following the CHMP oral explanation. At that time we announced that, subject to the outcome of the CHMP vote and opinion expected in February 2026, we intend to request a re-examination of the opinion. We are preparing for a potential launch in anticipation of a potential approval in the third quarter of 2026. In Japan, where we estimate a prevalent population of 1,000 to 2,000 Rett syndrome patients, we are conducting a small Phase 3 study to support a future JNDA to that regulatory agency. We expect to report top-line results from this Phase 3 trial either in the fourth quarter of 2026 or in the first quarter of 2027. In Canada, where we estimate a prevalent population of 600 to 900 Rett syndrome patients, Health Canada granted marketing authorization of DAYBUE in October 2024. In Israel, where we estimate a prevalent population of about 200 Rett syndrome patients, the Ministry of Health in Israel granted marketing authorization of DAYBUE in December 2025.
- ***Develop our early-stage product candidates and other business development opportunities.*** We have a deep and diverse early-stage portfolio of product candidates that includes disclosed and undisclosed programs focused on neurological and rare diseases that we believe represent significant opportunities to continue to build on our current growth. We continue to look to add product candidates to the portfolio through business development.

In addition, we are investing in the development of four core strategic capabilities to support and accelerate our growth over the long term. These capabilities form the foundation of our operational strategy and are designed to enhance our competitive position, drive innovation, and meet the evolving needs of patients worldwide. The four core capabilities in which we are investing are:

1. ***Precision Medicine***. We are focused on integrating strategies that address the variability in patients' responses to therapies by identifying and incorporating the use of targeted biomarkers at the early stages of drug development. Through the incorporation of precision medicine, we aim to increase the likelihood of clinical success, enhance treatment outcomes, and reduce overall development costs.
2. ***Data Innovation***. We plan to leverage advanced technologies, including artificial intelligence (AI) and machine learning (ML) throughout our business from discovery through commercialization. By utilizing these tools, we hope to generate, analyze, and apply data in innovative ways to enhance the efficiency and effectiveness of our operations in ways that ultimately drive growth and improve patient outcomes.
3. ***Globalization***. We are building targeted capabilities beyond the United States including in the European Union, and Japan in order to meet patient needs on a global scale.
4. ***Patient Empowerment***. We seek to engage with patients, caregivers and advocacy organizations and incorporate their feedback into our drug development and commercialization efforts. By creating an integrated ecosystem of our patients, caregivers and advocates, our goal is to transform patient feedback and needs into actionable plans for product development and support.

Our Pipeline

Neurological and Rare Diseases Products and Pipeline

PROGRAM	INDICATION	MOLECULE DESCRIPTION	DISCOVERY	IND ENABLING	PHASE 1	PHASE 2	PHASE 3	LAUNCHED
Neurological diseases								
NUPLAZID®	Parkinson's Disease Psychosis	5HT2A inverse agonist and antagonist						
Remlifanserin (ACP-204)	Alzheimer's Disease Psychosis	New 5HT2A inverse agonist						
Remlifanserin (ACP-204)	Lewy Body Dementia w/ Psychosis	New 5HT2A inverse agonist						
ACP-211	Major Depressive Disorder	Deuterated R-norketamine						
ACP-711	Essential Tremor	Selective $GABA_A$-α3 modulator						
ACP-271	Tardive Dyskinesia	GPR88 agonist						
Rare diseases								
DAYBUE®	Rett Syndrome	Analog of GPE						
ACP-2591	Rett Syndrome, Fragile X Syndrome	cGP analog						
ACP-271	Huntington's Disease	GPR88 agonist						
STOKE ASO	SYNGAP1	Antisense oligonucleotide (ASO)						

Product candidates and investigational agents, for which the safety and efficacy of these agents have not been established. There is no guarantee these investigational agents will be filed with or approved by any regulatory agency.
More information regarding our acquired or licensed product candidates (ACP-211, ACP-711, ACP-271, ACP-2591 and Stoke ASO) available in Acadia's public filings.

NUPLAZID (pimavanserin) as a Treatment for Parkinson's Disease Psychosis

Pimavanserin is a chemical entity that we discovered and developed. NUPLAZID is a selective serotonin inverse agonist/antagonist preferentially targeting the $5\text{-}HT_{2A}$ receptor, a key serotonin receptor that plays an important role in psychosis. Through this novel mechanism, NUPLAZID demonstrated significant efficacy in reducing the hallucinations and delusions associated with PDP without negatively impacting motor function in our Phase 3 pivotal trial. NUPLAZID has the potential to avoid many of the debilitating side effects of existing antipsychotics, none of which are approved by the FDA in the treatment of PDP. We hold worldwide commercialization rights to NUPLAZID for all indications and have established a broad patent portfolio, which includes numerous issued patents in the United States, Europe, and several additional countries. NUPLAZID is available in 34 mg capsule and 10 mg tablet dosage forms.

Parkinson's disease is the second most common neurodegenerative disorder after Alzheimer's disease. According to the Parkinson's Disease Foundation, about one million people in the United States and more than 10 million people globally suffer from this disease and this number is projected to increase to over 12 million by 2040. Approximately 50% of Parkinson's patients will experience psychosis over the course of their disease. We estimate that approximately 130,000 Parkinson's disease patients are treated with an atypical antipsychotic annually in the United States. Of these patients, we estimate that approximately 20% are currently being treated with NUPLAZID.

Parkinson's disease is more common in people over 60 years of age and the prevalence of this disease is expected to increase significantly as the population ages. At this time, the fastest growing neurological disorder in the world is Parkinson's disease. The development of psychosis in patients with Parkinson's disease substantially contributes to the burden of Parkinson's disease and deeply affects their quality of life. PDP is associated with a diminished quality of life, nursing home placement, and increased caregiver stress and burden.

NUPLAZID was approved by the FDA in April 2016 for the treatment of hallucinations and delusions associated with PDP. It is the only drug approved in the United States for this condition and is marketed under the tradename NUPLAZID in the United States.

As the first and only drug approved by the FDA for the treatment of hallucinations and delusions associated with PDP, NUPLAZID provides an innovative approach to the treatment of PDP without compromising motor control and potentially avoiding many of the debilitating side effects of existing antipsychotics.

Other Indications Recently Evaluated with Pimavanserin

In March 2024 we reported top-line results from a Phase 3 study of pimavanserin for the treatment of the negative symptoms of schizophrenia. Pimavanserin did not demonstrate a statistically significant improvement over placebo on the study's primary endpoint, the change from baseline to week 26 on the Negative Symptom Assessment-16. The safety and tolerability profile of pimavanserin was consistent with previous clinical trials, showing a low rate of adverse events.

In October 2024 we completed a Phase 2 trial to evaluate the efficacy and safety of pimavanserin for the treatment of irritability associated with autism spectrum disorder in pediatric populations. The trial did not meet either of its primary or secondary endpoints. With the completion of the trial, we believe we now have completed the FDA's requirements to qualify for a pediatric exclusivity for pimavanserin. If the pediatric exclusivity is granted, exclusivity of the NUPLAZID franchise would be extended by six months.

We do not intend to further explore pimavanserin in these or any additional indications.

DAYBUE (trofinetide) as a Treatment for Rett Syndrome

Trofinetide is a novel synthetic analog of the amino-terminal tripeptide of insulin-like growth factor 1 (IGF-1) designed to treat the core symptoms of Rett syndrome by reducing neuroinflammation and supporting synaptic function. We acquired an exclusive North American license to develop and commercialize trofinetide from Neuren Pharmaceuticals Limited (Neuren) in August 2018. In July 2023, we expanded the 2018 licensing agreement with Neuren to acquire rights to trofinetide outside of North America as well as global rights to Neuren's development candidate NNZ-2591 in Rett syndrome and Fragile X syndrome. Trofinetide has been granted FDA Fast Track Status and Orphan Drug Designation in the U.S. and Orphan Designation in Europe.

Rett syndrome is a debilitating neurological disorder that occurs primarily in females following apparently normal development for the first six months of life. Rett syndrome has been most often misdiagnosed as autism, cerebral palsy, or non-specific developmental delay. Rett syndrome is caused by mutations on the X chromosome on a gene called MECP2. There are more than 200 different mutations found on the MECP2 gene that interfere with its ability to generate a normal gene product. Rett syndrome occurs worldwide in approximately one of every 10,000 to 15,000 female births causing problems in brain function that are responsible for cognitive, sensory, emotional, motor and autonomic function. Typically, between six to eighteen months of age, patients experience a period of rapid decline with loss of purposeful hand use and spoken communication and inability to independently conduct activities of daily living. Symptoms also include seizures, disorganized breathing patterns, an abnormal side-to-side curvature of the spine (scoliosis) and sleep disturbances. Based on 2024 claims data, we estimate that approximately 6,000 people are diagnosed with Rett Syndrome in the U.S. We estimate a prevalent population of 6,000 to 9,000 people in the U.S.

In March 2023, the FDA approved DAYBUE for the treatment of Rett syndrome, making it the first and only drug approved for this condition. DAYBUE became available for prescription in the United States in April 2023. The FDA approval of DAYBUE for the treatment of Rett syndrome was based on the positive results from our pivotal Phase 3 LAVENDER™ study which demonstrated statistically significant and clinically meaningful improvement over placebo for both co-primary endpoints in the study as well as the key secondary endpoint of the study.

In addition, we were granted a Rare Pediatric Disease Priority Review Voucher (PRV) following the FDA approval of DAYBUE. In December 2024, we completed the sale of our PRV for $150 million before fees and expenses, of which we paid Neuren one-third of the net proceeds, pursuant to the license agreement between the companies.

In connection with the FDA approval of DAYBUE, we are required to conduct post-marketing work, including a nonclinical carcinogenicity studies and nonclinical in vitro studies.

In October 2024, Health Canada granted marketing authorization of DAYBUE (trofinetide) for the treatment of Rett syndrome in adult and pediatric patients two years of age and older under the Priority Review process, making DAYBUE the first and only drug approved in Canada for the treatment of Rett syndrome.

In December 2025, we received FDA approval for DAYBUE STIX (trofinetide) for oral solution, a dye- and preservative-free powder formulation of trofinetide for the treatment of Rett syndrome in adult and pediatric patients two years of age and older. DAYBUE STIX is expected to deliver the same efficacy and safety profile of DAYBUE oral solution, while offering children and adults living with Rett syndrome new flexibility and choice regarding the dose volume and taste of their DAYBUE treatment.

In December 2025, the Ministry of Health in Israel approved DAYBUE (trofinetide) for the treatment of Rett syndrome in adults and pediatric patients 2 years of age and older and weighing at least 9 kg.

In January 2025, we announced the submission of a MAA with the EMA. In January 2026 we were informed by the CHMP of the EMA of a negative trend vote on our MAA for trofinetide for the treatment of Rett syndrome, following a CHMP oral explanation. At that time we announced that, subject to the outcome of the CHMP vote and opinion expected in February 2026, we intend to request a re-examination of the opinion.

Remlifanserin (formerly ACP-204)

Remlifanserin is a new chemical entity that we discovered and developed, targeting the serotonergic system. Remlifanserin features a combination of structural changes compared with pimavanserin and designed to reduced off-target effects along with potential for equal or increased potency. Specifically with remlifanserin, we believe we may have an opportunity to maximize the efficacy potential through increased dose, while reducing the risk of QT prolongation. We also believe the onset of action will be faster than pimavanserin.

Remlifanserin as a Treatment for Alzheimer's Disease Psychosis

An estimated over 7.0 million people in the United States are living with Alzheimer's disease dementia and studies suggest that approximately 30% of them have psychosis, commonly consisting of delusions and hallucinations. Approximately 800,000 to 850,000 patients in the United States are currently treated for ADP and of those treated, approximately two-thirds are treated with off-label anti-psychotics.

Symptoms of ADP are often persistent and may occur with increasing frequency with progression of disease as patients become more impaired. Serious consequences have been associated with persistent or severe psychosis in persons with dementia such as repeated hospital admissions, earlier progression to nursing home care, severe dementia, and death. There are currently no FDA-approved treatments for ADP. Off-label use of typical and atypical antipsychotics is associated with modest and often equivocal efficacy in these patients. In addition, use of currently available antipsychotics is associated with a significant acceleration in cognitive decline in patients with dementia as well as numerous off-target toxicities, thus negatively impacting the primary illness. The cognitive effects of treatment with an atypical antipsychotic were evaluated in the National Institute of Mental Health Clinical Antipsychotic Trials of Intervention Effectiveness–Alzheimer's Disease (CATIE-AD) study. In this study, patients on any atypical antipsychotic had significantly greater rates of decline in cognitive function compared to patients on placebo. This pronounced negative impact of currently used antipsychotics on cognitive function is believed to be associated with the common pharmacologic property of these drugs, namely blocking of dopamine receptors. Atypical antipsychotics are associated with a number of off-target and dose-limiting side effects, such as

extrapyramidal symptoms, orthostatic hypotension, hematologic abnormalities, and metabolic, gastrointestinal and sedative effects. These off-target toxicities are associated with increased risk for falls, infection, aspiration pneumonia, and other serious complications in this vulnerable patient population. With no approved therapies for the treatment of patients with ADP and current off-label use of atypical antipsychotics carrying significant morbidity risks including worsening in cognitive decline and other off target toxicities, we believe that ADP represents an area of high unmet need.

We completed Phase 1 studies of remlifanserin in over 200 patients; data to date support its target product profile as a potential treatment for ADP.

In the fourth quarter of 2023, we initiated the Phase 2 RADIANT study of remlifanserin for the treatment of hallucinations and delusions associated with ADP. The Phase 2 RADIANT study is part of a Phase 2 / Phase 3 program that includes three studies: a single Phase 2 study and two Phase 3 studies which have almost identical design. The Phase 2 RADIANT study is a global, multi-center, randomized, double-blind, placebo-controlled trial that will enroll approximately 318 patients who have satisfied defined enrollment criteria and evaluate remlifanserin 30 mg and 60 mg doses compared to placebo. The primary endpoint is change from baseline to week 6 on the Scale for the Assessment of Positive Symptoms–Hallucinations and Delusions subscales (SAPS-H+D) total score. The clinical trial sites will enroll seamlessly from Phase 2 into Phase 3. Patients who complete the study will have the option of participating in our LUMINOUS long-term open-label extension study.

We expect to complete enrollment in the Phase 2 RADIANT study in the first half of 2026 and subsequently report top-line results in the August to October 2026 timeframe.

Remlifanserin as a Treatment for Lewy Body Dementia with Psychosis

LBDP is a progressive brain disorder that affects thinking, movement, mood and behavior. LBDP is associated with abnormal deposits of a protein called alpha-synuclein in the brain.

There are no approved therapies for LBDP. More than 1 million people in the United States may be living with Lewy Body Dementia, of which an estimated 50% to 75% experience psychosis during the course of the disease. We estimate that approximately 200,000 of these patients are being treated with antipsychotics today.

In the third quarter of 2025, we initiated the Phase 2 ILLUMERA study of remlifanserin in LBDP.

ACP-211

ACP-211 is selectively deuterated R-norketamine which we are evaluating for potential use in the treatment of treatment-resistant depression (TRD), MDD and other potential rare neurological indications.

In the fourth quarter of 2025 we initiated a Phase 2 study of ACP-211 in MDD and expect to report top-line results sometime between the second and third quarters of 2027.

ACP-711 as a Treatment for Essential Tremor

In November 2024, we entered into an exclusive worldwide license agreement with Saniona A/S (Saniona) for the development and commercialization of ACP-711 (formerly SAN711). We intend to study ACP-711 as a potential treatment for essential tremor. ACP-711 is a highly selective $GABA_A$-α3 positive allosteric modulator. Under the terms of the license agreement, Saniona received $28 million upfront plus potential milestone payments of up to $582 million. In addition, Saniona is eligible to receive tiered royalties of mid-single digits to low double digits on net sales of commercial products that may result from development of ACP-711. The potential milestone payments to Saniona consist of up to $147 million subject to achievement of development and commercial milestones related to potential first and second indications, and up to $435 million subject to achievement of thresholds of annual net sales of ACP-711 worldwide. Acadia will lead further clinical development, regulatory submissions, and global commercialization efforts for ACP-711 while also providing financial support for Saniona's ongoing Phase 1 study and preparations for Phase 2.

Essential tremor is a disorder that causes involuntary shaking in the hands, head, voice, and sometimes the legs. Approximately 7 million people in the United States suffer from this disorder and an estimated 1 million people are being treated for it with some form of medication. Due to the limited treatment options available to sufferers of essential tremor, we see an opportunity to provide much needed innovation for this disorder.

We plan to initiate a Phase 2 study of ACP-711 in essential tremor in the fourth quarter of 2026 after completion of an ongoing Phase 1 study.

ACP-271

ACP-271 is a GPR88 agonist with current target indications of tardive dyskinesia and Huntington's disease. We expect to start a phase 1 study in healthy volunteers in the first quarter of 2026.

ACP-2591

ACP-2591 is a cGP analogue for which we obtained global rights to evaluate for use in Rett syndrome and Fragile X syndrome from Neuren as part of our expanded licensing agreement in July 2023. ACP-2591 is currently in Phase 1 development.

Antisense Oligonucleotide (ASO) Program

In January 2022, we entered into a license and collaboration with Stoke Therapeutics, Inc. (Stoke) to discover, develop and commercialize novel RNA-based medicines for the potential treatment of severe and rare genetic neurodevelopmental diseases of the central nervous system (CNS). The collaboration includes a discovery program for SYNGAP1 syndrome.

Competition

We face, and will continue to face, intense competition from pharmaceutical and biotechnology companies, as well as numerous academic and research institutions and governmental agencies, both in the United States and abroad. We compete, or will compete, with existing and new products being developed by our competitors. Some of these competitors have products or are pursuing the development of pharmaceuticals that target the same diseases and conditions that our research and development programs target.

For example, the use of NUPLAZID for the treatment of PDP competes with off-label use of various antipsychotic drugs, including the generic drugs quetiapine, clozapine, risperidone, aripiprazole, and olanzapine.

DAYBUE competes indirectly with off-label usage of branded and generic prescription medications targeted at individual symptoms of Rett syndrome, including antiepileptics, antipsychotics, antidepressants and benzodiazepines. In addition, there are several currently disclosed programs in development for Rett syndrome. UCB S.A. has announced plans to initiate a Phase 3 clinical trial of fenfluramine in patients with Rett syndrome during 2026. Taysha Gene Therapies is conducting a pivotal clinical trial of a AAV9 intrathecal delivered gene therapy to treat Rett syndrome. Neurogene has initiated a pivotal clinical trial of its investigational adeno-associated virus gene therapy candidate, NGN-401, delivered using intracerebroventricular administration to treat Rett Syndrome. Several academic institutions and pharmaceutical companies are currently conducting clinical trials for the treatment of various symptoms of Rett syndrome, including Unravel Bio and Vanderbilt University Medical Center, which are jointly conducting an early-stage study with vorinostat (RVL-001). Other pharmaceutical companies are or may in future consider developing pipeline or currently marketed products for Rett syndrome.

Other competitors may have a variety of drugs in development or awaiting approval from the FDA or comparable foreign regulatory authorities that could reach the market and become established before we have a product to sell for the applicable disorder. Our competitors may also develop alternative therapies that could further limit the market for any drugs that we may develop. Many of our competitors are using technologies or methods different or similar to ours to identify and validate drug targets and to discover and develop drug candidates. Many of our competitors and their collaborators have significantly greater experience than we do in the following:

- identifying and validating targets;
- screening compounds against targets;
- preclinical studies and clinical trials of potential pharmaceutical products;
- obtaining FDA and other regulatory approvals; and
- commercializing pharmaceutical products.

In addition, many of our competitors and their collaborators have substantially greater advantages in the following areas:

- capital resources;
- research and development resources;
- manufacturing capabilities;
- sales and marketing; and
- production and testing facilities.

Smaller companies also may prove to be significant competitors, particularly through proprietary research discoveries and collaboration arrangements with large pharmaceutical and established biotechnology companies. Many of our competitors have products that have been approved or are in advanced development and may develop superior technologies or methods to identify and validate drug targets and to discover novel small molecule drugs. We face competition from other companies, academic institutions, governmental agencies and other public and private research organizations for collaborative arrangements with pharmaceutical and biotechnology companies, in recruiting and retaining highly qualified scientific, sales and marketing, and management personnel and for licenses to additional technologies. Our competitors, either alone or with their collaborators, may succeed in developing technologies or drugs that are more effective, safer, more affordable, or more easily administered than ours and may achieve patent protection or commercialize drugs sooner than us. Our competitors may also develop alternative therapies that could further limit the market for any drugs that we may develop. Our failure to compete effectively could have a material adverse effect on our business.

Intellectual Property

We currently hold approximately 49 issued U.S. patents and a significant number of related issued foreign patents. We have also exclusively licensed rights to an additional 33 issued U.S. patents, and a number of related foreign patents. Patents and other proprietary intellectual property rights are an essential element of our business. Our strategy is to file patent applications in the United States and any other country that represents an important potential commercial market to us. In addition, we seek to protect our technology and inventions (and improvements to inventions) that are important to the development of our business. Our patent applications claim proprietary technology, including chemical synthetic or manufacturing methods, drug assays, novel compounds, compositions, formulations and methods of treatment. We also rely upon trade secrets, including technologies that may be used to discover and validate targets, to identify and develop novel drugs, as well as manufacturing or clinical development technologies, among others. We protect our trade secrets by, among other things, requiring employees and third parties who have access to our proprietary information to sign confidentiality and nondisclosure agreements. We are a party to various license agreements that give us rights to use certain technologies in our research and development, subject to certain limitations.

Pimavanserin

We currently hold 25 U.S. patents that relate to pimavanserin, NUPLAZID and methods of use of pimavanserin. Nine of these are Orange Book-listed patents that relate to pimavanserin, NUPLAZID and our approved indication, and cover the general formula of the compound, the composition of matter, with claims specifically directed to pimavanserin and salts thereof, the specific polymorph form of pimavanserin, the approved formulations, and the use thereof for treating our approved indication. The composition of matter patent covering pimavanserin and salts thereof currently has an expiration date in 2030, including a patent term extension approved by the U.S. Patent and Trademark Office. The patents covering the polymorph form and the use of pimavanserin or NUPLAZID for our approved indication are currently set to expire between 2026 and 2028. These patent terms include adjustments made by the U.S. Patent and Trademark Office, but not extensions.

In the United States, under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as “Hatch-Waxman,” we are permitted to extend the term of one U.S. patent for pimavanserin or the use thereof. Patent terms may be subject to change not only due to potential patent term extensions but also to any terminal disclaimer that reduces patent term, as well as other factors. Because the U.S. patent laws and judicial interpretations thereof change, modifications or new interpretations of the laws may impact our patent terms.

The remaining 16 U.S. patents relating to pimavanserin that have been issued to us cover methods of use of pimavanserin, salts and methods of manufacturing pimavanserin. We also have foreign patents that cover manufacturing of pimavanserin in Europe and Asia.

We continue to prosecute patent applications directed to pimavanserin, formulations of pimavanserin, methods of manufacturing, and to methods of treating various diseases using pimavanserin, either alone or in combination with other agents. For example, in late 2019 and in 2020, we obtained and listed in the Orange Book six additional U.S. issued patents, two patents directed to method of use for our 10 mg tablet, expiring in 2037, and four patents directed to our 34 mg capsule formulation, each expiring in 2038.

Trofinetide

We currently hold the exclusive licenses to 7 U.S. patents from Neuren that relate to trofinetide, methods of manufacturing and methods of use of trofinetide. We also hold a U.S. patent to crystalline trofinetide. Three of the U.S. patents are listed in the Orange Book, including a patent claiming the use of trofinetide for treating Rett syndrome. The use patent for treating Rett syndrome has an expiration date in 2032. Subject to a patent term extension request, the expiration date of such patent may be extended to January 2036. We also hold the exclusive licenses to issued foreign patents that relate to the use of trofinetide in Europe and Asia as well as in Australia, Canada, Mexico and other countries.

Under the license agreement with Neuren, we continue to file and prosecute patent applications directed to trofinetide, formulations of trofinetide, methods of manufacturing and methods of treating Rett syndrome using trofinetide.

Remlifanserin (formerly ACP-204)

We currently hold two U.S. patents that relate to remlifanserin and methods of use of remlifanserin. The patents cover the general formula of the compound, the composition of matter (with claims specifically directed to remlifanserin and salts thereof), and the use thereof for treating certain indications, including ADP and LBDP. The composition of matter patent covering remlifanserin and salts thereof currently has an expiration date in 2038. These patent terms include adjustments made by the U.S. Patent and Trademark Office, but not extensions. We also hold issued foreign patents in Europe, Australia, China, Japan, Mexico and other countries.

We continue to file and prosecute patent applications directed to remlifanserin worldwide.

ACP-211

We currently hold five U.S. patents that relate to ACP-211 with claims specifically and generally directed to ACP-211 and salts thereof. The composition of matter patent covering ACP-211 and salts thereof currently has an expiration date in 2035. This patent term does not include extensions. We also hold issued foreign patents in Europe, parts of Asia and other countries.

We continue to file and prosecute patent applications directed to ACP-211 worldwide.

ACP-711

We currently hold the exclusive licenses to one U.S. patent that relates to ACP-711 from Saniona A/S, with claims specifically directed to ACP-711 and salts thereof. The composition of matter patent covering ACP-711 and salts thereof currently has an expiration date in 2039. This parent term includes adjustments made by the U.S. Patent and Trademark Office, but not extensions. We also hold the exclusive licenses to issued foreign patents in Europe, parts of Asia and Mexico, as well as other countries.

We continue to file and prosecute patent applications directed to ACP-711 worldwide.

ACP-271

We currently hold patent applications relevant to ACP-271 which are being prosecuted in U.S., Europe, Asia and other countries.

Government Regulation

Our business activities, including the manufacturing and marketing of our products and any future approved products and our ongoing research and development activities, are subject to extensive regulation by numerous governmental authorities in the United States and other countries. Before marketing in the United States, any new drug developed by us

must undergo rigorous preclinical testing, clinical trials and an extensive regulatory clearance process implemented by the FDA under the Federal Food, Drug, and Cosmetic Act, as amended. The FDA regulates, among other things, the development, testing, manufacture, safety, efficacy, record keeping, labeling, storage, approval, advertising, promotion, import, export, sale and distribution of biopharmaceutical products. The regulatory review and approval process, which includes preclinical testing and clinical trials of each product candidate, is lengthy, expensive and uncertain. Moreover, government coverage and reimbursement policies will both directly and indirectly impact our ability to successfully commercialize our current products and any future approved products, and such coverage and reimbursement policies will be impacted by enacted and any applicable future healthcare reform and drug pricing measures. In addition, we are subject to state and federal laws, including, among others, anti-kickback laws, false claims laws, data privacy and security laws, and transparency laws that restrict certain business practices in the pharmaceutical industry.

In the United States, drug product candidates intended for human use undergo laboratory and animal testing until adequate proof of safety is established. Clinical trials for new product candidates are then typically conducted in humans in three sequential phases that may overlap. Phase 1 trials involve the initial introduction of the product candidate into healthy human volunteers. The emphasis of Phase 1 trials is on testing for safety or adverse effects, dosage, tolerance, metabolism, distribution, excretion and clinical pharmacology. Phase 2 involves studies in a limited patient population to determine the initial efficacy of the compound for specific targeted indications, to determine dosage tolerance and optimal dosage, and to identify possible adverse side effects and safety risks. Once a compound shows initial evidence of effectiveness and is found to have an acceptable safety profile in Phase 2 evaluations, Phase 3 trials are undertaken to more fully evaluate clinical outcomes. Before commencing clinical investigations in humans, we or our collaborators must submit an Investigational New Drug Application (IND), to the FDA.

Regulatory authorities, Institutional Review Boards and Data Monitoring Committees may require additional data before allowing the clinical studies to commence, continue or proceed from one phase to another, and could demand that the studies be discontinued or suspended at any time if there are significant safety issues. Clinical testing must also meet requirements for clinical trial registration, institutional review board oversight, informed consent, health information privacy, and good clinical practices (GCPs). Additionally, the manufacture of our drug product must be done in accordance with current good manufacturing practices (cGMPs).

To establish a new product candidate's safety and efficacy, the FDA requires companies seeking approval to market a drug product to submit extensive preclinical and clinical data, along with other information, for each indication for which the product will be labeled. The data and information are submitted to the FDA in the form of a New Drug Application (NDA), which must be accompanied by payment of a significant user fee unless a waiver or exemption applies. Generating the required data and information for an NDA takes many years and requires the expenditure of substantial resources. Information generated in this process is susceptible to varying interpretations that could delay, limit or prevent regulatory approval at any stage of the process. The failure to demonstrate adequately the quality, safety and efficacy of a product candidate under development would delay or prevent regulatory approval of the product candidate. Under applicable laws and FDA regulations, each NDA submitted for FDA approval is given an internal administrative review within 60 days following submission of the NDA. If deemed sufficiently complete to permit a substantive review, the FDA will "file" the NDA. The FDA can refuse to file any NDA that it deems incomplete or not properly reviewable. The FDA has established internal goals of eight months from submission for priority review of NDAs that cover new product candidates that offer major advances in treatment or provide a treatment where no adequate therapy exists, and 12 months from submission for the standard review of NDAs. However, the FDA is not legally required to complete its review within these periods, these performance goals may change over time and the review is often extended by FDA requests for additional information or clarification. Moreover, the outcome of the review, even if generally favorable, may not be an actual approval but a "complete response letter" that describes additional work that must be done before the NDA can be approved. Before approving an NDA, the FDA can choose to inspect the facilities at which the product is manufactured and will not approve the product unless the manufacturing facility complies with cGMPs. The FDA may also audit sites at which clinical trials have been conducted to determine compliance with GCPs and data integrity. The FDA's review of an NDA may also involve review and recommendations by an independent FDA advisory committee, particularly for novel indications. The FDA is not bound by the recommendation of an advisory committee.

In addition, delays or rejections may be encountered based upon changes in regulatory policy, regulations or statutes governing product approval during the period of product development and regulatory agency review.

Before receiving FDA approval to market a potential product, we or our collaborators must demonstrate through adequate and well-controlled clinical studies that the potential product is safe and effective in the patient population that will be treated. In addition, under the Pediatric Research Equity Act (PREA), an NDA or supplement to an NDA must contain data or a plan to collect such data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective, unless a waiver applies. If regulatory approval of a potential product is granted, this approval will be limited to those disease states and conditions for which the product is approved. Marketing or promoting a drug for an unapproved indication is generally prohibited. Furthermore, FDA approval may entail ongoing requirements for risk management, including post-marketing, or Phase 4, studies. Even if approval is obtained, each marketed product, is subject to payment of a significant annual program user fee and continuing review and periodic inspections by the FDA. Discovery of previously unknown problems with a product, manufacturer or facility may result in restrictions on the product or manufacturer, including labeling changes, warning letters, costly recalls or withdrawal of the product from the market.

Any drug is likely to produce some toxicities or undesirable side effects in animals and in humans when administered at sufficiently high doses and/or for sufficiently long periods of time. Unacceptable toxicities or side effects may occur at any dose level at any time in the course of studies in animals designed to identify unacceptable effects of a product candidate, known as toxicological studies, or during clinical trials of our potential products. The appearance of any unacceptable toxicity or side effect could cause us or regulatory authorities to interrupt, limit, delay or abort the development of any of our product candidates. Further, such unacceptable toxicity or side effects could ultimately prevent a potential product's approval by the FDA or foreign regulatory authorities for any or all targeted indications or limit any labeling claims and market acceptance, even if the product is approved.

In addition, as a condition of approval, the FDA may require an applicant to develop a risk evaluation and mitigation strategy (REMS). A REMS uses risk minimization strategies beyond the professional labeling to ensure that the benefits of the product outweigh the potential risks. To determine whether a REMS is needed, the FDA will consider the size of the population likely to use the product, seriousness of the disease, expected benefit of the product, expected duration of treatment, seriousness of known or potential adverse events, and whether the product is a new molecular entity. REMS can include medication guides, physician communication plans for healthcare professionals, and elements to assure safe use (ETASU). ETASU may include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The FDA may require a REMS before approval or post-approval if it becomes aware of a serious risk associated with use of the product. The requirement for a REMS can materially affect the potential market and profitability of a product.

We and our collaborators and contract manufacturers also are required to comply with the applicable FDA GMP regulations. cGMP regulations include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation. Manufacturing facilities are subject to inspection by the FDA. These facilities must be approved before we can use them in commercial manufacturing of our potential products and must maintain ongoing compliance for commercial product manufacture, testing, storage and distribution. The FDA may conclude that we or our collaborators or contract manufacturers are not in compliance with applicable cGMP requirements and other FDA regulatory requirements, which may result in delay or failure to approve applications, warning letters, product recalls and/or imposition of fines or penalties.

If a product is approved, we must also comply with post-marketing requirements, including, but not limited to, compliance with advertising and promotion laws enforced by various government agencies, including the FDA's Office of Prescription Drug Promotion, and through such laws as federal and state anti-fraud and abuse laws, including anti-kickback and false claims laws, healthcare information privacy and security laws, post-marketing safety surveillance, and disclosure of payments or other transfers of value to healthcare professionals and entities. In addition, we are subject to other federal and state regulation including, for example, the implementation of corporate compliance programs.

In order to distribute products commercially, we must comply with state laws that require the registration of manufacturers and wholesale distributors of pharmaceutical products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain.

Coverage and Reimbursement

Sales of our products and our product candidates, if approved, depend and will depend, in part, on the extent to which such products will be covered by third-party payors, such as government healthcare programs, commercial insurance and managed healthcare organizations. These third-party payors are increasingly limiting coverage and/or reducing reimbursements for medical products and services. A third-party payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a drug product does not ensure that other payors will also provide coverage for the drug product. Coverage policies and third-party payor reimbursement rates may change at any time. Therefore, even if favorable coverage and reimbursement status is attained for one or more products for which we receive marketing approval, less favorable coverage policies and reimbursement rates may be implemented in the future. In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. For example, the U.S. Department of Health and Human Services (HHS) imposes rebates on many Medicare Part B and Medicare Part D products to penalize price increases that outpace inflation on an annual basis. Further, HHS has been empowered to negotiate the price of certain single-source drugs that have been on the market for at least seven years covered under Medicare as part of the Medicare Drug Price Negotiation Program. Each year up to 20 products will be selected by HHS for the Medicare Drug Price Negotiation Program. Products subject to the Medicare Drug Price Negotiation Program are expected to experience a significant reduction in reimbursement from the Medicare program on a per unit basis. If coverage and adequate reimbursement are not available, or are available only to limited levels, we may not be able to successfully commercialize our current and any future product candidates that we develop, which could have an adverse effect on our operating results and our overall financial condition. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. Decreases in third-party payor reimbursement or a decision by a third-party payor to not cover our products or any other future approved products could reduce physician usage of our products, and have a material adverse effect on our sales, results of operations and financial condition.

In the United States, the Medicare Part D program provides a voluntary outpatient drug benefit to Medicare beneficiaries for certain products. Our products are available for coverage under Medicare Part D, but the individual Part D plans offer coverage subject to various factors such as those described above. In addition, while Medicare Part D plans have historically included "all or substantially all" drugs in the following designated classes of "clinical concern" on their formularies: anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants, the Centers for Medicare & Medicaid Services (CMS), has in the past proposed, but not adopted, changes to this policy. If this policy is changed in the future and if CMS no longer considers the antipsychotic class to be of "clinical concern," Medicare Part D plans would have significantly more discretion to reduce the number of products covered in that class, including coverage of our products. Furthermore, private third-party payors often follow Medicare coverage policies and payment limitations in setting their own coverage policies.

Healthcare Laws and Regulations

We are subject to healthcare regulation and enforcement by the federal government and the states and foreign governments in which we conduct our business. The healthcare laws and regulations that may affect our ability to operate include the following:

- The federal Anti-Kickback Statute makes it illegal for any person or entity to knowingly and willfully, directly or indirectly, solicit, receive, offer, or pay any remuneration that is in exchange for or to induce the referral of business, including the purchase, order, lease of any good, facility, item or service for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. The term "remuneration" has been broadly interpreted to include anything of value.
- Federal false claims and false statement laws, including the federal civil False Claims Act, and civil monetary penalties laws, prohibit, among other things, any person or entity from knowingly presenting, or causing to be presented, for payment to, or approval by, federal programs, including Medicare and Medicaid, claims for items or services, including drugs, that are false or fraudulent.
- The U.S. federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), created additional federal criminal statutes that prohibit among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors or making any false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services.

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH), and their implementing regulations, imposes obligations on covered entities, including certain healthcare providers, health plans, and healthcare clearinghouses, and their respective business associates that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity as well as their covered subcontractors, with respect to safeguarding the privacy, security and transmission of individually identifiable health information. In addition, the European Union (EU) and United Kingdom (UK) have each established their own data security and privacy legal framework, including but not limited to the EU's General Data Protection Regulation (EU) 2016/79 and the so-called "UK GDPR" (together, the GDPR), which contain provisions specifically directed at the processing of health information, higher sanctions than previously applicable data protection laws and extra-territoriality measures intended to bring non-EU/-UK companies' processing operations under the scope of these regulations in certain circumstances (including where the relevant processing relates to the monitoring of behaviors of individuals in the EU/UK – such as in the context of the conduct of a clinical trial). We currently conduct clinical trials in the EU and the UK and will need to be compliant with these requirements. We anticipate that over time we may expand our business operations to include additional operations in the EU and/or UK. With such expansion, we could be subject to increased governmental regulation in the territories in which we might operate.
- The federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to CMS information related to payments or other transfers of value made to physicians (as defined to include doctors of medicine, dentists, optometrists, podiatrists and chiropractors by such law), other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members.

Also, many U.S. states have similar laws and regulations, such as anti-kickback and false claims laws that may be broader in scope and may apply regardless of payor, in addition to items and services reimbursed under Medicaid and other state programs. Additionally, we may be subject to state laws that require pharmaceutical companies to comply with the federal government's and/or pharmaceutical industry's voluntary compliance guidelines, state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures, state laws that require drug manufacturers to report information on the pricing of certain drugs, state and local laws that require the registration of pharmaceutical sales representatives, as well as state and foreign laws governing the privacy and security of health information, many of which differ from each other in significant ways and often are not preempted by HIPAA.

If we are found to be in violation of any of these laws or any other federal or state regulations, we may be subject to significant administrative, civil and/or criminal penalties, damages, fines, disgorgement, imprisonment, exclusion from federal healthcare programs, additional reporting requirements and/or oversight, and the curtailment or restructuring of our operations.

Additionally, to the extent that our product is sold in a foreign country, we may be subject to similar foreign laws.

Healthcare Reform

The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. By way of example, in March 2010, Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the ACA) was signed into law, which intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add transparency requirements for the healthcare and health insurance industries, impose taxes and fees on the health industry and impose additional health policy reforms.

There have been amendments and executive, judicial and Congressional challenges to certain aspects of the ACA. For example, on July 4, 2025, the One Big Beautiful Bill Act (the OBBBA) was signed into law, which narrowed access to ACA marketplace exchange enrollment and declined to extend the ACA enhanced advanced premium tax credits that expired at the end of 2025, which, among other provisions in the law, are anticipated to reduce the number of Americans with health insurance. The OBBBA also is expected to reduce Medicaid spending and enrollment by implementing work requirements for some beneficiaries, capping state-directed payments, reducing federal funding, and limiting provider taxes used to fund the program. Congress is considering proposed legislation intended to further reduce healthcare costs with alternatives to

replace the expired ACA subsidies. It is unclear how such challenges and the healthcare reform measures of the current administration will impact the ACA.

Other legislative changes have been proposed and adopted in the United States since the ACA. Through the process created by the Budget Control Act of 2011, there are automatic reductions of Medicare payments to providers up to 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments, including the Infrastructure Investment and Jobs Act, will remain in effect through 2032 unless additional Congressional action is taken. Additionally, on March 11, 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024.

The current administration is pursuing policies to reduce regulations and expenditures across government agencies including at HHS, the FDA, CMS and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. For example, the current administration has announced agreements with several pharmaceutical companies that require the drug manufacturers to offer, through a direct to consumer platform, U.S. patients and Medicaid programs prescription drug Most-Favored Nation pricing equal to or lower than those paid in other developed nations, with additional mandates for direct-to-patient discounts and repatriation of foreign revenues. Other recent actions, for example, include (1) directing agencies to reduce agency workforce and cut programs; (2) directing HHS and other agencies to lower prescription drug costs through a variety of initiatives, including by improving upon the Medicare Drug Price Negotiation Program and establishing Most-Favored-Nation pricing for pharmaceutical products; (3) imposing tariffs on imported pharmaceutical products; and (4) as part of the Make America Healthy Again (MAHA) Commission's Strategy Report released in September 2025, working across government agencies to increase enforcement on direct-to-consumer pharmaceutical advertising. Additionally, the current administration recently called on Congress to enact "The Great Healthcare Plan," to codify and expand Most-Favored Nation pricing, lower government subsidies to private insurance companies, increase healthcare price transparency, expand pharmaceutical drugs available for over-the-counter purchase, and enact restrictions on pharmacy benefit manager (PBM) payment methodologies, among other things. These actions and policies may significantly reduce U.S. drug prices, potentially impacting manufacturers' global pricing strategies and profitability, while increasing their operational costs and compliance risks. In June 2024, the U.S. Supreme Court's Loper Bright decision greatly reduced judicial deference to regulatory agencies, which could increase successful legal challenges to federal regulations affecting our operations. Congress may introduce and ultimately pass healthcare related legislation that could impact the drug approval process and make changes to the Medicare Drug Price Negotiation Program.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological 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. Any such approved importation plans, if implemented, may result in lower drug prices for products covered by those programs.

In addition to direct pricing impacts, healthcare reform measures may adversely affect our products through changes to coverage, reimbursement methodologies, utilization management tools (such as prior authorization, step therapy, or site-of-care restrictions), pharmacy benefit manager practices, and other access controls that could reduce or delay patient access, negatively affect demand, and increase gross-to-net adjustments. Reforms affecting federal and state pricing programs, including Medicaid rebates, the 340B Drug Pricing Program, and PBM payment structures, could further increase pricing pressure, compliance complexity, and operational costs, and may result in disputes, audits, or enforcement actions. Moreover, reductions in U.S. drug prices may influence pricing benchmarks and reimbursement outcomes in foreign jurisdictions, potentially impacting our global pricing strategy and launch sequencing.

We expect that healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and lower reimbursement, and additional downward pressure on the price that we receive for our products and any future approved products. We cannot predict what healthcare reform initiatives may be adopted in the future.

Europe / Rest of World Government Regulation

Outside of the United States, our ability to market a product is contingent upon receiving a marketing authorization from the appropriate regulatory authorities. The requirements governing the conduct of clinical trials, marketing authorization, pricing and reimbursement vary widely from country to country. If the regulatory authority is satisfied that adequate evidence of safety, quality and efficacy has been presented, marketing authorization will be granted. This foreign regulatory approval process involves all of the risks associated with FDA marketing approval discussed above. In addition, foreign regulations may include applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws, and implementation of corporate compliance programs and reporting of payments or other transfers of value to healthcare professionals and entities.

For other countries outside of the EU, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, the clinical trials must be conducted in accordance with GCPs and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

In addition, in many jurisdictions outside the United States, including in the European Union, obtaining marketing authorization does not ensure timely or favorable pricing, reimbursement, or broad patient access. Following approval, our products may be subject to national or regional pricing negotiations, health technology assessment evaluations, budgetary constraints, and other market access requirements that can delay commercialization, limit uptake, or constrain pricing. We may also participate in named patient supply or early access programs in certain countries prior to full commercial availability, which may involve additional regulatory oversight, pharmacovigilance obligations, cost-recovery limitations, or discontinuation risk if authorization or reimbursement is not obtained. The evolving regulatory, pricing, and reimbursement landscape outside the United States may increase compliance costs, impose operational complexity, and adversely affect the timing, scope, or profitability of commercialization.

If we or our potential collaborators fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension, variation or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Pre-Clinical and Clinical Trials in the EU

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

Non-clinical studies are performed to demonstrate the health or environmental safety of new chemical or biological substances. Non-clinical studies must be conducted in compliance with the principles of good laboratory practice, as set forth in EU Directive 2004/10/EC. In particular, non-clinical studies, both *in vitro* and *in vivo*, must be planned, performed, monitored, recorded, reported and archived in accordance with the GLP principles, which define a set of rules and criteria for a quality system for the organizational process and the conditions for non-clinical studies. These GLP standards reflect the Organization for Economic Co-operation and Development requirements.

In the EU, clinical trials are governed by the Clinical Trials Regulation (EU) No 536/2014 (CTR), which entered into application on January 31, 2022 repealing and replacing the former Clinical Trials Directive 2001/20 (CTD).

The CTR is intended to harmonize and streamline clinical trial authorizations, simplify adverse-event reporting procedures, improve the supervision of clinical trials and increase transparency. Specifically, the CTR, which is directly applicable in all EU Member States, introduces a streamlined application procedure through a single-entry point, the “EU portal”, the Clinical Trials Information System (CTIS); a single set of documents to be prepared and submitted for the application; as well as simplified reporting procedures for clinical trial sponsors. A harmonized procedure for the assessment of applications for clinical trials has been introduced and is divided into two parts. Part I assessment is led by the competent authorities of a reference EU Member State selected by the trial sponsor and relates to clinical trial aspects that are considered to be scientifically harmonized across EU Member States. This assessment is then submitted to the competent authorities of all concerned EU Member States in which the trial is to be conducted for their review. Part II is assessed separately by the competent authorities and Ethics Committees in each concerned EU Member State. Individual EU Member States retain the power to authorize the conduct of clinical trials on their territory.

The CTR foresaw a three-year transition period that ended on January 31, 2025. Since this date, all new or ongoing trials are subject to the provisions of the CTR.

In all cases, clinical trials must be conducted in accordance with GCPs and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki. Medicines used in clinical trials, including advanced therapy medicinal products, must be manufactured in accordance with the guidelines on cGMP and in a GMP-licensed facility, which can be subject to GMP inspections.

EU Review and Approval Process of Medicinal Products

In the EU, medicinal products can only be commercialized after a related marketing authorization (MA) has been granted. To obtain an MA for a product in the EU, an applicant must submit a MAA either under a centralized procedure administered by the EMA, or one of the procedures administered by the competent authorities of EU Member States (decentralized procedure, national procedure or mutual recognition procedure). An MA may be granted only to an applicant established in the EU.

The centralized procedure provides for the grant of a single MA by the European Commission that is valid throughout the EEA (which is comprised of the 27 EU Member States plus Norway, Iceland and Liechtenstein). Pursuant to Regulation (EC) No 726/2004, the centralized procedure is compulsory for specific products, including for (i) medicinal products derived from biotechnological processes, (ii) products designated as orphan medicinal products, (iii) advanced therapy medicinal products and (iv) products with a new active substance indicated for the treatment of HIV/AIDS, cancer, neurodegenerative diseases, diabetes, auto-immune and other immune dysfunctions and viral diseases. For products with a new active substance indicated for the treatment of other diseases and products that are highly innovative or for which a centralized process is in the interest of patients, authorization through the centralized procedure is optional on related approval.

Under the centralized procedure, the EMA's CHMP conducts the initial assessment of a product. The CHMP is also responsible for several post-authorization and maintenance activities, such as the assessment of modifications or extensions to an existing MA. The maximum timeframe for the evaluation of an MAA under the centralized procedure is 210 days, excluding clock stops when additional information or written or oral explanation is to be provided by the applicant in response to questions of the CHMP. Accelerated assessment may be granted by the CHMP in exceptional cases, when a medicinal product targeting an unmet medical need is expected to be of major interest from the point of view of public health and, in particular, from the viewpoint of therapeutic innovation. If the CHMP accepts a request for accelerated assessment, the time limit of 210 days will be reduced to 150 days (excluding clock stops). The CHMP can, however, revert to the standard time limit for the centralized procedure if it considers that it is no longer appropriate to conduct an accelerated assessment.

Unlike the centralized authorization procedure, the decentralized MA procedure requires a separate application to, and leads to separate approval by, the competent authorities of each EU Member State in which the product is to be marketed. This application is identical to the application that would be submitted to the EMA for authorization through the centralized procedure. The reference EU Member State prepares a draft assessment and drafts of the related materials within 120 days after receipt of a valid application. The resulting assessment report is submitted to the concerned EU Member States who, within 90 days of receipt, must decide whether to approve the assessment report and related materials. If a concerned EU Member State cannot approve the assessment report and related materials due to concerns relating to a potential serious risk to public health, disputed elements may be referred to the Heads of Medicines Agencies' Coordination Group for Mutual Recognition and Decentralised Procedures—Human (CMDh) for review. The subsequent decision of the European Commission is binding on all EU Member States.

The mutual recognition procedure allows companies that have a medicinal product already authorized in one EU Member State to apply for this authorization to be recognized by the competent authorities in other EU Member States. Like the decentralized procedure, the mutual recognition procedure is based on the acceptance by the competent authorities of the EU Member States of the MA of a medicinal product by the competent authorities of other EU Member States. The holder of a national MA may submit an application to the competent authority of an EU Member State requesting that this authority recognize the MA delivered by the competent authority of another EU Member State.

An MA has, in principle, an initial validity of five years. The MA may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the EU Member State in which the original MA was granted. To support the application, the MA holder must provide the EMA or the competent authority with

a consolidated version of the Common Technical Document providing up-to-date data concerning the quality, safety and efficacy of the product, including all variations introduced since the MA was granted, at least nine months before the MA ceases to be valid. The European Commission or the competent authorities of the EU Member States may decide on justified grounds relating to pharmacovigilance, to proceed with one further five-year renewal period for the MA. Once subsequently definitively renewed, the MA shall be valid for an unlimited period. Any authorization which is not followed by the actual placing of the medicinal product on the EU market (for a centralized MA) or on the market of the authorizing EU Member State within three years after authorization ceases to be valid (the so-called sunset clause).

Innovative products that target an unmet medical need and are expected to be of major public health interest may be eligible for a number of expedited development and review programs, such as the Priority Medicines (PRIME) scheme, which provides incentives similar to the breakthrough therapy designation in the U.S. PRIME is a voluntary scheme aimed at enhancing the EMA's support for the development of medicinal products that target unmet medical needs. Eligible products must target conditions for which there is an unmet medical need (there is no satisfactory method of diagnosis, prevention or treatment in the EU or, if there is, the new medicinal product will bring a major therapeutic advantage) and they must demonstrate the potential to address the unmet medical need by introducing new methods of therapy or improving existing ones. Benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and potentially accelerated MAA assessment once a dossier has been submitted. Importantly, a dedicated contact and rapporteur from the EMA's CHMP or Committee for Advanced Therapies, are appointed early in the PRIME scheme facilitating increased understanding of the product at EMA's Committee level. A kick-off meeting initiates these relationships and includes a team of multidisciplinary experts at the EMA to provide guidance on the overall development and regulatory strategies. Where, during the course of development, a medicine no longer meets the eligibility criteria, support under the PRIME scheme may be withdrawn.

In the EU, a "conditional" MA may be granted in cases where all the required safety and efficacy data are not yet available. The European Commission may grant a conditional MA for a medicinal product if it is demonstrated that all of the following criteria are met: (i) the benefit-risk balance of the medicinal product is positive; (ii) it is likely that the applicant will be able to provide comprehensive data post-authorization; (iii) the medicinal product fulfils an unmet medical need; and (iv) the benefit of the immediate availability to patients of the medicinal product is greater than the risk inherent in the fact that additional data are still required. The conditional MA is subject to conditions to be fulfilled for generating the missing data or ensuring increased safety measures. It is valid for one year and must be renewed annually until all related conditions have been fulfilled. Once any pending studies are provided, the conditional MA can be converted into a traditional MA. However, if the conditions are not fulfilled within the timeframe set by the EMA and approved by the European Commission, the MA will cease to be renewed.

An MA may also be granted "under exceptional circumstances" where the applicant can show that it is unable to provide comprehensive data on efficacy and safety under normal conditions of use even after the product has been authorized and subject to specific procedures being introduced. These circumstances may arise in particular when the intended indications are very rare and, in the state of scientific knowledge at that time, it is not possible to provide comprehensive information, or when generating data may be contrary to generally accepted ethical principles. Like a conditional MA, an MA granted in exceptional circumstances is reserved to medicinal products intended to be authorized for treatment of rare diseases or unmet medical needs for which the applicant does not hold a complete data set that is required for the grant of a standard MA. However, unlike the conditional MA, an applicant for authorization in exceptional circumstances is not subsequently required to provide the missing data. Although the MA "under exceptional circumstances" is granted definitively, the risk-benefit balance of the medicinal product is reviewed annually, and the MA will be withdrawn if the risk-benefit ratio is no longer favorable.

Pediatric Development in the EU

In the EU, Regulation (EC) No 1901/2006 provides that all MAAs for new medicinal products have to include the results of trials conducted in the pediatric population, in compliance with a pediatric investigation plan (PIP) agreed with the EMA's Pediatric Committee (PDCO). The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the medicinal product for which MA is being sought. The PDCO can grant a deferral of the obligation to implement some or all of the measures provided in the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults. Further, the obligation to provide pediatric clinical trial data can be waived by the PDCO when these data are not needed or appropriate because the product is likely to be ineffective or unsafe in children, the disease or condition for which the product is intended occurs only in adult populations, or when the product does not represent a significant therapeutic benefit over existing treatments for pediatric patients. Once the MA is obtained in all EU Member

States and study results are included in the product information, even when negative, the product is eligible for a six-month extension to the Supplementary Protection Certificate, if any is in effect at the time of authorization or, in the case of orphan medicinal products, a two-year extension of orphan market exclusivity.

Data and Market Exclusivity in the EU

The EU provides opportunities for data and market exclusivity related to MAs. Upon receiving an MA, innovative medicinal products are generally entitled to receive eight years of data exclusivity and ten years of market exclusivity. Data exclusivity, if granted, prevents regulatory authorities in the EU from referencing the innovator's data to assess a generic application or biosimilar application for eight years from the date of authorization of the innovative product, after which a generic or biosimilar MAA can be submitted, and the innovator's data may be referenced. The market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the EU until 10 years have elapsed from the initial MA of the reference product in the EU. The overall ten-year period may, occasionally, be extended for a further year to a maximum of 11 years if, during the first eight years of those ten years, the MA holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. However, there is no guarantee that a product will be considered by the EU's regulatory authorities to be a new chemical/biological entity, and products may not qualify for data exclusivity.

In the EU, there is a special regime for biosimilars, or biological medicinal products that are similar to a reference medicinal product but that do not meet the definition of a generic medicinal product. For such products, the results of appropriate preclinical or clinical trials must be provided in support of an application for MA. Guidelines from the EMA detail the type of quantity of supplementary data to be provided for different types of biological product.

Orphan Designation

In the EU, Regulation (EC) No. 141/2000, as implemented by Regulation (EC) No. 847/2000 provides that a medicinal product can be designated as an orphan medicinal product by the European Commission if its sponsor can establish that: (i) the product is intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions; (ii) either (a) such conditions affect not more than five in 10,000 persons in the EU when the application is made, or (b) the product without the benefits derived from orphan status, would not generate sufficient return in the EU to justify the necessary investment in developing the medicinal product; and (iii) there exists no satisfactory authorized method of diagnosis, prevention, or treatment of the condition that has been authorized in the EU, or even if such method exists, the product will be of significant benefit to those affected by that condition.

Regulation (EC) No 847/2000 sets out further provisions for implementation of the criteria for designation of a medicinal product as an orphan medicinal product. An application for the designation of a medicinal product as an orphan medicinal product must be submitted at any stage of development of the medicinal product but before filing of an MAA. An MA for an orphan medicinal product may only include indications designated as orphan. For non-orphan indications treated with the same active pharmaceutical ingredient, a separate MA has to be sought.

Orphan medicinal product designation entitles an applicant to incentives such fee reductions or fee waivers, protocol assistance, and access to the centralized marketing authorization procedure. Upon grant of an MA, orphan medicinal products are entitled to a ten-year period of market exclusivity for the approved therapeutic indication, which means that the EMA cannot accept another MAA or accept an application to extend for a similar product and the European Commission cannot grant an MA for the same indication for a period of ten years. The period of market exclusivity is extended by two years for orphan medicinal products that have also complied with an agreed PIP. No extension to any supplementary protection certificate can be granted on the basis of pediatric studies for orphan indications. Orphan medicinal product designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The period of market exclusivity may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria on the basis of which it received orphan medicinal product designation, including where it can be demonstrated on the basis of available evidence that the original orphan medicinal product is sufficiently profitable not to justify maintenance of market exclusivity or where the prevalence of the condition has increased above the threshold. Additionally, an MA may be granted to a similar medicinal product with the same orphan indication during the 10 year period if: (i) if the applicant consents to a second original orphan medicinal product application, (ii) if the manufacturer of the original orphan medicinal product is unable to supply sufficient quantities; or (iii) if the second applicant can establish

that its product, although similar, is safer, more effective or otherwise clinically superior to the original orphan medicinal product. A company may voluntarily remove a product from the register of orphan products.

Manufacturing Requirements

In addition to an MA, various other requirements apply to the manufacturing and placing on the EU market of medicinal products. The manufacturing of medicinal products in the EU requires a manufacturing authorization and import of medicinal products into the EU requires a manufacturing authorization allowing for import. The manufacturing authorization holder must comply with various requirements set out in the applicable EU laws, regulations and guidance, including EU GMP standards. Similarly, the distribution of medicinal products within the EU is subject to compliance with the applicable EU laws, regulations and guidelines, including the requirement to hold appropriate authorizations for distribution granted by the competent authorities of EU Member States. MA holders and/or manufacturing and import authorization, or MA holders and/or distribution authorization holders may be subject to civil, criminal or administrative sanctions, including suspension of manufacturing authorization, in case of non-compliance with the EU or EU Member States' requirements applicable to the manufacturing of medicinal products.

Post-Authorization Requirements

Where an MA is granted in relation to a medicinal product in the EU, the holder of the MA is required to comply with a range of regulatory requirements applicable to the manufacturing, marketing, promotion and sale of medicinal products. Similar to the United States, both MA holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA, the European Commission and/or the competent regulatory authorities of the individual EU Member States. The holder of an MA must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance who is responsible for oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports (PSURs).
All new MAAs must include a risk management plan, describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the MA. Such risk-minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorization safety studies.

Pricing, Coverage and Reimbursement

In the EU, pricing and reimbursement schemes vary widely from country to country. Some EU Member States may approve a specific price for a product, or they may instead adopt a system of direct or indirect controls on the profitability of the company placing the product on the market. Other EU Member States allow companies to fix their own prices for products but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions.

Moreover, in order to obtain reimbursement for our products in some European countries, including some EU Member States, we may be required to compile additional data comparing the cost-effectiveness of our products to other available therapies. This Health Technology Assessment (HTA) of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EU Member States, including those representing the larger markets. The HTA process is the procedure to assess therapeutic, economic and societal impact of a given medicinal product in the national healthcare systems of the individual country. The outcome of an HTA will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product currently varies between EU Member States. On January 12, 2025, Regulation No 2021/2282 on HTA (HTA Regulation) entered into application through a phased implementation. The HTA Regulation initially applies to new active substances for oncology and ATMPs. It will be expanded to orphan medicinal products in January 2028, and to all centrally authorized medicinal products as of 2030. Select high-risk medical devices also came into scope in 2026. It is intended to boost cooperation among EU Member States in assessing clinical aspects of health technologies, including new medicinal products, by establishing a framework for joint clinical assessments, joint scientific consultations and the early identification of emerging health technologies. The HTA Regulation permits EU Member States to use common tools, methodologies, and procedures and requires them to rely on EU-level joint clinical assessment reports for the clinical components of their national HTA evaluations. Individual EU Member States continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technologies, and making decisions on pricing and reimbursement.

Other EU Compliance Requirements

In the EU, the advertising and promotion of medicinal products are subject to both EU and EU Member States' laws governing promotion of medicinal products, interactions with physicians and other healthcare professionals, misleading and comparative advertising and unfair commercial practices. General requirements for advertising and promotion of medicinal products, such as direct-to-consumer advertising of prescription medicinal products are established in EU law. However, the details are governed by regulations in individual EU Member States and can differ from one country to another. For example, applicable laws require that promotional materials and advertising in relation to medicinal products comply with the product's Summary of Product Characteristics (SmPC), which may require approval by the competent national authorities in connection with an MA. The SmPC is the document that provides information to physicians and other healthcare professionals concerning the safe and effective use of the product. Promotional activity that does not comply with the SmPC is considered off-label and is prohibited in the EU.

Much like the Anti-Kickback Statute prohibition in the United States, as described below, the provision of benefits or advantages to physicians and other healthcare professionals to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the EU. Interactions between pharmaceutical companies and healthcare professionals are governed by strict laws, such as national anti-bribery laws of European countries, national sunshine rules, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment. Infringement of related laws could result in substantial fines and imprisonment.

Payments made to physicians and other healthcare professionals in certain EU Member States must be publicly disclosed. Moreover, agreements with healthcare professionals may require prior notification or approval by the healthcare professional's employer, his or her competent professional organization and/or the regulatory authorities of the individual EU Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

Manufacturing and Distribution

We currently outsource, and plan to continue to outsource, manufacturing activities for our products and our existing and future product candidates for development and commercial purposes. We believe this manufacturing strategy will enable us to direct our financial resources to our commercial activities and to the ongoing development of pimavanserin, trofinetide and other product candidates without devoting the substantial resources and capital required to build manufacturing facilities.

NUPLAZID (pimavanserin)

We licensed worldwide intellectual property rights related to pimavanserin in certain indications to Acadia Pharmaceuticals GmbH, our wholly-owned Swiss subsidiary (Acadia GmbH). Our active pharmaceutical ingredient (API) has been manufactured in Switzerland for over 10 years and we anticipate continuing to manufacture in Switzerland. Acadia GmbH manages the worldwide supply chain of our pimavanserin API and maintains sufficient inventory in our Switzerland contract warehouse.

Acadia GmbH has contracted with Siegfried AG (Siegfried), to manufacture the pimavanserin API for use in NUPLAZID drug product for commercial sale. Under the manufacturing agreement with Siegfried, Acadia GmbH has agreed to purchase specified percentages of our commercial requirements of the pimavanserin API at a predefined price. The parties may also agree in the future on additional services under the manufacturing agreement with respect to non-commercial supply or development activities. The initial term of the manufacturing agreement ended in December 2021, but the agreement automatically renewed for two-year terms, and will automatically renew for subsequent two-year terms unless either party provides timely notice of its intent not to renew, or unless the manufacturing agreement is terminated earlier pursuant to its terms. Either party may terminate the manufacturing agreement prior to expiration upon an uncured material breach by the other party, upon the dissolution or liquidation of the other party, the commencement of insolvency procedures that are not dismissed within a certain period of time, the appointment of any receiver, trustee or assignee to take possession of the properties of the other party or the cessation of all or substantially all of the other party's business operations, upon certain continuing patent infringement, regulatory litigation or other legal proceedings involving the manufacture of our API, upon a continuing force majeure affecting the other party, or if no services are currently being provided under the manufacturing agreement. Additionally, if the parties agree on development services under the manufacturing agreement, the parties may terminate such services by mutual agreement if reasonable efforts to achieve the goals of such services fail.

Acadia GmbH also may terminate any services under the manufacturing agreement for any reason on 90 days' prior notice to Siegfried, subject to the requirements of the manufacturing agreement.

We have contracted with Patheon Pharmaceuticals Inc. (Patheon), a subsidiary of Thermo Fisher Scientific Inc., to manufacture NUPLAZID 10 mg tablet and 34 mg capsule drug product for commercial use in the United States. We have also contracted with Catalent Pharma Solutions LLC (Catalent) to manufacture NUPLAZID 34 mg drug product for commercial use in the United States.

- Under the manufacturing agreement with Patheon, we have agreed to purchase from Patheon a specified percentage of our commercial requirements of NUPLAZID for the United States. Under the agreement, Patheon will also perform specified validation services. The initial term of the manufacturing agreement ended in the first quarter of 2023, but the agreement automatically renewed for two-year terms and will automatically renew for subsequent two-year terms unless either party provides timely notice of its intent not to renew, or unless the manufacturing agreement is terminated early pursuant to its terms. Each party may terminate the manufacturing agreement prior to expiration upon the uncured material breach by the other party, upon the bankruptcy or insolvency of the other party or in the event of a continuing force majeure event affecting the other party. The manufacturing agreement will also terminate if we provide notice to Patheon that we no longer require manufacturing services because NUPLAZID has been discontinued. Additionally, we may terminate the manufacturing agreement, subject to certain limitations, if any regulatory authority takes any action or raises any objection that prevents us from continuing to commercialize NUPLAZID or takes an enforcement action against Patheon's manufacturing site that relates to NUPLAZID or could reasonably be expected to adversely affect Patheon's ability to supply NUPLAZID, if we determine to discontinue commercialization of NUPLAZID for safety or efficacy reasons, or if Patheon uses any debarred person in performing its service obligations under the manufacturing agreement. We also may terminate the manufacturing agreement for any other reason on three years' prior notice to Patheon. Patheon may terminate the manufacturing agreement if we assign the manufacturing agreement or any of our rights under the manufacturing agreement to a Patheon competitor.
- Under the manufacturing agreement with Catalent, we have agreed to purchase from Catalent NUPLAZID for commercial use in the United States. Under the agreement, Catalent will also perform specified validation services. The initial term of the manufacturing agreement ended in the first quarter of 2023, but the agreement automatically renewed for two-year terms and will automatically renew for subsequent two-year terms unless either party provides timely notice of its intent not to renew, or unless the manufacturing agreement is terminated early pursuant to its terms. Each party may terminate the manufacturing agreement prior to expiration upon the uncured material breach by the other party, or upon the bankruptcy or insolvency of the other party. Additionally, we may terminate the manufacturing agreement if any regulatory authority takes any action or raises any objection that prevents us from continuing to commercialize NUPLAZID or takes an enforcement or other regulatory action against Catalent's manufacturing site which affects Catalent's ability to manufacture NUPLAZID.

We sell NUPLAZID to a limited number of specialty pharmacies (SPs), and specialty distributors (SDs), which we collectively refer to as our customers. SPs subsequently dispense NUPLAZID to patients based on the fulfillment of a prescription and SDs subsequently sell NUPLAZID to government facilities, long-term care pharmacies, and in-patient hospital pharmacies. Four of such customers, each based in the United States, accounted for approximately 79% of our NUPLAZID product revenue and 44% of our total product revenue for the year ended December 31, 2025. We have retained third-party logistics service providers to perform a variety of functions related to the distribution of NUPLAZID, including warehousing, customer service, order-taking, invoicing, collections, and shipment and returns processing.

DAYBUE (trofinetide)

We have contracted with manufacturers to produce supplies of trofinetide to support the development program and for commercial sale. We have contracted with Corden Pharma Bergamo S.p.A. (Corden), to manufacture the API for trofinetide products. We have also contracted with additional contract manufacturing organizations (F.I.S. Fabbrica Italiana Sintetici S.p.A. (FIS) and Flamma Group S.p.A (Flamma)) to manufacture trofinetide drug substance. Under the manufacturing agreement with Corden, we have agreed to purchase from Corden the API for trofinetide products at specified price per volume and a specified percentage of our commercial requirements of trofinetide API for the United States and Canada market. We and Corden may also agree in the future on additional services under the manufacturing agreement. The initial term of the manufacturing agreement will end in November 2027, but the agreement will automatically renew for subsequent two-year terms unless either party provides timely notice of its intent not to renew, or unless the manufacturing agreement is

terminated early pursuant to its terms. Either party may terminate the manufacturing agreement prior to expiration upon an uncured material breach by the other party, upon the commencement of bankruptcy, reorganization, liquidation or receivership proceedings by or against the other party or the other party ceases for any reason to carry on its business or makes assignment for the benefit of its creditors, or is the subject of any proposal for a voluntary arrangement. Additionally, either party may terminate the manufacturing agreement on 12 months' prior notice to the other party at any time.

Under the manufacturing agreement with Patheon described above, we also have the right to have manufactured trofinetide products for commercial use. In addition, we have contracted with Bend Biosciences, formerly known as CoreRx Inc., (Bend) to manufacture trofinetide products for commercial use. We and Bend may also agree in the future on additional services under the agreement. The initial term of the agreement will end in March 2028, but the agreement will automatically renew for subsequent two-year terms unless either party provides timely notice of its intent not to renew, or unless the agreement is terminated early pursuant to its terms. Either party may terminate the agreement prior to expiration upon an uncured material breach by the other party or upon the commencement of bankruptcy, reorganization, liquidation or receivership proceedings by or against the other party. In addition, we may terminate the agreement prior to expiration upon timely notice to Bend in the event (i) any regulatory authority takes an enforcement or other regulatory action against Bend's facility which affects Bend's ability to process trofinetide products, (ii) any regulatory authority takes an action or raises any objection that prevents us from manufacturing, importing, exporting, purchasing or selling trofinetide products, or (iii) we determine to discontinue commercialization of trofinetide products in the U.S. due to safety or efficacy reasons.

We have contracted with Halo Pharmaceuticals, Inc. (Halo) to manufacture DAYBUE STIX 5g, 6g, and 8g drug product stick packs for commercial use in the United States. Under the manufacturing agreement with Halo, we have agreed to purchase from Halo a specified number of bathes of our commercial requirements of DAYBUE STIX for the United States. Under the agreement, Halo may also perform qualification, validation, stability and other services. The initial term of the manufacturing agreement will end in December 2030, but the agreement will automatically renew for subsequent two-year terms unless either party provides timely notice of its intent not to renew, or unless the agreement is terminated early pursuant to its terms. Either party may terminate the agreement prior to expiration upon an uncured material breach by the other party, upon the commencement of bankruptcy, reorganization, liquidation or receivership proceedings by or against the other party, or upon a continuing force majeure affecting the other party. In addition, we may terminate the agreement prior to expiration upon timely notice to Halo in the event any regulatory authority takes an action or raises any objection that prevents us from manufacturing, importing, exporting, purchasing or selling trofinetide products, or we determine to discontinue commercialization of trofinetide products in the U.S.

We sell DAYBUE in the U.S. to a single wholesale distributor with specialty pharmacy service, which performs a variety of functions related to the distribution of DAYBUE, including warehousing, customer service, order-taking, shipment and returns processing. We sell DAYBUE outside of the U.S. through third party distributors.

Other Products

If any product candidate is approved by the FDA or comparable foreign regulatory authorities for commercial sale, we will need to contract with a third party, which may be an existing service provider or a new service provider, to manufacture such product for commercial sale in the U.S. and/or other applicable jurisdictions.

Sales and Marketing

We have U.S. sales specialists that are focused on promoting NUPLAZID to physicians who treat PDP patients, including neurologists, psychiatrists and long-term care physicians. This sales force is supported by an experienced sales leadership team. Our experienced commercial team is comprised of experienced professionals in marketing, key account management, patient access services, commercial operations, and sales force planning and management. In addition, our commercial infrastructure includes capabilities in manufacturing, health outcomes, medical affairs, quality control, and compliance.

We launched NUPLAZID in May 2016, and our focus is to continue to establish NUPLAZID as the standard of care for patients with PDP. In order to help us achieve this goal, we are continuing to increase awareness of NUPLAZID's benefits in PDP with a prescriber and patient education campaign consisting of key opinion leader speaker programs, attendance at medical meetings, digital outreach, multimedia campaigns, and direct-to-patient programs.

In addition, we have U.S. sales specialists that are focused on promoting DAYBUE to physicians who treat Rett syndrome patients, including those at Centers of Excellence, high volume institutions and in the community setting. The sales force is supported by an experienced sales leadership team. Our experienced commercial team is comprised of rare disease field-based specialists, patient access services, commercial operations, and sales force planning and management. In addition, our commercial infrastructure includes capabilities in manufacturing, health outcomes, medical affairs, quality control, and compliance.

We launched DAYBUE in April 2023, and our focus is to continue to establish DAYBUE as the standard of care for patients with Rett syndrome. In order to help us achieve this goal, we are continuing to increase awareness of DAYBUE's benefits in Rett syndrome with a prescriber and patient education campaign consisting of key opinion leader speaker programs, attendance at medical meetings, digital outreach, and multimedia campaigns.

We also have support services including the Acadia Connect hub for physicians, patients and their families that provide broad resources to help with access, reimbursement and the continual clinical support to help patients start and stay on therapy. For healthcare providers and practices, Acadia Connect provides access and coverage support services, information on appropriate financial assistance options for eligible patients, and coordination of medication delivery to patients through our specialty pharmacy.

In selected markets outside of the United States in which DAYBUE may be approved, if any, we may choose to commercialize DAYBUE independently or by establishing one or more strategic alliances.

Long-Lived Assets

Our tangible long-lived assets are comprised of intangible assets and property and equipment. Our property and equipment totaled $7.5 million, $4.2 million, and $4.6 million as of December 31, 2025, 2024 and 2023, respectively. A majority of our tangible long-lived assets are located in the United States. Our intangible assets, comprised of right-of-use assets and other intangibles acquired, totaled $156.2 million, $166.4 million and $117.3 million as of December 31, 2025, 2024 and 2023, respectively.

Employees and Human Capital

Employees. At December 31, 2025, we had a total of 798 employees, 796 of whom were full-time. Our workforce includes physicians, scientists and professionals in research and development, regulatory, manufacturing, marketing, sales, finance, legal and other functions that are important to our business. We also utilize temporary workers when doing so enhances operational flexibility, and we engage external advisers and consultants when this approach best supports our business needs.

Employee Engagement, Benefits & Development. We believe that our future success is dependent upon our ability to recruit, hire and retain exceptional employees. We offer competitive cash compensation, opportunities to own equity, and a comprehensive benefits program designed to support employee well-being. These benefits include wellness programs, healthcare coverage, life and disability insurance, retirement planning and paid time off.

We invest in employee growth through leadership and professional development programs, as well as tuition reimbursement. To assess our employee engagement and inform continuous improvement, we regularly conduct employee surveys and review insights to guide organizational initiatives.

Diversity, Equity, Inclusion & Belonging (DEIB). We are committed to fostering a diverse, equitable, inclusive workplace where all employees feel a sense of belonging. Our DEIB efforts support our mission and values, and aim to strengthen our culture, enhance employee experience, and contribute positively to the communities we serve. We continue to advance initiatives that promote inclusive talent practices, equitable opportunities, and a workplace environment in which diverse perspectives are recognized and valued.

Item 1A. ***Risk Factors.***

You should consider carefully the following information about the risks described below, together with the other information contained in this Annual Report and in our other public filings, in evaluating our business. If any of the following risks actually occurs, our business, financial condition, results of operations, and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock would likely decline.

Risks Related to Our Products and Product Candidates

Our prospects are highly dependent on the successful commercialization of our products. To the extent we cannot establish, maintain or increase sales of our products, our business, financial condition and results of operations may be materially adversely affected and the price of our common stock may decline.

We have two products that are approved for commercialization in the U.S.: NUPLAZID and DAYBUE. The successful commercialization of such products is subject to many risks, and there is no guarantee that we will be able to maintain or increase sales of such products. Our business, financial condition and results of operations may be materially adversely affected and the price of our common stock may decline because of many factors, some of which are outside our control, including, but not limited to, the following:

- the extent to which patients, caregivers and physicians recognize and diagnose the indications for which our products are approved and accept and adopt our products as a treatment for such indications;
- the scope and terms of the FDA's approval of our products, including the inclusion of a boxed warning for NUPLAZID or other warnings and precautions for our products;
- physicians may not prescribe our products and patients may be unwilling to use our products, due to a number of factors, including if coverage is not provided, coverage changes in the future, reimbursement is inadequate to cover a significant portion of the cost, negative or changing perceptions of each product's clinical profile and clinical benefits or due to the prevalence and severity of any adverse side effects;
- the experiences of those adopting our products earlier could have significant impact on future adoption of our products by other physicians, patients and caregivers, either favorably or unfavorably, based on clinical benefits and side effects experienced;
- any new clinical data, post-approval studies or real world results, including in jurisdictions other than the U.S., could result in the FDA making changes to the product label or withdrawal from the market, and could impact regulatory approvals for other indications in the U.S. or other jurisdictions, if any, any of which could result in significant expense and delay or limit our ability to generate sales revenues;
- our products are becoming available to a larger number of patients and patients' experiences and results with our products may not be consistent with, or may be more negative when compared to, the experiences and results of those treated in our clinical trials;
- successful expansion and development of our commercial team and sales forces; and
- any negative publicity related to our products.

Additionally, our success is dependent on our ability to obtain regulatory approval for, and successfully commercialize, trofinetide in jurisdictions outside the U.S., including the EU. We will face in jurisdictions outside the U.S., such as the EU, if approved for marketing, risks and uncertainties similar to the risks and uncertainties faced in the U.S. with respect to commercialization outside of the U.S., including, but not limited to, government reimbursement of the cost of trofinetide. If the commercialization of our products and future sales is less successful than expected or perceived as disappointing, our stock price could decline significantly and the long-term success of our products and our company could be harmed.

Our products may not gain maximal acceptance among physicians, patients, caregivers and the medical community, thereby limiting our potential to generate revenues.

The degree of market acceptance by physicians, healthcare professionals, patients, caregivers and third-party payors of our products, and our profitability and growth, will depend on a number of factors, including:

- the ability to provide acceptable evidence of safety and efficacy;

- the scope of the approved indication(s) for the product;
- the inclusion of any warnings or contraindications in the product label;
- the relative convenience and ease of administration;
- the relative timing, or perceived timing, in which patients experience outcomes;
- the prevalence and severity of any actual or expected adverse side effects;
- the availability of alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- our ability to increase awareness of our approved products through marketing efforts;
- pricing and cost effectiveness, which may be subject to regulatory control;
- effectiveness of our or our collaborators' sales and marketing strategy;
- publicity concerning us, our products or competing products and treatments; and
- our ability to obtain and maintain sufficient third-party insurance coverage or adequate reimbursement levels.

If a product does not provide a treatment regimen that is at least as beneficial as the current standard of care or otherwise does not provide patient benefit, that product will not achieve market acceptance and will not generate sufficient revenues to achieve or maintain profitability. With respect to our products specifically, successful commercialization will depend on whether and to what extent physicians, patients, caregivers, long-term care facilities and pharmacies, over whom we have no control, determine to utilize our products. NUPLAZID is available in the U.S. to treat hallucinations and delusions associated with PDP, and DAYBUE is available in the U.S. to treat Rett syndrome, both indications for which no other FDA-approved pharmaceutical treatments currently exist. DAYBUE is also the first and only product approved in Canada and Israel for the treatment of Rett syndrome.

As there are no approved competitors for our products, it is particularly difficult to estimate the market potential for our products and how physicians, patients, caregivers, long-term care facilities and payors will respond to changes in the price of our products. Industry sources and analysts have a divergence of estimates for the near- and long-term market potential of our products, and a variety of assumptions directly impact the estimates for our products' market potential, including assumptions regarding the prevalence of PDP and Rett syndrome, the rate of diagnosis of PDP and Rett syndrome, the prevalence and rate of hallucinations and delusions in patients diagnosed with PDP with respect to NUPLAZID, the rate of physician adoption, the potential impact of payor restrictions, and patient adherence and compliance rates. Small differences in these assumptions can lead to widely divergent estimates of the market potential of our products.

For example, with respect to NUPLAZID, certain research suggests that patients with Parkinson's disease may be hesitant to report symptoms of PDP to their treating physicians for a variety of reasons, including apprehension about societal stigmas relating to mental illness. Research also suggests that physicians who typically treat patients with Parkinson's disease may not ask about or identify symptoms of PDP. For these reasons, even if PDP occurs in high rates among patients with Parkinson's disease, it may be underdiagnosed. Even if PDP is diagnosed, physicians may not prescribe treatment for hallucinations and delusions associated with PDP, and if they do prescribe treatment, they may prescribe drugs other than NUPLAZID, even though they are not approved in PDP. Further, NUPLAZID may take several weeks to show efficacy. Even if NUPLAZID is prescribed for the treatment of hallucinations and delusions associated with PDP, patients may stop taking NUPLAZID because they may not see results in the timeframe they desire or expect.

Similarly, even if DAYBUE is prescribed for the treatment of Rett syndrome, issues may arise with respect to patient acceptance, adherence, persistence and compliance rates for a variety of reasons, including due to the expected clinical benefits or expected and actual side effects a patient might incur. If patients do not adhere to the recommended dosing of DAYBUE, or do not maintain the recommended dosing of DAYBUE for sufficient periods of time, patients and physicians may believe that DAYBUE is less effective, and as a result they may discontinue taking it and prescribing it. Additionally, if physicians or patients titrate DAYBUE below the recommended doses, patients may not experience the desired outcomes, and physicians or patients may develop negative beliefs about the effectiveness of DAYBUE and/or discontinue its use.

The label for NUPLAZID also contains a "boxed" warning related to particularly important prescribing information, and the FDA reminded healthcare providers to be aware of the risks described in the NUPLAZID prescribing information following its observation of potentially concerning prescribing patterns. There has also been attention to publicly reported deaths of patients that were prescribed NUPLAZID, and the FDA conducted an evaluation of available information about NUPLAZID. Perceptions that NUPLAZID is unsafe, even if unfounded, may discourage physicians from prescribing or patients from taking NUPLAZID.

The commercial success of our products depends on acceptance by patients, caregivers and physicians, and there are a number of factors that could skew our or others' estimates about prescribing behaviors and market adoption. If we fail to gain the acceptance of patients, caregivers and physicians, or if our estimates are inaccurate, these events could negatively impact our business, results of operations, financial condition and prospects.

Our ability to generate product revenues will be diminished if coverage for our products from commercial or government payors is not provided, is decreased or if patients have unacceptably high out-of-pocket requirements.

Patients who are prescribed medicine for the treatment of their conditions generally rely on third-party payors, including governmental healthcare programs, such as Medicare and Medicaid, managed care organizations and commercial payors, among others, to reimburse all or part of the costs associated with their prescription drugs. Coverage and adequate reimbursement from third-party payors are critical to product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor drug products when lower cost therapeutic alternatives are already available or subsequently become available. Even with coverage for our products, the resulting reimbursement payment rates might not be adequate or may require out-of-pocket obligations, such as deductibles and co-pay or coinsurance payments, that patients find unacceptably high. Patients may not use our products if coverage is not provided or reimbursement is inadequate to cover a significant portion of its cost.

In addition, the market for our products depends significantly on access to third-party payors' drug formularies, or lists of medications for which third-party payors provide coverage and reimbursement. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical companies. Also, third-party payors may refuse to include a particular branded drug in their formularies or otherwise restrict patient access to a branded drug when a less costly alternative is available, even if not approved for the indication for which our products are approved.

Legislators, policymakers and healthcare insurance funds in the EU may continue to propose and implement cost-containing measures to keep healthcare costs down. These measures could include limitations on the prices we would be able to charge for product candidates that we may successfully develop and for which we may obtain regulatory approval or the level of reimbursement available for these products from governmental authorities or third-party payors. Consequently, a downward trend in prices of medicinal products in some countries could contribute to similar downward trends elsewhere.

Third-party payors, whether governmental or commercial, whether in the U.S. or globally, are developing increasingly sophisticated methods of controlling healthcare costs. The current environment is putting pressure on companies to price products below what they may feel is appropriate. For example, the HHS imposes rebates on many Medicare Part B and Medicare Part D products to penalize price increases that outpace inflation on an annual basis. In addition, HHS has been empowered to negotiate the price of certain single-source drugs that have been on the market for at least 7 years covered under Medicare as part of the Medicare Drug Price Negotiation Program. Each year up to 20 products will be selected by HHS for the Medicare Drug Price Negotiation Program. Based upon the current law, we believe that 2029 is the earliest year NUPLAZID could be subject to a negotiated price, as we expect to apply and qualify for the small biotech exception, which provides an exemption from selection until 2027 (for initial price negotiation in 2029). In 2029, if selected, we expect that the price negotiation for NUPLAZID would be limited as we qualify as a "specified small manufacturer" and will receive the discount phase-in for NUPLAZID in years 2029 and 2030. Products subject to the Medicare Drug Price Negotiation Program are expected to experience a significant reduction in reimbursement from the Medicare program on a per unit basis. If coverage and adequate reimbursement are not available, or are available only to limited levels, we may not be able to successfully commercialize our current and any future product candidates that we develop, which could have an adverse effect on our operating results and our overall financial condition. Selling our products at less than an optimized price would impact our revenues and could impact our overall success as a company. We have changed, and may continue to change, the price of our products from time to time, however, we do not know if the price we have selected, or may select in the future, for our products is or will be the optimized price. Additionally, we do not know whether and to what extent third-party payors will react to any possible future changes in the price of our products. In the U.S., no uniform policy of coverage and reimbursement for drug products exists among third-party payors. Outside the U.S., reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies.

Further, one payor's determination to provide coverage and reimbursement for a product does not ensure that other payors will also provide coverage and reimbursement for the product. Therefore, coverage and reimbursement for our products both in the U.S. and outside may differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage will be obtained. Coverage policies and third-party payor reimbursement rates may change at any time. Therefore, even if favorable coverage and reimbursement status is attained, less favorable coverage policies and reimbursement rates may be implemented in the future.

In most international markets, where the government is the primary payor, manufacturers must operate in an environment of government-directed cost-containment programs – designs such as price controls, international reference pricing, mandatory discounts and rebates, regulatory hurdles and restrictions on physician-level prescribing. In these markets, healthcare services and determination of a product's pricing and reimbursement are impacted by government control. For example, the EU provides options for EU Member States to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. An EU Member State may approve a specific price for the medicinal product, it may refuse to reimburse a product at the price set by the manufacturer or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Many EU Member States also periodically review their reimbursement procedures for medicinal products, which could have an adverse impact on reimbursement status. Moreover, in order to obtain reimbursement for our products in some European countries, including some EU Member States, we may be required to compile additional data comparing the cost-effectiveness of our products to other available therapies in an HTA.

An HTA of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EU Member States, including those representing the larger markets. The HTA process is the procedure to assess therapeutic, economic and societal impact of a given medicinal product in the national healthcare systems of the individual country. The outcome of an HTA will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product currently varies between EU Member States. On January 12, 2025, Regulation No 2021/2282 on HTA entered into application through a phased implementation. It is intended to boost cooperation among EU Member States in assessing health technologies, including new medicinal products. The HTA Regulation establishes a framework for joint clinical assessments, joint scientific consultations, and the early identification of emerging health technologies. This regulation permits EU Member States to use common HTA tools, methodologies, and procedures across the EU and requires them to rely on EU-level joint clinical assessment reports for the clinical components of their national HTA evaluations. Individual EU Member States continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technologies, and making decisions on pricing and reimbursement. As implementation of the HTA Regulation is phased in and key methodological and procedural guidance continues to evolve, there remains uncertainty regarding the evidence requirements, timing, and impact of joint clinical assessments on national reimbursement processes. The new framework may result in additional or differently structured evidentiary expectations, misalignment between assessment and regulatory timelines, or delays in national decisions. Any adverse or delayed HTA outcomes, or divergent national reimbursement decisions, could negatively affect our ability to obtain or maintain favorable pricing and reimbursement status for any product candidates, if approved. If we are unable to maintain favorable pricing and reimbursement status in EU Member States for product candidates that we may successfully develop and for which we may obtain regulatory approval, any anticipated revenue from and growth prospects for those products in the EU could be negatively affected.

So, for present and future considerations, if we are unable to obtain coverage of, and adequate payment levels for, our products we may market to third-party payors, physicians may limit how much or under what circumstances they will prescribe or administer them and patients may decline to purchase them. This in turn could affect our ability to successfully commercialize our products or any other products we may market, and thereby adversely impact our profitability, results of operations, financial condition, and future success.

Our products are subject to ongoing regulatory requirements that could cause us significant expense and delay or limit our ability to generate sales revenues.

In connection with the FDA approval of DAYBUE, we agreed to the following post-marketing requirements (PMRs): a clinical study of renal impairment in healthy volunteers, nonclinical carcinogenicity studies and nonclinical in vitro and clinical in vivo drug interaction studies. The FDA has released us from one of the five PMRs. In addition, we have fulfilled three of the five PMRs. The results of any post-marketing study may cause the FDA to update the label, request additional studies and/or require risk mitigation plans.

The manufacturing processes, labeling, packaging, export, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for our products will also continue to be subject to extensive and ongoing regulatory requirements in the U.S. and in other foreign countries in which we operate, engage third-party manufacturers and obtain marketing approvals. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs, licensing requirements, good clinical practices, international council for harmonization guidelines and good laboratory practices, each of which are regulations and guidelines enforced by regulatory authorities for all of our nonclinical and clinical development and for any clinical trials that we conduct post-approval.

Discovery of any issues post-approval, including any safety concerns, such as carcinogenicity, unexpected side effects or drug-drug interaction problems, adverse events of unanticipated severity or frequency, or concerns over misuse or abuse of the product, problems with the facilities where the product is manufactured, tested, packaged or distributed, or failure to comply with regulatory requirements, may result in, among other things, restrictions on our products or on us, including:

- withdrawal or variation of approval, addition of warnings or narrowing of the approved indication in the product label;
- requirement of a Risk Evaluation and Mitigation Strategy to mitigate the risk of off-label use in populations where the FDA may believe that the potential risks of use may outweigh its benefits;
- voluntary or mandatory recalls;
- warning letters;
- suspension, variation or termination of any ongoing clinical studies;
- refusal by the FDA or comparable foreign regulatory authorities to approve pending applications or supplements to approved applications filed by us, or suspension, variation or revocation of product approvals;
- restrictions on operations, including restrictions on the marketing or manufacturing of the product or the imposition of costly new manufacturing requirements;
- material fines or other types of penalties; or
- seizure or detention, or refusal to permit the import or export of products.

If any of these actions were to occur, we may have to discontinue the commercialization of the applicable product, limit our sales and marketing efforts, conduct further post-approval studies, and/or discontinue or change any other ongoing or planned clinical studies, which in turn could result in significant expense and delay or limit our ability to generate sales revenues.

We rely on a limited network of third-party distributors and pharmacies to market and sell our products. If this approach ceases to be effective, commercialization of our products may be adversely affected, and our products may not be profitable.

Our strategy includes distributing NUPLAZID in the U.S. and DAYBUE or trofinetide, as applicable, in the U.S. and other jurisdictions in which marketing is approved solely through a limited network of third-party specialty distributors, specialty pharmacies or other third-party partners. While we have entered into agreements with each of these distributors and pharmacies to distribute NUPLAZID in the U.S. and DAYBUE in the U.S. and other jurisdictions in which marketing is approved, we will need to enter into similar agreements in any jurisdictions in which trofinetide is approved, and such distributors and pharmacies may not perform as agreed or they may terminate their agreements with us. Also, we may need to enter into agreements with additional distributors, pharmacies or other entities, and there is no guarantee that we will be able to do so on commercially reasonable terms or at all.

In the event we are unable to maintain and, if needed, expand, our network of third-party specialty distributors and specialty pharmacies, our ability to continue commercializing our products would be limited, and our products may not be profitable.

Drug development is a long, expensive and unpredictable process with a high risk of failure, and there is no guarantee that our products or product candidates will be successful in ongoing or future clinical trials or obtain regulatory approval.

Preclinical testing and clinical trials are long, expensive and unpredictable processes that can be subject to delays. Preliminary, initial, top-line or interim results of clinical trials do not necessarily predict final results and such results may change as more patient data becomes available and are subject to audit and verification procedures that could result in material changes in the final results. In addition, success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials even after promising results in earlier trials. Of the large number of product candidates in development, only a small percentage result in the submission of an NDA to the FDA or comparable regulatory filing to regulatory authorities in other jurisdictions, and even fewer are approved for marketing. Even if clinical trials are completed, we or our collaborators may not submit applications for required authorizations to manufacture and/or market potential products or any such application may not be reviewed and approved by the appropriate regulatory authorities in a timely manner, if at all.

Our clinical trials face a number of risks, and our product candidates may fail regardless of whether our collaborators successfully complete the clinical trials and apply for such required authorizations for a number of reasons, including:

- a product candidate may fail to receive the regulatory clearances required to market them as drugs;
- a product candidate may be subject to proprietary rights held by others requiring the negotiation of a license agreement prior to marketing;
- a product candidate may be difficult or expensive to manufacture on a commercial scale;
- a product candidate may have adverse side effects that make their use less desirable;
- a product candidate may fail to compete with product candidates or other treatments commercialized by competitors;
- a product candidate may not prove to be efficacious or safe;
- patients may die or suffer other adverse effects for reasons that may or may not be related to the product candidate being tested;
- the results of clinical trials may not be consistent with positive results of earlier trials; and
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities.

Our drug development programs are at various stages of development and the historical rate of failures for product candidates in our industry is extremely high. We have had several clinical studies that did not achieve statistical significance on certain endpoints, including the unsuccessful Phase 3 ADVANCE-2 study of pimavanserin for the treatment of the negative symptoms of schizophrenia in March 2024, the unsuccessful Phase 2 study of pimavanserin for the treatment of irritability associated with autism spectrum disorder in pediatric populations (Pediatric Phase 2 Trial) in October 2024 and the unsuccessful Phase 3 COMPASS PWS study of intranasal carbetocin for the treatment of hyperphagia in Prader-Willi Syndrome in September 2025. At this time, we are not planning to conduct any additional clinical studies for any new indications for pimavanserin or any additional clinical studies with intranasal carbetocin.

With the completion of the Pediatric Phase 2 Trial, we believe we now have completed the FDA’s requirements to qualify for a pediatric exclusivity for pimavanserin. However, there is no assurance that the FDA will confirm that such requirements have been met and that the pediatric exclusivity will be granted.

An unfavorable outcome in any of our ongoing or future development efforts for trofinetide or in the post-marketing studies for DAYBUE could be a major set-back for the programs and for us, generally. In particular, an unfavorable outcome in our trofinetide programs or in the post-marketing studies for DAYBUE, may require us to delay, devote additional substantial resources to, reduce the scope of, or eliminate the affected program and could have a material adverse effect on us and the value of our common stock. Also, although we have submitted a marketing application for the approval of trofinetide in the EU, there is no guarantee we will receive regulatory approval.

We are currently conducting studies with our product candidates. Even if we complete all planned clinical trials for our product candidates on schedule, such completion does not guarantee that we will obtain regulatory approval from the regulatory authorities. The results of our clinical trials may not meet the requirements for approval, or regulatory authorities may interpret the data differently than we do. In addition, completion of clinical trials does not ensure that regulatory authorities will view the results as sufficient to demonstrate safety, efficacy, or clinical benefit. For example, regulators may disagree with the design or implementation of our clinical trials, the appropriateness or relevance of endpoints of our clinical trials, duration of our clinical trials, whether the patient population is sufficiently representative of the desired indication in their geography or at all, the nature or existence of comparative data, size and duration of safety database, and our interpretation of meaningfulness and/or generalizability of findings. Consequently, the successful completion of clinical trials may not be predictive of a positive outcome with any or all regulatory authorities. If we are unable to develop, or obtain marketing approval for, or, if approved, successfully commercialize our product candidates, we may not be able to generate sufficient revenue and our business operations and financial performance may be materially and adversely affected.

The regulatory approval processes in the EU and outside North America are lengthy, time consuming and inherently unpredictable, and if we do not obtain regulatory approval of trofinetide outside North America, we will not be able to market trofinetide outside North America, which will limit our trofinetide commercial revenues.

In the U.S., the EU and many foreign countries, we are not permitted to market our product candidates until we receive regulatory approval from the FDA, European Commission or comparable foreign regulatory authorities. DAYBUE was approved in 2023 in the U.S. by the FDA, in 2024 in Canada by Health Canada, and in 2025 in Israel by the Ministry of Health. In January 2025, we submitted a MAA for the approval of trofinetide for the treatment of Rett syndrome in the EU.

The process of obtaining regulatory approval of medicinal products in the EU and elsewhere, is expensive, often takes many years following the commencement of clinical trials and can vary substantially based upon the type, complexity and novelty of the product candidates involved, as well as the target indications and patient population. Approval policies or regulations may change, and regulatory authorities have substantial discretion in the drug approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. Despite the time and expense invested in clinical development of product candidates, regulatory approval is never guaranteed.

Prior to obtaining approval to commercialize trofinetide in the EU or internationally, we must demonstrate with substantial evidence from adequate and well-controlled clinical trials, and to the satisfaction of the EMA, the European Commission or comparable foreign regulatory authorities, that trofinetide is safe and effective for its intended uses. Results from non-clinical studies and clinical trials can be interpreted in different ways. Even if we believe the non-clinical or clinical data for trofinetide are promising, such data may not be sufficient to support approval by the European Commission or comparable foreign regulatory authorities. For example, in January 2026 we were informed by the EMA's CHMP of a negative trend vote on our MAA for trofinetide for the treatment of Rett syndrome, following a CHMP oral explanation. While we announced our intent to request a re-examination once the CHMP opinion is adopted, the results of the re-examination may not be favorable to us and our ability to ultimately obtain approval for trofinetide for the treatment of Rett syndrome may be negatively impacted.

The EMA or comparable foreign regulatory authorities may also require us to conduct additional preclinical studies or clinical trials for trofinetide either prior to or post-approval or may object to elements of our clinical development program. If we were required to conduct such additional preclinical studies or clinical trials, the EMA or comparable foreign regulatory authorities may not agree with our interpretation of the results and we may not receive approval for trofinetide for the desired indication, or marketing of trofinetide, if approved, may be subject to additional requirements.

Trofinetide could fail to receive regulatory approval for many reasons, including the following:

- the EMA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials, the appropriateness or relevance of endpoints of our clinical trials, duration of our clinical trials, whether the patient population is sufficiently representative of the desired indication, the nature or existence of comparative data, size and duration of safety database, and our interpretation of meaningfulness and/or generalizability of findings;
- the EMA or comparable foreign regulatory authorities may not accept clinical data from trials which are conducted at clinical facilities or in countries where the standard of care is potentially different from that of the EU or the applicable foreign jurisdiction;

- we may be unable to demonstrate to the satisfaction of the EMA or comparable foreign regulatory authorities that trofinetide is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the EMA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that trofinetide's clinical and other benefits outweigh its safety risks to the satisfaction of the EMA or comparable foreign regulatory authorities;
- the EMA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to obtain regulatory approval in the EU or elsewhere for the proposed indication in the proposed population; and
- the approval policies or regulations of the EMA, the European Commission or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Any of the above events could prevent us from achieving market approval of trofinetide and could substantially increase the costs of commercializing trofinetide.

Of the large number of drugs in development, only a small percentage successfully complete European Commission or comparable foreign regulatory approval processes and are commercialized. Even if we receive approval for trofinetide, the European Commission or comparable foreign regulatory authorities may grant approval contingent on the performance of costly additional clinical trials, including post-approval clinical trials, and/or the implementation of risk management strategies, which may be required to ensure safe use of the drug after approval. The European Commission or comparable foreign regulatory authorities also may approve trofinetide for a more limited indication or patient population than we originally requested, and the European Commission or comparable foreign regulatory authorities may not approve the labeling that we believe is necessary or desirable for the successful commercialization of trofinetide. As a result, any approval may fail to create the value we were expecting trofinetide to generate. Further, if we do not receive marketing approval for trofinetide in the EU or other jurisdictions outside of North America, including Japan, we will not be able to commercialize trofinetide in such jurisdictions at all.

If the results or timing of regulatory filings, the regulatory process, regulatory developments, clinical trials or preclinical studies, or other activities, actions or decisions related to DAYBUE or trofinetide do not meet our or others' expectations, the market price of our common stock could decline significantly and the long-term success of the product and our company could be harmed.

Expanded access or compassionate use programs could subject us to additional risks.

We currently provide and may provide in the future access to unapproved products or product candidates outside of clinical trials through expanded access or compassionate use programs (sometimes referred to as named patient or right to try programs). These patients generally have life-threatening or severe illnesses for which there are no alternative therapies or they have exhausted all other available therapies, and unapproved products or product candidates may be provided to eligible patients based upon the request of healthcare professionals as allowed by country specific laws and regulations. There are a number of risks that we may face as a result of our expanded access or compassionate use programs. For example, the risk for serious adverse events in certain of these patient populations is high, which, if those adverse events are determined (or perceived) to be drug-related, could have a negative impact on the safety profile of our products and product candidates and cause significant delays, result in an inability to successfully commercialize our products and materially harm our business.

In certain jurisdictions, we may provide our product for a charge, and in others, we may be required to provide our products free of charge if we participate in expanded access or compassionate use programs. In other jurisdictions we may be required to return some or all of the revenue we may generate through our expanded access or compassionate use programs if the appropriate foreign regulatory authority ultimately does not approve our products or product candidates for marketing in the jurisdiction of our expanded access or compassionate use programs. If this were to occur, it could materially and adversely affect our business operations and financial performance.

Delays, suspensions, variations and terminations in our clinical trials for our product candidates could result in increased costs to us and delay our ability to generate product revenues.

The commencement of clinical trials can be delayed for a variety of reasons, including delays in:

- demonstrating sufficient safety and efficacy to obtain regulatory approval to commence a clinical trial;
- reaching agreement on acceptable terms with prospective contract research organizations (CROs) and clinical trial sites;
- manufacturing sufficient quantities of a product candidate;
- obtaining clearance from the FDA to commence clinical trials pursuant to an Investigational New Drug application;
- obtaining approval to conduct clinical trials in countries or jurisdictions outside the United States pursuant to evolving regional and local regulations (e.g., EU Clinical Trials Regulation (EU No. 536/2014));
- obtaining institutional review board approval or a positive Ethics Committee opinion to conduct a clinical trial at a prospective clinical trial site; and
- patient recruitment, which is a function of many factors, most of which is outside our control, including the size of the patient population, the nature of the protocol (including limitations in the protocol that further limit the size of the potential trial population), the proximity of patients to clinical trial sites, the availability of effective treatments for the relevant disease and the eligibility criteria for the clinical trial.

Once a clinical trial has begun, it may be delayed, suspended, varied or terminated due to a number of factors, including:

- competition for internal and external resources, including clinical sites and study patients, that we may choose to allocate to other programs;
- ongoing discussions with regulatory authorities regarding the scope or design of our clinical trials or requests by them for supplemental information with respect to our clinical trial results;
- imposition of clinical holds by regulatory authorities, institutional review boards or Ethics Committees;
- failure to conduct clinical trials in accordance with regulatory requirements or other irregularities in clinical trial conduct;
- inability to monitor patients adequately during or after treatment;
- difficulty monitoring multiple study sites;
- patient enrollment, which is a function of many factors, most of which is outside our control, including the size of the patient population, the nature of the protocol (including limitations in the protocol that further limit the size of the potential trial population such as, for example, our Phase 2 RADIANT study, which is subject to certain defined enrollment criteria that has caused enrollment to take longer than expected), the proximity of patients to clinical trial sites, the availability of effective treatments for the relevant disease and the eligibility criteria for the clinical trial;
- lower than anticipated screening or retention rates of patients in clinical trials;
- serious adverse events or side effects experienced by participants; and
- insufficient supply or deficient quality of product candidates or other materials necessary for the conduct of our clinical trials.

In addition, enrollment and retention of patients in, or the ability to receive results from, clinical trials could be disrupted by geopolitical or macroeconomic developments. For example, as a result of the conflict between Ukraine and Russia, we experienced temporary delays in accessing historical records of certain clinical trial sites located in Russia. It is possible that enrollment in future studies, could be impacted due to the same or similar geopolitical or macroeconomic developments. If patients withdraw from our trials, miss scheduled doses or follow-up visits or otherwise fail to follow trial protocols, or if our trial results are otherwise disrupted or disputed due to such developments, the integrity of data from our trials may be compromised or not accepted by the FDA or other regulatory authorities, which would represent a significant setback for the applicable program.

Many of these factors may also ultimately lead to denial of regulatory approval of a current or potential future product candidate. If we experience delays, suspensions or terminations in a clinical trial, clinical trial materials or investigational products, the commercial prospects for the related product candidate will be harmed, and our ability to generate product revenues will be delayed.

If we are unable to attract, retain, and motivate key management, research and development, and sales and marketing personnel, our drug development programs, our research and discovery efforts, and our commercialization plans may be delayed and we may be unable to successfully commercialize our products, or develop our product candidates.

Our success depends on our ability to attract, retain, and motivate highly qualified management, scientific, and commercial personnel. In particular, our development programs depend on our ability to attract and retain highly skilled development personnel, especially in the fields of neurological and rare diseases. We are currently hiring, and in the future we expect to need to continue to hire, additional personnel as we expand our research and development efforts for our products and product candidates, and commercial activities for our products. We face competition for experienced management, scientists, clinical operations personnel, commercial and other personnel from numerous companies and academic and other research institutions across all jurisdictions in which our products may be commercialized. Many of the other biotechnology and pharmaceutical companies with whom we compete for qualified personnel have greater financial and other resources, different risk profiles and longer histories in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high quality candidates than that which we have to offer. If we are unable to continue to attract and retain high quality personnel, the rate and success at which we can develop and commercialize products and product candidates, if approved, will be limited. If we are unable to attract and retain the necessary personnel, it will significantly impede our commercialization efforts for our products, and the achievement of our research and development objectives.

All of our employees are “at will” employees, which means that any employee may quit at any time and we may terminate any employee at any time. We do not carry “key person” insurance covering members of senior management.

Risks Related to Our Business

If we fail to develop, acquire or in-license other product candidates or products, our business and prospects would be limited. Even if we obtain rights to other product candidates or products, we will incur a variety of costs and may never realize the anticipated benefits.

Part of our corporate strategy is to develop, acquire or in-license businesses, technologies, product candidates or products that we believe are a strategic fit with our business. The success of this strategy depends in large part on the combination of our regulatory, development and commercial capabilities and expertise and our ability to identify, select and acquire or in-license clinically-enabled product candidates for the treatment of neurological and rare diseases, or for therapeutic indications that complement or augment our current products and product candidates, or that otherwise fit into our development or strategic plans on terms that are acceptable to us. Identifying, selecting and acquiring or in-licensing promising product candidates requires substantial technical, financial and human resources expertise, and we may not be successful in identifying acquisition targets, completing proposed acquisitions and integrating any acquired businesses, technologies, services or products into our current infrastructure. Efforts to do so may not result in the actual acquisition or in-license of a particular product candidate, potentially resulting in a diversion of our management’s time and the expenditure of our resources with no resulting benefit. If we are unable to identify, select and acquire or license suitable product candidates from third parties on terms acceptable to us, our business and prospects will be limited.

The process of integrating any acquired business, technology, service, or product may result in unforeseen operating difficulties and expenditures and may divert significant management attention from our ongoing business operations. As a result, we will incur a variety of costs in connection with an acquisition and may never realize its anticipated benefits.

Moreover, any product candidate we identify, select and acquire or license may require additional, time-consuming development or regulatory efforts prior to commercial sale, including preclinical studies, if applicable, and extensive clinical testing and approval by the FDA and applicable foreign regulatory authorities. All product candidates are prone to the risk of failure that is inherent in pharmaceutical product development, including the possibility that the product candidate will not be shown to be sufficiently safe and/or effective for approval by regulatory authorities. In addition, any such products that are approved may not be manufactured or produced economically, successfully commercialized or widely accepted in the marketplace or be more effective or desired than other commercially available alternatives.

We may require additional financing in the future to fund our operations. If we cannot raise additional financing in the future, we may be unable to fund our business plan and our future research, development, commercial and manufacturing efforts.

We have funded our operations primarily with revenues from sales of our products since their approvals, and through sales of our equity securities and interest income. We anticipate that the level of cash used in our operations will fluctuate in future periods depending on the levels of spending required for our ongoing and planned commercial activities for our products, our ongoing and planned development activities for remlifanserin as a treatment for ADP and LBDP, studies to be conducted pursuant to our PMRs, our ongoing and planned development activities for other early- and late-stage product candidates and strategic business development to further expand our portfolio. We expect that our cash, cash equivalents and investment securities, as well as funds generated by anticipated sales of our products, will be sufficient to fund our planned operations through and beyond the next 12 months.

We may require additional financing in the future to fund our operations. Our future capital requirements will depend on, and could increase significantly as a result of, many factors, including:

- the costs of acquiring additional product candidates or research and development programs;
- the scope, prioritization and number of our research and development programs;
- the ability of our collaborators and us to reach the milestones and other events or developments triggering payments under our collaboration or license agreements, or our collaborators' ability to make payments under these agreements;
- our ability to enter into new collaboration and license agreements;
- the progress in, and the costs of, our ongoing and planned development activities for pimavanserin, post-marketing studies for DAYBUE to be conducted over the next several years, and ongoing and planned commercial activities for our products;
- the costs of our development activities for our product candidates;
- the costs of commercializing our products, including the maintenance and development of our sales and marketing capabilities;
- the costs of establishing, or contracting for, sales and marketing capabilities for our product candidates;
- the amount of U.S. product sales from our products;
- the costs of preparing applications for regulatory approvals for DAYBUE in jurisdictions other than the U.S. and for other product candidates, as well as the costs required to support review of such applications;
- the costs of manufacturing and distributing our products for commercial use in the U.S.;
- our ability to obtain regulatory approval for, and subsequently generate product sales from our product candidates;
- the extent to which we are obligated to reimburse collaborators or collaborators are obligated to reimburse us for costs under collaboration agreements;
- the costs involved in filing, prosecuting, enforcing, and defending patent claims and other intellectual property rights;
- the costs of maintaining or securing manufacturing arrangements for clinical or commercial production of pimavanserin, trofinetide or other product candidates; and

- the costs associated with litigation, including the costs incurred in defending against any product liability claims that may be brought against us related to our products.

In the past, periods of turmoil and volatility in the financial markets have adversely affected the market capitalizations of many biotechnology companies, and generally made equity and debt financing more difficult to obtain. For example, as a result of geopolitical and macroeconomic developments, the global credit and financial markets have experienced extreme volatility and disruptions, including diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. These events, coupled with other factors, may limit our access to additional financing in the future if needed, and could have a material adverse effect on our ability to access sufficient funding. We cannot be certain that additional funding will be available to us on a timely basis, on acceptable terms, or at all. If additional funds are not available, we will be required to delay, reduce the scope of, or eliminate one or more of our research or development programs or our commercialization efforts. We also may be required to relinquish greater or all rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose. Additional funding, if necessary and obtained, may significantly dilute existing stockholders and could negatively impact the price of our stock.

We expect that our results of operations will fluctuate, which may make it difficult to predict our future performance from period to period.

Our operating results have fluctuated in the past and are likely to do so in future periods. Some of the factors that could cause our operating results to fluctuate from period to period include:

- the success of our commercialization of our products;
- the impact of geopolitical and macroeconomic developments, international tariffs, general political, health and economic conditions, as well as any related political or economic responses and counter-responses or otherwise by various global actors or the general effect on the global economy and supply chain, pandemics or epidemics, economic slowdowns, recessions, inflation, high interest rates and tightening of credit markets on our business;
- the status and cost of our PMRs for DAYBUE;
- the variation in our gross-to-net adjustments from quarter to quarter, primarily because of the fluctuation in our share of the donut hole for Medicare Part D patients;
- the status and cost of development and commercialization of our product candidates, if approved, including compounds being developed under our collaborations;
- whether we acquire or in-license additional product candidates or products, and the status of development and commercialization of such product candidates, if approved, or products;
- whether we are required to make payments due to achieving specified milestones under any licensing or similar agreements or otherwise make payments under these agreements;
- the incurrence of preclinical or clinical expenses that could fluctuate significantly from period to period, including reimbursement obligations pursuant to our collaboration agreements;
- the initiation, termination, or reduction in the scope of our collaborations or any disputes regarding these collaborations;
- the timing of our satisfaction of applicable regulatory requirements;
- the rate of expansion of our clinical development, other internal research and development efforts, and pre-commercial and commercial efforts;
- the effect of competing technologies and products and market developments;
- the costs associated with litigation, including the costs incurred in defending against any product liability claims that may be brought against us related to our products or our product candidates; and
- general and industry-specific economic conditions.

We believe that comparisons from period to period of our financial results are not necessarily meaningful and should not be relied upon as indications of our future performance.

From time to time, we provide guidance relating to our expectations for total revenue, net sales of our products and certain expense line items based on estimates and the judgment of management at the time. If, for any reason, our actual total revenue, net sales or expenses differ materially from our guidance, we may have to revise our previously announced financial guidance. If we revise previously announced financial guidance, such revisions may not reflect actual results due to, among other things, being based on our management's estimates and judgments at the time. If we change, update or fail to meet any element of such guidance, our stock price could decline.

Changes in tax laws or regulations that are applied adversely to us or our customers may have a material adverse effect on our business, cash flow, financial condition or results of operations.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business operations and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, legislation referred to as the OBBBA, enacted in 2025, along with prior U.S. federal tax reform legislation, enacted many significant changes to the U.S. taxation of business entities, including, among other changes, changes to the taxation of income derived from international operations, changes in the deduction and amortization of research and development expenditures, and limitations on the deductibility of business interest. For example, for tax years beginning after December 31, 2024, the OBBBA restores the tax deductibility of domestic research and development expenses in the year incurred, which expenses had been required under prior legislation to be capitalized and subsequently amortized over five years. The OBBBA did not change the tax treatment of expenses incurred in research and development activities conducted outside the United States, which expenses continue to be required to be capitalized and amortized over 15 years. We are evaluating the potential impacts this and other changes under the OBBBA may have on our business. Future guidance from the Internal Revenue Service and other tax authorities with respect to any legislation may affect us, and certain aspects of such legislation could be repealed or modified in future legislation or sunset in future years. In addition, it is uncertain if and to what extent various states will conform to federal tax laws. Future tax reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges, and could increase our future U.S. tax expense.

Our ability to use net operating loss carryforwards and certain other tax attributes to offset future taxable income or taxes may be limited.

Portions of our net operating loss carryforwards could expire unused and be unavailable to offset future income tax liabilities. U.S. federal net operating losses incurred in tax years beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such federal net operating loss carryforwards in a taxable year is limited to 80% of taxable income in such year. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the Code), and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50 percent change, by value, in its equity ownership over a three-year period, the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. We have experienced ownership changes in the past and we may experience additional ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. If an ownership change occurs and our ability to use our net operating loss carryforwards is materially limited, it would harm our future operating results by effectively increasing our future tax obligations. In addition, at the state level, there may be periods during which the use of net operating loss carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. For example, California imposed limits on the usability of California state net operating losses to offset taxable income in tax years beginning after 2023 and before 2027. As a result, if we earn net taxable income, we may be unable to use all or a material portion of our net operating loss carryforwards and other tax attributes, which could potentially result in increased future tax liability to us and adversely affect our future cash flows.

Tax authorities could reallocate our taxable income among our subsidiaries, which could increase our overall tax liability.

The amount of taxes we pay in different jurisdictions depends on the application of the tax laws of various jurisdictions, including the United States, to our international business activities, tax rates, new or revised tax laws, or interpretations of tax laws and policies, and our ability to operate our business in a manner consistent with our corporate structure and intercompany arrangements. In 2015, we licensed worldwide intellectual property rights related to pimavanserin in certain indications to Acadia Pharmaceuticals GmbH, our wholly owned Swiss subsidiary (Acadia GmbH), and in July 2020 we licensed additional related rights to Acadia GmbH. Our goals for the establishment of Acadia GmbH, and the licensing of worldwide intellectual property rights for pimavanserin, include building a platform for long-term operational and financial efficiencies, including tax-related efficiencies. The taxing authorities of the jurisdictions in which we operate may challenge our methodologies for pricing intercompany transactions pursuant to our intercompany arrangements or

disagree with our determinations as to the income and expenses attributable to specific jurisdictions. In addition, future changes in U.S. and non-U.S. tax laws, including implementation of international tax reform relating to the tax treatment of multinational corporations, if enacted, may reduce or eliminate any potential financial efficiencies that we hoped to achieve by establishing this operational structure. Additionally, taxing authorities, such as the U.S. Internal Revenue Service, may audit and otherwise challenge these types of arrangements, and have done so with other companies in the pharmaceutical industry. If any such challenge or disagreement were to occur or change in tax law were enacted, we could be required to pay additional taxes, interest and penalties, which could result in one-time tax charges, higher effective tax rates, reduced cash flows and lower overall profitability of our operations. Our financial statements could fail to reflect adequate reserves to cover such a contingency. Similarly, a taxing authority could assert that we are subject to tax in a jurisdiction where we believe we have not established a taxable connection, often referred to as a "permanent establishment" under international tax treaties, and such an assertion, if successful, could increase our expected tax liability in one or more jurisdictions.

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

Our results of operations could be adversely affected by general conditions in the U.S. and global economies, the U.S. and global financial markets and adverse macroeconomic developments. U.S. and global market and economic conditions have been, and continue to be, disrupted and volatile due to many factors, including international tariffs, material shortages and related manufacturing and supply chain challenges, shutdowns of the federal government and the resulting effects on its regulatory agencies, geopolitical developments (as well as any related political or economic responses and counter-responses or otherwise by various global actors or the general effect on the global economy and manufacturing and supply chain), and the responses by central banking authorities to control inflation, among others. General business and economic conditions that could affect our business, financial condition or results of operations include fluctuations in economic growth, debt and equity capital markets, liquidity of the global financial markets, the availability and cost of credit, investor and consumer confidence, and the strength of the economies in which we, our collaborators, our manufacturers and our suppliers operate.

A severe or prolonged global economic downturn could result in a variety of risks to our business. For example, high inflation may result in increases in our operating costs (including our labor costs), reduced liquidity and limits on our ability to access credit or otherwise raise capital on acceptable terms, if at all. In addition, reduced government spending and volatility in financial markets may have the effect of further increasing economic uncertainty and heightening these risks. Risks of a prolonged global economic downturn are particularly true in Europe, which is undergoing a continued severe economic crisis. A weak or declining economy could also strain our suppliers and manufacturers, possibly resulting in supply and clinical trial disruption. 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 business.

International trade policies, including tariffs, sanctions and trade barriers may adversely affect our business, financial condition, results of operations and prospects.

We operate in a global economy, and our business depends on a global supply chain for the development, manufacturing, and distribution of our pharmaceutical products, and for the advancement of our preclinical and clinical development programs. There is inherent risk, based on the complex relationships among the U.S. and the countries in which we conduct our business, that political, diplomatic, and national security factors can lead to global trade restrictions and changes in trade policies and export regulations that may adversely affect our business and operations. The current international trade and regulatory environment is subject to significant ongoing uncertainty.

We source significant quantities of active pharmaceutical ingredients (APIs), precursor chemicals, and specialized equipment from international suppliers, with substantial reliance on foreign manufacturers, including China. Tariff policies, particularly those affecting China and pharmaceutical products, could materially increase our costs and reduce our profitability, including as a result of our inability to adjust pricing in formulary-based markets. Recent and potential future changes in international trade policies, including U.S.-China trade relations and pharmaceutical-specific tariffs, present material risks to our operations and financial performance.

Recent policy discussions have included potential targeted tariffs or other trade measures specifically aimed at pharmaceutical products and ingredients as part of broader healthcare cost control or national security initiatives. For example, the Bureau of Industry and Security, U.S. Department of Commerce, has initiated an investigation to determine whether pharmaceutical ingredients, including finished drug product, manufactured outside the United States pose a national security risk and should be subject to additional tariffs. Unlike consumer goods, pharmaceuticals face unique regulatory, technology and capacity constraints that make rapid supply chain adjustments particularly difficult and costly. Should the current tariffs hold or additional tariffs be imposed specifically targeting pharmaceutical imports, our production costs could

rise significantly, and it would be difficult and costly to qualify alternative sources within another country with a lower tariff rate or within the United States, as developing and qualifying alternative sources typically requires substantial lead time and substantial investment and regulatory approvals. Moreover, the dynamic and unpredictable tariff and trade landscape creates substantial uncertainty and significant planning challenges for our operations and to our CMOs' long term capital investment plans. Changes in tariff classifications, country-of-origin requirements, or customs procedures can occur with limited notice. This uncertainty complicates our long-term investment decisions regarding manufacturing facilities, supply chain optimization, and research and development locations.

Unlike many industries, our ability to pass increased costs to customers is limited by the structure of pharmaceutical pricing and reimbursement systems. Many of our products are included in formularies with pricing established through annual or multi-year contracts with commercial, third-party payors and pharmacy benefit managers, and reimbursement methodologies established by government programs, such as Medicare and Medicaid. These arrangements typically include fixed pricing terms that were determined prior to the implementation of the recently announced tariffs and well ahead of payors' fiscal cycles (typically 12-18 months ahead of a calendar year). As a result, and depending on their timing and scope, tariff-induced cost increases may be difficult or impossible to pass through to customers until the 2027 calendar year at the earliest, perhaps even a year later.

Current or future tariffs will also result in increased research and development expenses, including with respect to increased costs associated with APIs, raw materials, laboratory equipment and research materials and components. Trade restrictions affecting the import of materials necessary for clinical trials could result in delays to our development timelines. Increased development costs and extended development timelines could place us at a competitive disadvantage compared to companies operating in regions with more favorable trade relationships and could reduce investor confidence and negatively impact our business, results of operations, financial condition and growth prospects.

The complexity of announced or future tariffs may also increase the risk that we or our suppliers may be subject to civil or criminal enforcement actions in the United States or foreign jurisdictions related to compliance with trade regulations. Foreign governments may also adopt non-tariff measures, such as procurement preferences or informal disincentives to engage with, purchase from or invest in U.S. entities, which may limit our ability to compete internationally and attract non-U.S. investment, employees, customers and suppliers. Foreign governments may also take other retaliatory actions against U.S. entities, such as decreased intellectual property protection, increased enforcement actions, or delays in regulatory approvals, which may result in heightened international legal and operational risks. In addition, the United States and other governments have imposed and may continue to impose additional sanctions, such as trade restrictions or trade barriers, which could restrict us from doing business directly or indirectly in or with certain countries or parties and may impose additional costs and complexity to our business.

Trade disputes, tariffs, restrictions and other political tensions between the United States and other countries may also exacerbate unfavorable macroeconomic conditions including inflationary pressures, foreign exchange volatility, financial market instability, and economic recessions or downturns. The ultimate impact of current or future tariffs and trade restrictions remains uncertain and could materially and adversely affect our business, financial condition, and prospects. While we actively monitor these risks, any prolonged economic downturn, escalation in trade tensions, or deterioration in international perception of U.S.-based companies could materially and adversely affect our business, ability to access the capital markets or other financing sources, results of operations, financial condition and prospects. In addition, tariffs and other trade developments have and may continue to heighten the risks related to the other risk factors described elsewhere in this report.

We or the third parties upon whom we depend may be adversely affected by catastrophic events, such as earthquakes, fires or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

We depend on our employees, consultants, and CROs, as well as regulatory agencies and other parties, for the continued operation of our business. While we maintain disaster recovery plans, those plans may not adequately protect us. Despite any precautions that we or any third parties on whom we depend take for catastrophic events, including earthquakes, fires or other natural disasters, these events could result in significant disruptions to our research and development, clinical trials, manufacturing and the commercialization of our products. Long-term disruptions in the infrastructure caused by these types of events, particularly involving geographies in which we or third parties on whom we depend have offices or manufacturing, distribution or clinical trial sites, could adversely affect our businesses, including as a result of the affected third parties' decision to deprioritize their service commitments to us. Although we carry business interruption insurance policies and typically have provisions in our contracts that protect us in certain events, our coverage might not include or be adequate to compensate us for all losses that may occur. Any catastrophic event affecting us or the third parties on whom we depend could have a material adverse effect on our business, results of operations, financial condition and prospect.

We have incurred, and expect to continue to incur, significant costs as a result of laws, regulations and standards relating to various aspects of our business, including corporate governance, work force initiatives and other matters, and failure to comply with such laws, regulations and standards could adversely affect our business.

Laws, regulations and standards affecting various aspects of our business, including as a result of provisions of the Dodd-Frank Wall Street Reform and Consumer Protection Act that was enacted in July 2010, the provisions of the Sarbanes-Oxley Act of 2002 (SOX), rules adopted or proposed by the SEC and by The Nasdaq Stock Market and executive orders, have resulted in, and will continue to result in, significant costs to us as we evaluate the implications of these laws, regulations and standards and respond to their requirements. Certain laws, regulations and standards are subject to varying interpretations in some cases due to their lack of specificity, and as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies, which could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure, policies and governance practices. For example, in the future, if we are not able to issue an evaluation of our internal control over financial reporting, as required, or we or our independent registered public accounting firm determine that our internal control over financial reporting is not effective, this shortcoming could have an adverse effect on our business and financial results and the price of our common stock could be negatively affected. Further, new laws, regulations and standards could make it more difficult or more costly for us to operate our business, including obtaining certain types of insurance (such as director and officer liability insurance), and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the coverage that is the same or similar to our current coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors and board committees, and as our executive officers. If we fail, or are perceived to fail, to comply with these laws, regulations and standards, our reputation may be harmed and we might be subject to litigation, sanctions, investigations or other regulatory proceedings, which would adversely affect our financial results and our business. We cannot predict or estimate the total amount of the costs we may incur or the timing of such costs to comply with these laws, regulations and standards.

Our business involves the use of hazardous materials, and we and our third-party manufacturers and suppliers must comply with environmental, health and safety laws and regulations, which can be expensive and restrict how we do, or interrupt our, business.

Our research and development activities and our third-party manufacturers' and suppliers' activities involve the generation, storage, use and disposal of hazardous materials, including the components of our products and product candidates and other hazardous compounds and wastes. We and our manufacturers and suppliers are subject to environmental, health and safety laws and regulations governing, among other matters, the use, manufacture, generation, storage, handling, transportation, discharge and disposal of these hazardous materials and wastes and worker health and safety. In some cases, these hazardous materials and various wastes resulting from their use are stored at our and our manufacturers' facilities pending their use and disposal. We cannot eliminate the risk of contamination or injury, which could result in an interruption of our commercialization efforts, research and development efforts and business operations, damages and significant cleanup costs and liabilities under applicable environmental, health and safety laws and regulations. We also cannot guarantee that the safety procedures utilized by our third-party manufacturers for handling and disposing of these materials and wastes generally comply with the standards prescribed by these laws and regulations. We may be held liable for any resulting damages costs or liabilities, which could exceed our resources, and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental,

health and safety laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. Failure to comply with these environmental, health and safety laws and regulations may result in substantial fines, penalties or other sanctions. We do not currently carry hazardous waste insurance coverage.

Our management has broad discretion over the use of our cash and we may not use our cash effectively, which could adversely affect our results of operations.

Our management has significant flexibility in applying our cash resources and could use these resources for corporate purposes that do not increase our market value, or in ways with which our stockholders may not agree. We may use our cash resources for corporate purposes that do not yield a significant return or any return at all for our stockholders, which may cause our stock price to decline.

Risks Related to Our Relationships with Third Parties

We depend on collaborations with third parties to develop certain of our product candidates and may need to enter into future collaborations to develop and commercialize certain of our product candidates.

We depend on collaborations with third parties to develop certain of our product candidates and may need to enter into future collaborations to develop and commercialize certain of our product candidates. In addition, we may choose to rely on collaborations in the future for our products or other product candidates, including for the commercialization of DAYBUE in selected markets outside of the U.S.

Our collaborators may fail to develop or effectively commercialize products using our product candidates, if approved, or technologies because they:

- do not have sufficient resources or decide not to devote the necessary resources due to internal constraints such as limited cash or human resources or a change in strategic focus;
- may not properly maintain, enforce or defend our intellectual property rights or may use our proprietary information in a manner that could jeopardize or invalidate our proprietary information or expose us to potential litigation;
- terminate the arrangement or allow it to expire, which would delay the development and commercialization and may increase the cost of developing and commercializing our products or product candidates, if approved;
- may sell, transfer or divest assets or programs related to our partnered product or product candidates;
- may not pursue further development and commercialization of products resulting from the strategic collaboration arrangement;
- decide to pursue a competitive product developed outside of the collaboration; or
- cannot obtain the necessary regulatory approvals.

Collaborations are complex and time-consuming to negotiate and document. Given the current economic and industry environment, it is possible that competition for new collaborators may increase. We may not be able to negotiate additional collaborations on a timely basis, on acceptable terms, or at all. If we are unable to find new collaborations, we may not be able to continue advancing our programs alone.

Our collaborations may be subject to conflicts or disputes, which could have a material adverse effect on our business, results of operations and financial condition.

Conflicts may arise in our collaborations due to one or more of the following:

- disputes or breaches with respect to payments that we believe are due under the applicable agreements, particularly in the current environment when companies, including large established ones, may be seeking to reduce external payments;
- disputes on strategy as to what development or commercialization activities should be pursued under the applicable agreements;

- disputes as to the responsibility for conducting development and commercialization activities pursuant to the applicable collaboration, including the payment of costs related thereto;
- disagreements with respect to ownership of intellectual property rights;
- unwillingness on the part of a collaborator to keep us informed regarding the progress of its development and commercialization activities, or to permit public disclosure of these activities;
- delay or reduction of a collaborator's development or commercialization efforts with respect to our product candidates, if approved; or
- termination or non-renewal of the collaboration.

Conflicts arising with our collaborators could impair the progress of our product candidates, harm our reputation, result in a loss of revenues, reduce our cash position, and cause a decline in our stock price.

In addition, in our past collaborations, from time to time, we have agreed not to conduct independently, or with any third party, any research that is directly competitive with the research conducted under the applicable program. Any collaborations we establish in the future may have the effect of limiting the areas of research that we may pursue, either alone or with others. Conversely, the terms of any collaboration we may establish in the future might not restrict our collaborators from developing, either alone or with others, products or product candidates in related fields that are competitive with the products or product candidates that are the subject of these collaborations. Competing products and product candidates, either developed by our collaborators or to which our collaborators have rights, may result in the allocation of resources by our collaborators to competing products and product candidates, and their withdrawal of support for our products and product candidates or may otherwise result in lower demand for our potential products and product candidates.

In addition, disputes may arise between us and our licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patents and other rights to third parties;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, if approved, and what activities satisfy those diligence obligations;
- our right to transfer or assign the license; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may not be able to successfully develop and commercialize the related product candidates, if approved, which would have a material adverse effect on our business.

We rely on third parties to conduct our clinical trials and perform data collection and analysis, which may result in costs and delays that prevent us from successfully commercializing product candidates, if approved.

Although we design and manage our current preclinical studies and clinical trials, we currently do not have the ability to conduct clinical trials for our product candidates on our own. We rely on CROs, medical institutions, clinical investigators, and contract laboratories to perform data collection and analysis and other aspects of our clinical trials. In addition, we also rely on third parties to assist with our preclinical studies, including studies regarding biological activity, safety, absorption, metabolism, and excretion of product candidates. Some of these third parties may experience shutdowns or other disruptions as a result of adverse geopolitical or macroeconomic developments and therefore may be unable to provide the level of service that we have received in the past.

Our preclinical activities or clinical trials may be delayed, suspended, or terminated if:

- these third parties do not successfully carry out their contractual duties or fail to meet regulatory obligations or expected deadlines;

- these third parties need to be replaced; or
- the quality or accuracy of the data obtained by these third parties is compromised due to their failure to adhere to our clinical protocols or regulatory requirements or for other reasons.

Failure to perform by these third parties may increase our development costs, delay our ability to obtain regulatory approval, and delay or prevent the commercialization of our product candidates, if approved. We currently use several CROs to perform services for our preclinical studies and clinical trials. While we believe that there are numerous alternative sources to provide these services, in the event that we seek such alternative sources, we may not be able to enter into replacement arrangements without delays, additional expenditures, or at all, any of which could negatively affect our business, results of operations, financial condition and prospects.

We currently depend, and in the future will continue to depend, on third parties to manufacture our products and product candidates. If these manufacturers fail to provide us or our collaborators with adequate supplies of clinical trial materials and commercial product or fail to comply with the requirements of regulatory authorities, we may be unable to develop or commercialize our products or product candidates, if approved.

We have no manufacturing facilities and only limited experience as an organization in the manufacturing of drugs or in designing drug-manufacturing processes. We have contracted with third-party manufacturers to produce, in collaboration with us, our products and product candidates.

We have contracted with Patheon to manufacture NUPLAZID 10 mg tablet and 34 mg capsule drug product and DAYBUE for commercial use, Catalent to manufacture NUPLAZID 34 mg drug product for commercial use in the U.S., Bend to manufacture DAYBUE for commercial use, and Halo to manufacture trofinetide DAYBUE STIX 5g, 6g, and 8g drug product stick packs for commercial use in the U.S. Additionally, we have contracted with Siegfried to manufacture API to be used in the manufacture of NUPLAZID drug product for commercial use, and Corden, FIS and Flamma to manufacture API to be used in the manufacture of DAYBUE drug product for commercial use. However, we have not entered into any agreements with any alternate suppliers for 10 mg NUPLAZID drug product or NUPLAZID API. We may face delays or increased costs in our supply chain that could jeopardize the commercialization of our products. While we currently have sufficient API for both NUPLAZID and DAYBUE and NUPLAZID and DAYBUE finished products on hand to continue our commercial and clinical operations as planned, depending on the effects of geopolitical and macroeconomic developments and whether such developments cause disruptions, we may face such delays or costs in future years. If any third party in our supply or distribution chain for materials or finished product is adversely impacted by geopolitical and macroeconomic developments, including rapid changes in U.S. trade policy, such as the imposition of tariffs and trade barriers as well as potential retaliatory measures taken by other governments, our supply chain may be disrupted, limiting our ability to manufacture, test and distribute our products for commercial sales and our product candidates for our clinical trials and research and development operations. For example, it takes approximately two years for our third-party manufacturers to produce DAYBUE API, and a supply chain disruption in DAYBUE API would cause delays or increased costs to us that could jeopardize the commercialization of DAYBUE.

Even though we have agreements with third parties for the manufacture of our products, the FDA or comparable foreign regulatory authorities may not approve the facilities of such manufacturers, the manufacturers may not perform as agreed, or the manufacturers may terminate their agreements with us. If any of the foregoing circumstances occur, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, maintain or obtain, as applicable, regulatory approval for or market our products or product candidates. While we believe that there will be alternative sources available to manufacture our products and product candidates, in the event that we seek such alternative sources, we may not be able to enter into replacement arrangements without delays or additional expenditures. We cannot estimate these delays or costs with certainty but, if they were to occur, they could cause a delay in our development and commercialization efforts, which would have a negative effect on our business, results of operations, financial condition and prospects.

The manufacturers of our products and product candidates, including Patheon, Calatent, Bend, Halo, Siegfried, Corden, FIS and Flamma, are obliged to operate in accordance with FDA-mandated and comparable foreign regulatory authorities' current good manufacturing practices (cGMPs), and we have limited control over the ability of third-party manufacturers to maintain adequate quality control, quality assurance and qualified personnel to ensure compliance with cGMPs. In addition, the facilities used by our third-party manufacturers to manufacture our products and product candidates must be approved by the FDA pursuant to inspections that will be conducted prior to any grant of regulatory approval by the FDA. Similar requirements apply abroad. If any of our third-party manufacturers are unable to successfully manufacture material that conforms to our specifications and the FDA's or comparable foreign regulatory authorities' strict regulatory requirements, or

pass regulatory inspection, they will not be able to secure or maintain approval for the manufacturing facilities. We, or our contract manufacturers, any future collaborators and their contract manufacturers could be subject to periodic unannounced inspections by the FDA, competent authorities of EU Member States or other comparable foreign regulatory authorities, to monitor and ensure compliance with cGMP. Despite our efforts to audit and verify regulatory compliance, one or more of our third-party manufacturing vendors may be found on regulatory inspection by the FDA, competent authorities of EU Member States or other comparable foreign regulatory authorities to be noncompliant with cGMP regulations. Additionally, a failure by any of our third-party manufacturers to establish and follow cGMPs or to document their adherence to such practices may lead to significant delays in clinical trials or in obtaining regulatory approval of product candidates, or result in issues maintaining regulatory approval of our products and any product candidate that receives regulatory approval, negatively impact our commercialization of our products, or lead to significant delays in the launch and commercialization of any other products we may have in the future. Failure by our third-party manufacturers or us to comply with applicable regulations could result in sanctions being imposed on us, including shutdown of the third-party vendor or invalidation of drug product lots or processes, fines, injunctions, civil penalties, failure of regulatory authorities to grant pre-market approval of drugs, delays, suspension, variation or withdrawal of approvals, seizures or recalls of products, operating restrictions, and criminal prosecutions, any of which could significantly and adversely affect supplies of our products, if approved, and significantly harm our business, financial condition, results of operations and prospects.

The manufacture of pharmaceutical products requires significant capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production. These problems include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. We cannot assure you that any issues relating to the manufacture of our products or product candidates will not occur in the future. Additionally, our manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If our manufacturers were to encounter any of these difficulties, or otherwise fail to comply with their contractual obligations, our ability to commercialize our products, or provide our products or product candidates to patients in clinical trials, would be jeopardized. Any delay or interruption in our ability to meet commercial demand for our products and any other approved products will result in the loss of potential revenues and could adversely affect our ability to gain market acceptance for these products. In addition, any delay or interruption in the supply of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely.

Failures or difficulties faced at any level of our supply chain could materially adversely affect our business and delay or impede the development and commercialization of our products or product candidates, if approved, and could have a material adverse effect on our business, results of operations, financial condition and prospects. Further, changes in federal policy could affect the geopolitical landscape and could give rise to circumstances that negatively affect our business. The third parties that manufacture our products and product candidates have manufacturing activities located in Canada, the European Union and Switzerland. The U.S. has implemented, and has proposed to further implement, tariffs that may affect the availability of imported raw materials used in the production of our products and/or increase the costs of our third-party manufacturers and the expense to us to produce our products and product candidates. Additionally, other governments have enacted, and may continue to enact, retaliatory measures in response to such tariffs. If such actions were to materially affect us or our third-party manufacturers, we may not be able to successfully commercialize our products, which would have an adverse effect on our results of operations.

We may not be able to continue or fully exploit our collaborations with outside scientific and clinical advisors, which could impair the progress of our clinical trials and our research and development efforts.

We work with scientific and clinical advisors at academic and other institutions who are experts in the field of neurological and rare diseases. They assist us in our research and development efforts and advise us with respect to our clinical trials. These advisors are not our employees and may have other commitments that would limit their future availability to us. Although our scientific and clinical advisors generally agree not to engage in competing work, if a conflict of interest arises between their work for us and their work for another entity, we may lose their services, which may impair our reputation in the industry and delay the development or commercialization of our product candidates, if approved.

Risks Related to Our Intellectual Property

Our ability to compete may decline if we do not adequately protect our proprietary rights.

Our commercial success depends on obtaining and maintaining intellectual property rights to our products and product candidates and technologies, as well as successfully defending these rights against third-party challenges. Successful challenges to, or misappropriation of, our intellectual property could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market. To protect our intellectual property, we rely on a combination of patents, trade secret protection and contracts requiring confidentiality and nondisclosure. If our patents are successfully challenged, we may face generic competition prior to the expiration dates of our U.S. Orange Book listed patents. In addition, potential competitors have in the past and may in the future file an Abbreviated New Drug Application (ANDA) with the FDA for generic versions of NUPLAZID, seeking approval prior to the expiration of our patents. In response, we have filed complaints against these companies alleging infringement of certain of our Orange Book-listed patents covering NUPLAZID and DAYBUE. For a more detailed description of these matters, see the section captioned "Legal Proceedings" elsewhere in this report. While we intend to defend the validity of such patents vigorously, and will seek to use all appropriate methods to prevent their infringement, such efforts are expensive and time consuming. Any substantial decrease in the revenue and income derived from our products would have an adverse effect on our results of operations.

With regard to patents, although we control numerous patent applications worldwide with respect to pimavanserin and trofinetide, not all of our patent applications resulted in an issued patent, or they resulted in an issued patent that is susceptible to challenge by a third party. Our ability to obtain, maintain, and/or defend our patents covering our product candidates and technologies is uncertain due to a number of factors, including:

- we may not have been the first to make the inventions covered by our pending patent applications or issued patents;
- we may not have been the first to file patent applications for our product candidates or the technologies we rely upon;
- others may develop similar or alternative technologies or design around our patent claims to produce competitive products that fall outside of the scope of our patents;
- our disclosures in patent applications may not be sufficient to meet the statutory requirements for patentability;
- we may not seek or obtain patent protection in all countries that will eventually provide a significant business opportunity;
- any patents issued to us or our collaborators may not provide a basis for commercially viable products, may not provide us with any competitive advantages, or are easily susceptible to challenges by third parties;
- our proprietary technologies may not be patentable;
- changes to patent laws that limit the exclusivity rights of patent holders or make it easier to render a patent invalid;
- recent decisions by the U.S. Supreme Court limiting patent-eligible subject matter;
- litigation regarding our patents may include challenges to the validity, enforceability, scope and term of one or more patents;
- the passage of The Leahy-Smith America Invents Act (the America Invents Act), introduced new procedures for challenging pending patent applications and issued patents; and
- technology that we may in-license may become important to some aspects of our business; however, we generally would not control the patent prosecution, maintenance or enforcement of any such in-licensed technology.

Even if we have or obtain patents covering our product candidates or technologies, we may still be barred from making, using and selling our product candidates or technologies because of the patent rights of others. Others have or may have filed, and in the future are likely to file, patent applications covering compounds, assays, genes, gene products or therapeutic products that are similar or identical to ours. There are many issued U.S. and foreign patents relating to genes, nucleic acids, polypeptides, chemical compounds or therapeutic products, and some of these may encompass reagents utilized in the identification of candidate drug compounds or compounds that we desire to commercialize. Numerous U.S. and foreign

issued patents and pending patent applications owned by others exist in the area of neurological diseases and the other fields in which we are developing products. These could materially affect our freedom to operate. Moreover, because patent applications can take many years to issue, there may be currently pending applications, unknown to us, that may later result in issued patents that our product candidates or technologies may infringe. These patent applications may have priority over patent applications filed by us.

We regularly conduct searches to identify patents or patent applications that may prevent us from obtaining patent protection for our proprietary compounds or that could limit the rights we have claimed in our patents and patent applications. Disputes may arise regarding the ownership or inventorship of our inventions. For applications in which all claims are entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third-party or instituted by the U.S. Patent and Trademark Office (U.S. PTO), to determine who was the first to invent the invention at issue. It is difficult to determine how such disputes would be resolved. Applications containing a claim not entitled to priority before March 16, 2013, are not subject to interference proceedings due the change brought by the America Invents Act to a "first-to-file" system. However, a derivation proceeding can be brought by a third-party alleging that the inventor derived the invention from another.

Periodic maintenance fees on any issued patent are due to be paid to the U.S. PTO and foreign patent agencies in several stages over the lifetime of the patent. The U.S. PTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, 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. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

Some of our academic institutional licensors, research collaborators and scientific advisors have rights to publish data and information to which we have rights. We generally seek to prevent our collaborators from disclosing scientific discoveries until we have the opportunity to file patent applications on such discoveries, but in some cases, we are limited to relatively short periods to review a proposed publication and file a patent application. If we cannot maintain the confidentiality of our technology and other confidential information in connection with our collaborations, then our ability to receive patent protection or protect our proprietary information may be impaired.

Confidentiality agreements with employees and others may not adequately prevent disclosure of our trade secrets and other proprietary information and may not adequately protect our intellectual property, which could limit our ability to compete.

Because we operate in the highly technical field of drug discovery and development of small molecule drugs, we rely in part on trade secret protection in order to protect our proprietary technology and processes. However, trade secrets are difficult to protect. We enter into confidentiality, nondisclosure, and intellectual property assignment agreements with our corporate partners, employees, consultants, outside scientific collaborators, sponsored researchers, and other advisors. These agreements generally require that the other party keep confidential and not disclose to third parties all confidential information developed by the party or made known to the party by us during the course of the party's relationship with us. These agreements also generally provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, these agreements may not be honored and may not effectively assign intellectual property rights to us. Enforcing a claim that a party illegally obtained and is using our trade secrets is difficult, expensive and time consuming and the outcome is unpredictable. In addition, courts outside the U.S. may be less willing to protect trade secrets. We also have not entered into any noncompete agreements with any of our employees. Although each of our employees is required to sign a confidentiality agreement with us at the time of hire, we cannot guarantee that the confidential nature of our proprietary information will be maintained in the course of future employment with any of our competitors. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, operating results and financial condition.

A dispute concerning the infringement or misappropriation of our proprietary rights or the proprietary rights of others could be time-consuming and costly, and an unfavorable outcome could harm our business.

There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including post-issuance review proceedings before the U.S. PTO or oppositions and other comparable proceedings in foreign jurisdictions.

Central provisions of the America Invents Act went into effect on September 16, 2012 and on March 16, 2013. The America Invents Act includes a number of significant changes to U.S. patent law. These changes include provisions that affect the way patent applications are being filed, prosecuted and litigated. For example, the America Invents Act enacted proceedings involving post-issuance patent review procedures, such as inter partes review (IPR), and post-grant review, that allow third parties to challenge the validity of an issued patent in front of the U.S. PTO Patent Trial and Appeal Board. Each proceeding has different eligibility criteria and different patentability challenges that can be raised. IPRs permit any person (except a party who has been litigating the patent for more than a year) to challenge the validity of the patent on the grounds that it was anticipated or made obvious by prior art. Patents covering pharmaceutical products have been subject to attack in IPRs from generic drug companies and from hedge funds. If it is within nine months of the issuance of the challenged patent, a third party can petition the U.S. PTO for post-grant review, which can be based on any invalidity grounds and is not limited to prior art patents or printed publications.

In post-issuance proceedings, U.S. PTO rules and regulations generally tend to favor patent challengers over patent owners. For example, unlike in district court litigation, claims challenged in post-issuance proceedings are given their broadest reasonable meaning, which increases the chance a claim might be invalidated by prior art or lack support in the patent specification. As another example, unlike in district court litigation, there is no presumption of validity for an issued patent, and thus, a challenger's burden to prove invalidity is by a preponderance of the evidence, as opposed to the heightened clear and convincing evidence standard. As a result of these rules and others, statistics released by the U.S. PTO show a high percentage of claims being invalidated in post-issuance proceedings. Moreover, with few exceptions, there is no standing requirement to petition the U.S. PTO for inter partes review or post-grant review. In other words, companies that have not been charged with infringement or that lack commercial interest in the patented subject matter can still petition the U.S. PTO for review of an issued patent. Thus, even where we have issued patents, our rights under those patents may be challenged and ultimately not provide us with sufficient protection against competitive products or processes.

We may be exposed to future litigation by third parties based on claims that our product candidates, technologies or activities infringe the intellectual property rights of others. In particular, there are many patents relating to specific genes, nucleic acids, polypeptides or the uses thereof to identify product candidates. Some of these may encompass genes or polypeptides that we utilize in our drug development activities. If our drug development activities are found to infringe any such patents, and such patents are held to be valid and enforceable, we may have to pay significant damages or seek licenses to such patents. A patentee could prevent us from using the patented genes or polypeptides for the identification or development of drug compounds. There are also many patents relating to chemical compounds and the uses thereof. If our compounds are found to infringe any such patents, and such patents are held to be valid and enforceable, we may have to pay significant damages or seek licenses to such patents. A patentee could prevent us from making, using or selling the patented compounds.

In addition to the patent infringement lawsuits against the filers of ANDAs pertaining to NUPLAZID, we may need to resort to litigation to enforce other patents issued to us, protect our trade secrets or determine the scope and validity of third-party proprietary rights. From time to time, we may hire scientific personnel formerly employed by other companies involved in one or more areas similar to the activities conducted by us. Either we or these individuals may be subject to allegations of trade secret misappropriation or other similar claims as a result of their prior affiliations. If we become involved in litigation, it could consume a substantial portion of our managerial and financial resources, regardless of whether we win or lose. We may not be able to afford the costs of litigation. Any legal action against us or our collaborators could lead to:

- payment of damages, which could potentially be trebled if we are found to have willfully infringed a party's patent rights;
- injunctive or other equitable relief that may effectively block our ability to further develop, commercialize, and sell products; or
- we or our collaborators having to enter into license arrangements that may not be available on commercially acceptable terms, or at all.

As a result, we could be prevented from commercializing current or future products.

Furthermore, because of the substantial amount of pre-trial document and witness 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. In addition, during the course of this kind of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. Securities analysts and investors have in the past, and may again in the future perceive these results to be negative, it could have a substantial adverse effect on the trading price of our common stock.

The patent applications of pharmaceutical and biotechnology companies involve highly complex legal and factual questions, which, if determined adversely to us, could negatively impact our patent position.

The strength of patents in the pharmaceutical and biotechnology field can be highly uncertain and involve complex legal and factual questions. The U.S. PTO's interpretation of the Supreme Court's decisions and the standards for patentability it sets forth are uncertain and could change in the future. Consequently, the issuance and scope of patents cannot be predicted with certainty. Patents, if issued, may be challenged, invalidated or circumvented. U.S. patents and patent applications may also be subject to interference proceedings as mentioned above, and U.S. patents may be subject to reexamination and post-issuance proceedings in the U.S. PTO (and foreign patents may be subject to opposition or comparable proceedings in the corresponding foreign patent office), which proceedings could result in either loss of the patent or denial of the patent application or loss or reduction in the scope of one or more of the claims of the patent or patent application. Similarly, opposition or invalidity proceedings could result in loss of rights or reduction in the scope of one or more claims of a patent in foreign jurisdictions. In addition, such interference, reexamination, post-issuance and opposition proceedings may be costly. Accordingly, rights under any issued patents may not provide us with sufficient protection against competitive products or processes.

In addition, changes in or different interpretations of patent laws in the U.S. and foreign countries may permit others to use our discoveries or to develop and commercialize our technology and products without providing any compensation to us or may limit the number of patents or claims we can obtain. In particular, there have been proposals to shorten the exclusivity periods available under U.S. patent law that, if adopted, could substantially harm our business. The product candidates that we are developing are protected by intellectual property rights, including patents and patent applications. If any of our product candidates becomes a marketable product, we will rely on our exclusivity under patents to sell the compound and recoup our investments in the research and development of the compound. If the exclusivity period for patents is shortened, then our ability to generate revenues without competition will be reduced and our business could be materially adversely impacted. The laws of some countries do not protect intellectual property rights to the same extent as U.S. laws and those countries may lack adequate rules and procedures for defending our intellectual property rights. For example, some countries, including many in Europe, do not grant patent claims directed to methods of treating humans and, in these countries, patent protection may not be available at all to protect our products and product candidates. In addition, U.S. patent laws may change which could prevent or limit us from filing patent applications or patent claims to protect our products and/or technologies or limit the exclusivity periods that are available to patent holders. For example, the America Invents Act (2012) included a number of significant changes to U.S. patent law. These included changes to transition from a "first-to-invent" system to a "first-to-file" system and to the way issued patents are challenged. These changes may favor larger and more established companies that have more resources to devote to patent application filing and prosecution. It is still not clear what, if any, impact the America Invents Act will ultimately have on the cost of prosecuting our patent applications, our ability to obtain patents based on our discoveries and our ability to enforce or defend our issued patents.

If we fail to obtain and maintain patent protection and trade secret protection of our product candidates, proprietary technologies and their uses, we could lose our competitive advantage and competition we face would increase, reducing our potential revenues and adversely affecting our ability to attain or maintain profitability.

Risks Related to Government Regulation and Our Industry

Healthcare reform measures may negatively impact our ability to sell NUPLAZID, DAYBUE or our product candidates, if approved, profitably.

In both the U.S. and certain foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the healthcare system in ways that could impact our ability to sell our products, as described in greater detail in the Government Regulation section of this report.

For example, the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the ACA), as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we may receive for any of our approved products. The ACA, among other things, expanded and increased industry rebates for drugs covered by Medicaid, made changes to the coverage requirements under Medicare Part D, Medicare's prescription drug benefits program, and broadened access to health insurance. There have been legal and political challenges and amendments to certain aspects of the ACA.

For example, on July 4, 2025, the OBBBA was signed into law, which narrowed access to ACA marketplace exchange enrollment and declined to extend the ACA enhanced advanced premium tax credits that expired at the end of 2025, which, among other provisions in the law, are anticipated to reduce the number of Americans with health insurance. The OBBBA also is expected to reduce Medicaid spending and enrollment by implementing work requirements for some beneficiaries, capping state-directed payments, reducing federal funding, and limiting provider taxes used to fund the program. Congress is considering proposed legislation intended to further reduce healthcare costs with alternatives to replace the expired ACA subsidies. It is unclear how any healthcare reform measures of the current administration will impact the ACA and our business.

Other legislative changes have been proposed and adopted in the U.S. since the ACA. For example, through the process created by the Budget Control Act of 2011, there are automatic reductions of Medicare payments to providers up to 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments, including the Infrastructure Investment and Jobs Act and the Consolidated Appropriations Act of 2023, will remain in effect through 2032 unless additional Congressional action is taken.

An expansion in the government's role in the U.S. healthcare industry may increase existing congressional or governmental agency scrutiny on price increases, such as the ones we have implemented for NUPLAZID, cause general downward pressure on the prices of prescription drug products, lower reimbursements for providers using our products, reduce product utilization and adversely affect our business and results of operations.

The current administration is pursuing policies to reduce regulations and expenditures across government including at HHS, the FDA, the Centers for Medicare & Medicaid Services (CMS) and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. For example, the current administration has announced agreements with several pharmaceutical companies that require the drug manufacturers to offer, through a direct to consumer platform, U.S. patients and Medicaid programs prescription drug Most-Favored Nation pricing equal to or lower than those paid in other developed nations, with additional mandates for direct-to-patient discounts and repatriation of foreign revenues. Other recent actions include, for example: (1) directives to reduce agency workforce and program cuts; (2) directing HHS and other agencies to lower prescription drug costs for Medicare through a variety of initiatives, including by improving upon the Medicare Drug Price Negotiation Program and establishing Most-Favored-Nation pricing for pharmaceutical products; (3) imposing tariffs on imported pharmaceutical products; and (4) as part of the Make America Healthy Again (MAHA) Commission's recent Strategy Report, working across government agencies to increase enforcement on direct-to-consumer pharmaceutical advertising. Additionally, the current administration recently called on Congress to enact "The Great Healthcare Plan," to codify and expand Most-Favored Nation pricing, lower government subsidies to private insurance companies, increase healthcare price transparency, expand pharmaceutical drugs available for over-the-counter purchase, and enact restrictions on PBM payment methodologies, among other things. These actions and policies may significantly reduce U.S. drug prices, potentially impacting manufacturers' global pricing strategies and profitability, while increasing their operational costs and compliance risks. In the event Most-Favored-Nation pricing for pharmaceutical products is implemented and applicable to the products that we commercialize outside of the U.S., our revenue opportunities may be adversely affected, as our U.S. pricing would have to be reduced to the lowest price paid for the applicable product outside of the U.S. In such event, we may choose to forgo the ex-U.S. market to preserve more favorable U.S. pricing. In June 2024, the U.S. Supreme Court's Loper Bright decision greatly reduced judicial deference to regulatory agencies, which could increase successful legal challenges to federal regulations affecting our operations. Congress may introduce and ultimately pass healthcare related legislation that could impact the drug approval process and make changes to the Medicare Drug Price Negotiation Program.

Individual states in the U.S. have also increasingly passed legislation and implemented 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. Any such approved importation plans, if implemented, may result in lower drug prices for products covered by those programs.

In the EU, on January 12, 2025, Regulation (EU) 2021/2282 on HTA entered into application through a phased implementation. It is intended to increase cooperation among EU Member States in assessing clinical aspects of health technologies, including new medicinal products, by establishing a framework for joint clinical assessments, joint scientific consultations, and the early identification of emerging health technologies. The HTA Regulation permits EU Member States to use common tools, methodologies, and procedures and requires them to rely on EU-level joint clinical assessment reports for the clinical components of their national HTA evaluations. EU Member States, however, remain responsible for assessing non-clinical aspects, such as economic, ethical, and social considerations, and for making pricing and reimbursement decisions at the national level. As implementation of the HTA Regulation is phased in and key methodological and procedural guidance continues to evolve, there remains uncertainty regarding the evidence requirements, timing, and impact of joint clinical assessments on national reimbursement processes. The new framework may result in additional or differently structured evidentiary expectations, misalignment between assessment and regulatory timelines, or delays in national decisions. Any adverse or delayed HTA outcomes, or divergent national reimbursement decisions, could negatively affect our ability to obtain or maintain favorable pricing and reimbursement status for any product candidates, if approved. If we are unable to maintain favorable pricing and reimbursement status in EU Member States for product candidates that we may successfully develop and for which we may obtain regulatory approval, any anticipated revenue from and growth prospects for those products in the EU could be negatively affected.

The implementation of cost-containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products.

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

Our operations are directly, and indirectly through our customers and third-party payors, subject to various U.S. federal and state healthcare laws and regulations, including, without limitation, the U.S. federal Anti-Kickback Statute, the U.S. federal False Claims Act, and physician payment sunshine laws and regulations. These laws may impact, among other things, our clinical research, sales, marketing, grants, charitable donations, and education programs and constrain the business or financial arrangements with healthcare providers, physicians, charitable foundations that support Parkinson's disease patients generally, and other parties that have the ability to directly or indirectly influence the prescribing, ordering, marketing, or distribution of our products for which we obtain marketing approval. In addition, we and any current or potential future collaborators, partners or service providers are or may become subject to data privacy and security regulation by both the U.S. federal government and the states in which we conduct our business, including laws and regulations that apply to our processing of personal data or the processing of personal data on our behalf. Finally, we may be subject to additional healthcare, statutory and regulatory requirements and enforcement by foreign regulatory authorities in jurisdictions in which we conduct our business. The laws that may affect our ability to operate include:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration (including any kickback, bribe, or certain rebates), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service, for which payment may be made, in whole or in part, under U.S. federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the U.S. federal civil and criminal false claims laws, including the civil False Claims Act, which can be enforced through civil whistleblower or *qui tam* actions, and civil monetary penalties laws, which impose criminal and civil penalties on individuals or entities for, among other things, knowingly presenting, or causing to be presented to the U.S. federal government, claims for payment or approval that are false or fraudulent or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;

- the U.S. federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, and its implementing regulations, and as amended again by the Final HIPAA Omnibus Rule, Modifications to the HIPAA Privacy, Security, Enforcement and Breach Notification Rules Under the Health Information Technology for Economic and Clinical Health Act (HITECH) and the Genetic Information Nondiscrimination Act; Other Modifications to the HIPAA Rules, published in January 2013, which imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information on covered entities subject to the rule, such as health plans, healthcare clearinghouses and certain healthcare providers as well as their business associates, individuals or entities that perform certain services involving the use or disclosure of individually identifiable health information on behalf of a covered entity and their subcontractors that use, disclose or otherwise process individually identifiable health information;
- the U.S. Federal Food, Drug and Cosmetic Act (FDCA), which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;
- the U.S. federal physician payment transparency requirements, sometimes referred to as the "Physician Payments Sunshine Act", which was enacted as part of the ACA and its implementing regulations and requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to the CMS information related to certain payments and other transfers of value made to physicians (as defined to include doctors of medicine, dentists, optometrists, podiatrists and chiropractors under such law), other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals, as well as information regarding ownership and investment interests held by physicians and their immediate family members; and
- analogous state and local laws and regulations, including: state and foreign anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state and local laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities and/or the registration of pharmaceutical sales representatives; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. For example, contributions to third-party charitable foundations are a current area of significant governmental and congressional scrutiny, and we could face action if a federal or state governmental authority were to conclude that our charitable contributions to foundations that support Parkinson's disease patients generally are not compliant. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from U.S. government-funded healthcare programs, such as Medicare and Medicaid, disgorgement, imprisonment, contractual damages, reputational harm, diminished profits, additional reporting requirements and/or oversight, and the curtailment or restructuring of our operations. Moreover, while we do not bill third-party payors directly and our customers make the ultimate decision on how to submit claims, from time-to-time, for our products, we may provide reimbursement guidance to patients and healthcare providers. If a government authority were to conclude that we provided improper advice and/or encouraged the submission of a false claim for reimbursement, we could

face action against us by government authorities. If any of the physicians, healthcare professions, or other providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government-funded healthcare programs and imprisonment. If any of the above occur, it could adversely affect our ability to operate our business and our results of operations.

Outside the U.S., interactions between pharmaceutical companies and healthcare professionals are also governed by strict laws, such as national anti-bribery laws of European countries, national sunshine rules, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment, any of which could adversely affect our ability to operate our business and our results of operations.

We and the third parties with whom we work are subject to stringent and evolving U.S. and foreign laws, regulations and rules, contractual obligations, industry standards, policies and other obligations related to data privacy and security. Our (or the third parties with whom we work) actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse business consequences.

In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, process) personal data and other sensitive information, including proprietary and confidential business data, trade secrets, intellectual property, data we collect about trial participants in connection with clinical trials, sensitive third-party data, business plans, transactions, financial information and medical information collected by our patient access management team (collectively, sensitive data). Our data processing activities may subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations relating to data privacy and security.

In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), and other similar laws (e.g., wiretapping laws). For example, HIPAA, as amended by HITECH, imposes specific requirements relating to the privacy, security, and transmission of individually identifiable health information. Additionally, numerous U.S. states have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct, or delete certain personal data, and to opt-out of certain data processing activities, such as targeted advertising, profiling, and automated decision-making. The exercise of these rights may impact our business and ability to provide our products and services. Certain states also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments. These state laws allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act of 2018 (CCPA) requires businesses to provide specific disclosures in privacy notices and honor requests of California residents to exercise certain privacy rights. The CCPA provides for fines for intentional violations and allows private litigants affected by certain data breaches to recover significant statutory damages. Although some U.S. comprehensive privacy laws exempt some data processed in the context of clinical trials, these laws may increase compliance costs and potential liability with respect to other personal data we may maintain about California residents. Similar laws are being considered in several other states, as well as at the federal and local levels, and we expect more jurisdictions to pass similar laws in the future.

Outside the United States, an increasing number of laws, regulations, and industry standards may govern data privacy and security. For example, the European Union's General Data Protection Regulation (EU GDPR), United Kingdom's GDPR (UK GDPR) (collectively, the GDPR), Switzerland's Federal Act on Data Protection (FADP), Brazil's General Data Protection Law (Lei Geral de Proteção de Dados Pessoais, or LGPD) (Law No. 13,709/2018), China's Personal Information Protection Law (PIPL), and Canada's Personal Information Protection and Electronic Documents Act (PIPEDA) impose strict requirements for processing personal data. For example, under the GDPR, companies may face temporary or definitive bans on data processing and other corrective actions; fines of up to 20 million Euros under the EU GDPR / 17.5 million pounds sterling under the UK GDPR or 4% of annual global revenue, whichever is greater; or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests.

In addition, we may be unable to transfer personal data from Europe and other jurisdictions to the United States or other countries due to data localization requirements or limitations on cross-border data flows. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the European Economic Area (EEA) and the UK have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it believes are inadequate. Other jurisdictions have adopted and may continue to adopt similarly stringent data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA standard contractual clauses, the UK's International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework and the UK extension thereto (which allows for transfers to relevant U.S.-based organizations who self-certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA, the UK, or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including by limiting our ability to conduct clinical trial activities in Europe and elsewhere, the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions (such as Europe) at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers of personal data to recipients outside Europe for allegedly violating the GDPR's cross-border data transfer limitations. Additionally, companies that transfer personal data to recipients outside of the EEA and/or UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators individual litigants and activist groups.

Our employees and personnel use generative artificial intelligence (AI) technologies to perform their work, and the disclosure and use of personal data in generative AI technologies is subject to various privacy laws and other privacy obligations. Governments have passed and are likely to pass additional laws and regulations regulating generative AI. Our use of this technology could result in additional compliance costs, regulatory investigations and actions, and lawsuits. If we are unable to use generative AI, it could make our business less efficient and result in competitive disadvantages.

In addition to data privacy and security laws, we may be contractually subject to industry standards adopted by industry groups and may become subject to additional such obligations in the future. We are also bound by other contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. We publish privacy policies, marketing materials, and other statements, such as statements related to compliance with certain certifications or self-regulatory principles, regarding artificial intelligence, data privacy and security. Regulators in the United States are increasingly scrutinizing these statements, and if these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, misleading or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators, or other adverse consequences.

Additionally, under various privacy laws and other obligations, we may be required to obtain certain consents to process personal data. For example, some of our data processing practices may be challenged under wiretapping laws, if we obtain consumer information from third parties through various methods, including chatbot and session replay providers, cookies or via third-party marketing pixels. These practices may be subject to increased challenges by class action plaintiffs. Our inability or failure to obtain consent for these practices could result in adverse consequences, including class action litigation and mass arbitration demands.

Obligations related to data privacy and security (and consumers' data privacy expectations) are quickly changing, becoming increasingly stringent, and creating uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources and may necessitate changes to our services, information technologies, systems, and practices and to those of any third parties that process personal data on our behalf.

We may at times fail (or be perceived to have failed) in our efforts to comply with our data privacy and security obligations. Moreover, despite our efforts, our personnel or third parties with whom we work may fail to comply with such obligations, which could negatively impact our business operations. If we or the third parties with whom we work fail, or are perceived to have failed, to address or comply with applicable data privacy and security obligations, we could face significant consequences, including but not limited to: government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-action claims) and mass arbitration demands; additional reporting requirements and/or oversight; bans or restrictions on processing personal data; and orders to destroy or not use personal

data. In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to loss of customers; inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations.

If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate Program or other governmental pricing programs in the U.S., we could be subject to additional reimbursement requirements, fines, sanctions and exposure under other laws which could have a material adverse effect on our business, results of operations and financial condition.

We participate in the Medicaid Drug Rebate Program, as administered by CMS, and other federal and state government pricing programs in the U.S., such as the Medicare Part D Prescription Drug Inflation Rebate Program, and we may participate in additional government pricing programs in the future. These programs generally require us to pay rebates or otherwise provide discounts to government payors in connection with drugs that are dispensed to beneficiaries/recipients of these programs. In some cases, such as with the Medicaid Drug Rebate Program, the rebates are based on pricing that we report on a monthly and quarterly basis to the government agencies that administer the programs. Pricing requirements and rebate/discount calculations are complex, vary among products and programs, and are often subject to interpretation by governmental or regulatory agencies and the courts. The requirements of these programs, including, by way of example, their respective terms and scope, change frequently. For example, American Rescue Plan Act of 2021 eliminated the statutory Medicaid drug rebate cap, previously set at 100% of a drug's average manufacturer price (AMP), for single source and innovator multiple source drugs, effective January 1, 2024. Responding to current and future changes may increase our costs, and the complexity of compliance will be time consuming. Invoicing for rebates is provided in arrears, and there is frequently a time lag of up to several months between the sales to which rebate notices relate and our receipt of those notices, which further complicates our ability to accurately estimate and accrue for rebates related to the Medicaid program as implemented by individual states. Thus, we may not be able to identify all factors that may cause our discount and rebate payment obligations to vary from period to period, and our actual results may differ significantly from our estimated allowances for discounts and rebates. Changes in estimates and assumptions, including accruals that are less than our ultimate payment obligations, may have a material adverse effect on our business, results of operations and financial condition.

In addition, the HHS Office of Inspector General and other Congressional, enforcement and administrative bodies have recently increased their focus on pricing requirements for products, including, but not limited to the methodologies used by manufacturers to calculate AMP, and best price (BP), for compliance with reporting requirements under the Medicaid Drug Rebate Program. We are liable for errors associated with our submission of pricing data and for any overcharging of government payors. For example, failure to submit monthly/quarterly AMP and BP data on a timely basis could result in significant civil monetary penalties for each day the submission is late beyond the due date. Failure to make necessary disclosures and/or to identify overpayments could result in allegations against us under the civil False Claims Act and other laws and regulations. Any required refunds to the U.S. government or responding to a government investigation or enforcement action would be expensive and time consuming and could have a material adverse effect on our business, results of operations and financial condition. In addition, in the event that the CMS were to terminate our rebate agreement, no federal payments would be available under Medicaid or Medicare for our covered outpatient drugs.

We could face liability if a regulatory authority determines that we are promoting our products for any "off-label" uses.

The FDA, Health Canada, the European Commission, competent authorities of individual EU Member States and other comparable foreign regulatory authorities and industry self-regulatory bodies strictly regulate the marketing and promotional claims that are made about drug and biologic products. In particular, a company may not promote "off-label" uses for its drug products. An off-label use is the use of a product for an indication, patient population, or manner that is not described in the product's approved labeling and that differs from those approved by the applicable regulatory authorities. Physicians and other persons qualified to prescribe medicinal products, on the other hand, may, in certain jurisdictions including the U.S., prescribe products for off-label uses. Although the FDA and certain comparable foreign regulatory authorities do not generally regulate a physician's or other person qualified to prescribe's choice of drug treatment made in the such person's independent medical judgment, they do restrict promotional communications from pharmaceutical companies or their sales force with respect to off-label uses of products for which marketing clearance has not been issued. A company that is found to have promoted off-label use of its product may be subject to significant liability, including civil and criminal sanctions.

We intend to comply with the requirements and restrictions of the FDA and comparable foreign regulatory authorities, governmental authorities and regulatory bodies in the jurisdictions that approve our products or product candidates with respect to our promotion of our products, but such authorities may nevertheless make us the target of an investigation or prosecution based on our marketing and promotional practices. As a result, we may be subject to criminal and civil liability for the promotion of off-label uses. In addition, our management's attention could be diverted to handle any such alleged violations, all of which could have a material adverse effect on our business, results of operations, financial condition and reputation.

A significant number of pharmaceutical companies have been the target of inquiries and investigations by various U.S. federal and state regulatory, investigative, prosecutorial and administrative entities in connection with the promotion of products for unapproved uses and other sales practices, including by the Department of Justice (DOJ), and various U.S. Attorneys' Offices, the HHS Office of Inspector General, the FDA, the Federal Trade Commission and various state Attorneys General offices. These investigations have alleged violations of various U.S. federal and state laws and regulations, including claims asserting antitrust violations, violations of the FDCA, the civil False Claims Act, the Prescription Drug Marketing Act, anti-kickback laws, and other alleged violations in connection with the promotion of products for unapproved uses, pricing and Medicare and/or Medicaid reimbursement. If the FDA, DOJ, or any other governmental agency initiates an enforcement action against us, or if we are the subject of a qui tam suit and it is determined that we violated prohibitions relating to the promotion of products for unapproved uses, we could be subject to substantial civil or criminal fines or damage awards and other sanctions such as consent decrees and corporate integrity agreements pursuant to which our activities would be subject to ongoing scrutiny and monitoring to ensure compliance with applicable laws and regulations. Any such fines, awards or other sanctions would have an adverse effect on our revenue, business, financial prospects, and reputation.

In the EU, the advertising and promotion of medicinal products are subject to both EU and EU Member States' laws governing promotion of medicinal products, interactions with physicians and other healthcare professionals, misleading and comparative advertising and unfair commercial practices. General requirements for advertising and promotion of medicinal products, such as direct-to-consumer advertising of prescription medicinal products, are established in EU law. However, the details are governed by regulations in individual EU Member States and can differ from one country to another. If the EU or an applicable EU Member State were to determine that we violated an applicable law or regulation, we could be subject to lawsuits, regulatory actions, penalties and other adverse consequences that would have an adverse effect on our revenue, business, financial prospects, and reputation.

Changes at the FDA and other government agencies could delay or prevent new products from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept payment of user fees, layoffs and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, including executive and congressional priorities, the impacts of which are inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical government employees and stop critical activities to the extent they are not funded by existing available user fees. In addition, the current administration has enacted substantial reductions in force at various government agencies that, if applied in a material way, could significantly reduce the FDA's and other agencies' capacities to perform their functions in a manner consistent with past practices and could negatively impact our business. Repeated or prolonged government shutdowns or material layoffs of agency personnel could significantly impact the ability of the FDA to timely review and process our regulatory submissions, and negatively impact other government operations on which we rely, which could have a material adverse effect on our business.

We are subject to stringent regulation in connection with the marketing of our products, which could delay the development, approval and commercialization of our products.

The pharmaceutical industry is subject to stringent regulation by the FDA and other regulatory agencies in the U.S. and by comparable foreign regulatory authorities in other jurisdictions. Neither we nor our collaborators can market a pharmaceutical product in the U.S. until it has completed rigorous preclinical testing and clinical trials and an extensive regulatory clearance process implemented by the FDA. Satisfaction of regulatory requirements typically takes many years, depends upon the type, complexity and novelty of the product, and requires substantial resources. Even if regulatory approval is obtained, the FDA and comparable foreign regulatory authorities may impose significant restrictions on the indicated uses, conditions for use, labeling, advertising, promotion, and/or marketing of such products, and requirements for post-approval studies, including additional research and development and clinical trials. These limitations may limit the size of the market for the product or result in the incurrence of additional costs. Any delay or failure in obtaining required approvals could have a material adverse effect on our ability to generate revenues from the particular product candidate, if approved.

Outside the U.S., the ability to market a product is contingent upon receiving approval from the appropriate regulatory authorities. The requirements governing the conduct of clinical trials, marketing authorization, pricing, and reimbursement vary widely from country to country. Only after the appropriate regulatory authority is satisfied that adequate evidence of safety, quality, and efficacy has been presented will it grant an MA. Approval by the FDA does not automatically lead to the approval by regulatory authorities outside the U.S. and, similarly, approval by regulatory authorities outside the U.S. will not automatically lead to FDA approval.

In addition, U.S. and foreign government regulations control access to and use of some human or other tissue samples in our research and development efforts. U.S. and foreign government agencies may also impose restrictions on the use of data derived from human or other tissue samples. Accordingly, if we fail to comply with these regulations and restrictions, the commercialization of our product candidates, if approved, may be delayed or suspended, which may delay or impede our ability to generate product revenues.

The policies of the FDA and other regulatory authorities may change and additional government regulations may be enacted that could prevent or delay regulatory approval of our product candidates in any additional indications or territories, or further restrict or regulate post-approval activities. For instance, the regulatory landscape related to clinical trials in the EU recently evolved. The EU CTR, which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. The CTR introduces, among other changes, a centralized application system, coordinated review procedures, expanded reporting and increased transparency obligations. The new requirements, together with evolving guidance from EU authorities, may impose additional operational burdens on us and our CROs and could result in delays in trial initiation, increased compliance costs, or other disruptions to our development programs.

In addition, on December 11, 2025, the European Commission, the Parliament and the European Council reached a political agreement on a comprehensive overhaul of EU pharmaceutical legislation (the Pharma Package). The reform has been under negotiation since the European Commission submitted its proposal in April 2023. This package, comprised of a new directive and regulation to replace existing legislation, aims to modernize the EU framework. The political agreement is still subject to formal approval by the European Parliament and Council. If approved in the form proposed, the Pharma Package will, among other changes, reduce the baseline market protection period by one year, with limited opportunities for extensions, capped at a maximum of eleven years; reshape the incentives regime for orphan medicinal products, by introducing “breakthrough” orphan medicinal products (those addressing diseases with no available medicinal treatment), which will benefit from 11 years of market exclusivity; and expand the “Bolar” exemption to permit generic and biosimilar manufacturers to conduct preparatory activities for regulatory submissions, including pricing and reimbursement, and participate in procurement tenders while patent protection remains in force. A decrease in market exclusivity opportunities for our product candidates in the EU, combined with the expanded Bolar exemption, could open them to generic or biosimilar competition earlier than under the current regime, potentially impacting reimbursement status and the commercial prospects of our product candidates

If our competitors develop and market products that are more effective than our products, they may reduce or eliminate our commercial opportunity.

Competition in the pharmaceutical and biotechnology industries is intense and expected to increase. We face, and will continue to face, intense competition from pharmaceutical and biotechnology companies, as well as numerous academic and research institutions and governmental agencies, both in the U.S. and abroad. We compete, or will compete, with existing and new products being developed by our competitors. Some of these competitors have products or are pursuing the development of pharmaceuticals that target the same diseases and conditions that our research and development programs target.

For example, the use of NUPLAZID for the treatment of PDP competes with off-label use of various antipsychotic drugs, including the generic drugs quetiapine, clozapine, risperidone, aripiprazole, and olanzapine. In addition, DAYBUE competes indirectly with off-label usage of branded and generic prescription medications targeted at individual symptoms of Rett syndrome, including antiepileptics, antipsychotics, antidepressants and benzodiazepines. Further, there are several currently disclosed programs in development for Rett syndrome. UCB S.A. has announced plans to initiate a Phase 3 clinical trial of fenfluramine in patients with Rett syndrome during 2026. Taysha Gene Therapies is conducting pivotal clinical trial of a AAV9 intrathecal delivered gene therapy to treat Rett syndrome. Neurogene has initiated a pivotal clinical trial of its investigational adeno-associated virus gene therapy candidate, NGN-401, delivered using intracerebroventricular administration to treat Rett Syndrome. Several academic institutions and pharmaceutical companies are currently conducting clinical trials for the treatment of various symptoms of Rett syndrome, including Unravel Bio and Vanderbilt University Medical Center, which are jointly conducting an early-stage study with vorinostat (RVL-001).

Other competitors may have a variety of drugs in development or awaiting approval from the FDA or comparable foreign regulatory authorities that could reach the market and become established before we have a product to sell for the applicable disorder. Our competitors may also develop alternative therapies that could further limit the market for any drugs that we may develop. Many of our competitors are using technologies or methods different or similar to ours to identify and validate drug targets and to discover novel small molecule drugs. Many of our competitors and their collaborators have significantly greater experience than we do in the following:

- identifying and validating targets;
- screening compounds against targets;
- preclinical studies and clinical trials of potential pharmaceutical products;
- obtaining FDA and other regulatory approvals; and
- commercializing pharmaceutical products.

In addition, many of our competitors and their collaborators have substantially greater advantages in the following areas: capital resources, research and development resources, manufacturing capabilities, sales and marketing, and production facilities. Smaller companies also may prove to be significant competitors, particularly through proprietary research discoveries and collaboration arrangements with large pharmaceutical and established biotechnology companies. Many of our competitors have products that have been approved or are in advanced development and may develop superior technologies or methods to identify and validate drug targets and to discover novel small molecule drugs. Our competitors, either alone or with their collaborators, may succeed in developing technologies or drugs that are more effective, safer, more affordable, or more easily administered than ours and may achieve patent protection or commercialize drugs sooner than us. Our competitors may also develop alternative therapies that could further limit the market for any drugs that we may develop. Our failure to compete effectively could have a material adverse effect on our business.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our products, or development or commercialization of our product candidates, if approved.

We face an inherent risk of product liability as a result of the commercial sales of our products and the clinical testing of our product candidates. For example, we may be sued if any of our products allegedly cause injury or are found to be otherwise unsuitable for administration in humans. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates, if approved. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our products or product candidates, if approved;
- injury to our reputation;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize our products or product candidates, if approved; and
- a decline in our stock price.

Although we currently have product liability insurance that covers our clinical trials and the commercialization of our products, we may need to increase and expand this coverage, including if we commence larger scale trials and if our product candidates are approved for commercial sale. This insurance may be prohibitively expensive or may not fully cover our potential liabilities. Inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or inhibit the commercialization of products that we or our collaborators develop. If we determine that it is prudent to increase our product liability coverage, we may be unable to obtain such increased coverage on acceptable terms or at all. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. Our liability could exceed our total assets if we do not prevail in a lawsuit from any injury caused by our drug products. Product liability claims could have a material adverse effect on our business and results of operations.

If our information technology systems or data, or those of third parties with whom we work, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions, interruptions to operations or clinical trials, reputational harm, litigation, fines and penalties, disruptions of our business operations, and a loss of customers or sales.

In the ordinary course of our business, we, or the third parties with whom we work, process proprietary, confidential, and sensitive data, including personal data (such as health-related data), intellectual property, and trade secrets.

Cyberattacks, malicious internet-based activity, online and offline fraud and other similar activities threaten the confidentiality, integrity, and availability of our sensitive data and information technology systems, and those of the third parties with whom we work. These threats are prevalent, continue to rise, and are becoming increasingly difficult to detect. These threats come from a variety of sources, including traditional computer "hackers," hacktivists, threat actors, personnel misconduct or error (such as through theft or misuse), organized criminal threat actors, sophisticated nation-states, and nation-state-supported actors. Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties with whom we work may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our goods and services.

We and the third parties with whom we work are subject to a variety of evolving threats, including but not limited to, social engineering attacks (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks, credential stuffing, credential harvesting, personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunction, software or hardware failures, loss of data or other information technology assets, adware, attacks enhanced or facilitated by AI, telecommunications failures, earthquakes, fire, flood, and other similar threats.

Ransomware attacks, including by organized criminal threat actors, nation-states, and nation-state-supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions, delays, or outages in our operations, disruption of clinical trials or otherwise affecting our ability to provide our products or product candidates, loss of sensitive data (including data related to clinical trials) and income, significant extra expenses to restore data or systems, reputational harm and the diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments (including, for example, if applicable laws or regulations prohibit such payments). Remote work has increased risks to our information technology systems and data, as our employees work from home, utilizing network connections, computers and devices outside our premises, including at home, while in transit or in public locations. Future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

We rely on third-party service providers and technologies to operate critical business systems to process sensitive data in a variety of contexts, including, without limitation, cloud-based infrastructure, drug suppliers, data center facilities, encryption and authentication technology, employee email, content delivery to customers, and other functions. Our ability to monitor these third parties' information security practices and posture (including whether any unremediated vulnerabilities exist or have been exploited) is limited, and these third parties may not have adequate information security measures in place. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or our third-party partners' supply chains have not been compromised. For example, we were made aware of a cyberattack against one of the largest prescription processors in the country in February 2024 that impacted the ability for our specialty pharmacy partners to have payors provide authorizations for patient refills and new patient starts for certain of our products. In April 2024, we were notified by a third-party patient support service provider of a data security incident that involved personal data of NUPLAZID patients.

It may be difficult and/or costly to detect, investigate, mitigate, contain and remediate a security incident. Our efforts to investigate, mitigate, contain and remediate a security incident may not be successful. Actions taken by us or the third parties with whom we work to detect, investigate, mitigate, contain and remediate a security incident could result in outages, data losses and disruptions of our business. Threat actors may also gain access to other networks and systems after a compromise of our networks and systems. For example, threat actors may use an initial compromise of one part of our environment to gain access to other parts of our environment, or leverage a compromise of our networks or systems to gain access to the networks or systems of third parties with whom we work, such as through phishing or supply chain attacks.

While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We take steps designed to detect, mitigate, and remediate vulnerabilities in our information security systems (such as our hardware and/or software, including that of third parties with whom we work). We and the third parties with whom we work may not, however, detect and remediate all such vulnerabilities including on a timely basis. For example, we have identified certain vulnerabilities in our information systems, and we take steps designed to mitigate the risks associated with known vulnerabilities. These steps include implementing compensating controls and other protective measures. Further, we and the third parties with whom we work may experience delays in developing and deploying remedial measures and patches designed to address identified vulnerabilities. Vulnerabilities could be exploited and result in a security incident.

Any of the previously identified or similar threats could cause, and in some cases have in the past caused, a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive information or our information technology systems, or those of the third parties with whom we work. A security incident or other interruption could disrupt our ability (and that of third parties with whom we work) to provide our products.

We may expend significant resources or fundamentally change our business activities and practices (including our clinical trials) to try to protect against security incidents. Certain data privacy and security obligations may require us to implement and maintain specific security measures or industry-standard or reasonable security measures to protect our information technology systems and sensitive data.

Applicable data privacy and security obligations may require us, or we may choose, to notify relevant stakeholders, including affected individuals, customers, regulators, and investors, of security incidents, or to implement other requirements, such as providing credit monitoring or identity theft protection services. Such disclosures and related actions are costly, and the disclosure or the failure to comply with applicable requirements could lead to adverse consequences. If we (or a third party with whom we work) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences. These consequences may include: government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive data (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; diversion of management attention; interruptions in our operations (including availability of data); financial loss; and other similar harms. Security incidents and attendant consequences may prevent or cause customers to stop using our products, deter new customers from using our products, and negatively impact our ability to grow and operate our business.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations.

In addition, our insurance coverage may not be adequate or sufficient in type or amount to protect us from or to mitigate liabilities arising out of our privacy and security practices. The successful assertion of one or more large claims against us that exceeds our available insurance coverage, or results in changes to our insurance policies (including premium increases or the imposition of large deductible or co-insurance requirements), could have an adverse effect on our business.

In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive data about us from public sources, data brokers or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position. Additionally, sensitive information of the Company could be leaked, disclosed, or revealed as a result of or in connection with our employees', personnel's, or vendors' use of generative AI technologies.

Risks Related to Our Common Stock

Our stock price historically has been, and is likely to remain, highly volatile.

The market prices for securities of biotechnology companies in general, and drug discovery and development companies in particular, have been highly volatile and may continue to be highly volatile in the future. From the period between January 2, 2025 to February 18, 2026, the closing price of our common stock has ranged from a low of $14.10 per share to a high of $28.06 per share. Furthermore, especially as we and our market capitalization have grown, the price of our common stock has been increasingly affected by quarterly and annual comparisons with the valuations and recommendations of the analysts who cover our business. The following factors, in addition to other risk factors described in this section, may have a significant impact on the market price of our common stock:

- the success of our commercialization of our products;
- the status and cost of development and commercialization of our products and product candidates, if approved, including compounds being developed under our collaborations;
- whether we acquire or in-license additional product candidates or products, and the status of development and commercialization of such product candidates, if approved, or products;
- the status and cost of development and commercialization of trofinetide for indications other than Rett syndrome and in jurisdictions outside North America;
- any other communications or guidance from the FDA or other regulatory authorities that pertain to our products or product candidates;
- the status and cost of our PMRs for DAYBUE;
- the initiation, termination, or reduction in the scope of our collaborations or any disputes or developments regarding our collaborations;
- market conditions or trends related to biotechnology and pharmaceutical industries, or the market in general;

- announcements of technological innovations, new products, or other material events by our competitors or us, including any new products that we may acquire or in-license;
- disputes or other developments concerning our proprietary and intellectual property rights;
- fluctuations in our operating results;
- changes in, or failure to meet, securities analysts' or investors' expectations of our financial performance;
- our failure to meet applicable Nasdaq listing standards and the possible delisting of our common stock from the Nasdaq Stock Market;
- additions or departures of key personnel;
- discussions of our business, products, financial performance, prospects, or stock price by the financial and scientific press and online investor communities such as blogs and chat rooms;
- public concern as to, and legislative action with respect to, genetic testing or other research areas of biopharmaceutical companies, the pricing and availability of prescription drugs, or the safety of drugs and drug delivery techniques;
- regulatory developments in the U.S. and in foreign countries;
- changes in the structure of healthcare payment systems;
- the announcement of, or developments in, any litigation matters;
- disruptions caused by geopolitical or macroeconomic developments or other business interruptions, as well as any related political or economic responses and counter-responses or otherwise by various global actors or the general effect on the global economy and supply chain; and
- economic and political factors, including but not limited to economic and financial crises, wars, terrorism, and political unrest.

In the past, following periods of volatility in the market price of a particular company's securities, securities class action litigation has been brought against that company. For example, we, and certain of our current and former officers and directors, are subject to numerous lawsuits related to prior statements about NUPLAZID and our sNDA seeking approval of pimavanserin for the treatment of hallucinations and delusions associated with DRP, as described in "Legal Proceedings". If we are not successful in defense of these claims, we may have to make significant payments to, or other settlements with, our stockholders and their attorneys. Even if such claims are not successful, the litigation has resulted in additional costs in the past and could result in further substantial costs and diversion of our management's attention and resources in the future, which could have a material adverse effect on our business, operating results or financial condition.

If we or our stockholders sell substantial amounts of our common stock, the market price of our common stock may decline.

A significant number of shares of our common stock are held by a small number of stockholders. Sales of a significant number of shares of our common stock, or the expectation that such sales may occur, could significantly reduce the market price of our common stock. In connection with our March 2014 public offering of common stock, we agreed to provide resale registration rights for the shares of our common stock held by entities affiliated with one of our principal stockholders and two of our directors, Julian C. Baker and Dr. Stephen R. Biggar, which we refer to as the Baker Entities. In connection with our January 2016 public offering of common stock, we entered into a formal registration rights agreement with the Baker Entities to provide for these rights (2016 Registration Rights Agreement). Under the 2016 Registration Rights Agreement, we agreed that, if at any time and from time to time, the Baker Entities demand that we register their shares of our common stock for resale under the Securities Act of 1933, as amended (the Securities Act), we would be obligated to effect such registration. On May 23, 2025, the SEC declared effective a registration statement that we filed on May 9, 2025 covering the sale of up to 43,576,075 shares of our common stock, which includes 492,407 shares of our common stock issuable upon the exercise of warrants that were owned by the Baker Entities as of April 30, 2025, and which represented approximately 26 percent of our outstanding shares at the time. In February 2026, following its expiration, we replaced the 2016 Registration Rights Agreement by entering into a new registration rights agreement with the Baker Entities (2026 Registration Rights Agreement). Our registration obligations under the 2026 Registration Rights Agreement, which cover all securities now held or later acquired by the Baker Entities, will be in effect for up to 10 years, and include our obligation to facilitate certain underwritten public offerings and block trades of our securities by the Baker Entities in the future. If the Baker Entities sell a

large number of our securities, or the market perceives that the Baker Entities intend to sell a large number of our securities, this could adversely affect the market price of our securities, including our common stock. We also may elect to sell from time to time an indeterminate number of securities on our own behalf pursuant to a registration statement or in a private placement. The price of our securities may decline as a result of the sale of the securities, including shares of our common stock, included in any of these registration statements or future financings.

If our officers, directors, and largest stockholders choose to act together, they may be able to significantly influence our management and operations, acting in their best interests and not necessarily those of our other stockholders.

Our directors, executive officers and holders of 5% or more of our outstanding common stock and their affiliates beneficially own a substantial portion of our outstanding common stock. As a result, these stockholders, acting together, have the ability to significantly influence all matters requiring approval by our stockholders, including the election of all of our board members, amendments to our certificate of incorporation, going-private transactions, and the approval of mergers or other business combination transactions. The interests of this group of stockholders may not always coincide with our interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of our other stockholders.

Anti-takeover provisions in our charter documents and under Delaware law may make an acquisition of us more complicated and may make the removal and replacement of our directors and management more difficult.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that may delay or prevent a change in control, discourage bids at a premium over the market price of our common stock and adversely affect the market price of our common stock and the voting and other rights of the holders of our common stock. These provisions may also make it difficult for stockholders to remove and replace our board of directors and management. These provisions:

- establish that members of the board of directors may be removed only for cause upon the affirmative vote of stockholders owning at least a majority of our capital stock;
- authorize the issuance of "blank check" preferred stock that could be issued by our board of directors to increase the number of outstanding shares and prevent or delay a takeover attempt;
- limit who may call a special meeting of stockholders;
- establish advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings;
- prohibit our stockholders from making certain changes to our amended and restated certificate of incorporation or amended and restated bylaws except with $66^{2/3}$% stockholder approval; and
- provide for a board of directors with staggered terms.

We are also subject to provisions of the General Corporation Law of the State of Delaware that, in general, prohibit any business combination with a beneficial owner of 15% or more of our common stock for three years unless the holder's acquisition of our stock was approved in advance by our board of directors. Although we believe these provisions collectively provide for an opportunity to receive higher bids by requiring potential acquirors to negotiate with our board of directors, they would apply even if the offer may be considered beneficial by some stockholders.

Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware is the exclusive forum for certain disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or employees to our company or our stockholders, (iii) any action asserting a claim against our company or any director, officer or other employee arising pursuant to any provision of the General Corporation Law of the State of Delaware or our amended and restated certificate of incorporation or bylaws, (iv) any action to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or bylaws; (v) any action as to which the General Corporation Law of the State of Delaware confers jurisdiction on the Court of Chancery of the State of Delaware; and (vi) any action asserting a claim against our company governed by the internal affairs doctrine. This choice of forum provision does not apply to suits brought to enforce a duty or liability created by the Securities Act.

This choice of forum provision may limit a stockholder's ability to bring certain claims in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, other employees or stockholders, which may discourage lawsuits with respect to such claims, although our stockholders will not be deemed to have waived our compliance with federal securities laws and the rules and regulations thereunder. If a court were to find this choice of forum provision to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition.

We do not intend to pay dividends on our common stock in the foreseeable future; as such, you must rely on stock appreciation for any return on your investment.

To date, we have not paid any cash dividends on our common stock, and we do not intend to pay any dividends in the foreseeable future. Instead, we intend to retain any future earnings to fund the development and growth of our business. For this reason, the success of an investment in our common stock, if any, will depend on the appreciation of our common stock, which may not occur. There is no guarantee that our common stock will appreciate, and therefore, a holder of our common stock may not realize a return on his or her investment.

Item 1B. ***Unresolved Staff Comments.***

This item is not applicable.

Item 1C. ***Cybersecurity.***

Risk management and strategy

We have implemented and maintain various information security processes designed to identify, assess and manage material risks from cybersecurity threats to our critical computer networks, third party hosted services, communications systems, hardware and software, and our critical data, including intellectual property, confidential information that is proprietary, strategic or competitive in nature, and data related to our clinical trials and products (Information Systems and Data).

Our information security function, led by our Chief Information and Data Officer (CIDO), with our legal and compliance teams, help identify, assess and manage the Company's cybersecurity threats and risks. This group works to identify and assess risks from cybersecurity threats by monitoring and evaluating our threat environment and the Company's risk profile using various methods in certain contexts, including, for example, manual tools, automated tools, subscribing to reports and services that identify cybersecurity threats, analyzing reports of threat actors, conducting scans of certain environments, evaluating our industry's risk profile, evaluating certain threats reported to us, coordinating with law enforcement concerning threats, internal and/or external audits, conducting threat and vulnerability assessments, using external intelligence feeds, using third parties to conduct tabletop incident response exercises and other tests, and participating in the Health Information Sharing and Analytics Center (H-ISAC).

Depending on the environment, we implement and maintain various technical, physical, and organizational measures, processes, standards and policies designed to manage and mitigate material risks from cybersecurity threats to our Information Systems and Data, including, for example: incident detection and response policies, disaster recovery/business

continuity policies, a vulnerability management policy, artificial intelligence policy, digital policy, a vendor risk management program, risk assessments, implementation of security standards/certifications, encryption of certain data, network security controls and data segregation for certain systems, access controls, physical security, asset management, tracking, and disposal, systems monitoring, employee training, penetration testing, cybersecurity insurance, and dedicated cybersecurity staff.

Our assessment and management of material risks from cybersecurity threats are integrated into the Company's overall risk management processes. For example, (1) cybersecurity risk is addressed as a component of the Company's enterprise risk management program; (2) the information security department works with management to prioritize our risk management processes and mitigate cybersecurity threats that are more likely to lead to a material impact to our business; and (3) our senior management evaluates material risks from cybersecurity threats against our overall business objectives and reports to the audit committee of the board of directors, which evaluates our overall enterprise risk.

We use third-party service providers to assist us from time to time to identify, assess, and manage material risks from cybersecurity threats, including for example, outside legal counsel, threat intelligence service providers, cybersecurity consultants, cybersecurity software providers, penetration testing firms, managed cybersecurity service providers, darkweb monitoring services, and forensic investigators.

We use third-party service providers to perform a variety of functions throughout our business, such as application providers, hosting companies, contract research organizations, contract manufacturing organizations, distributors, and supply chain resources. We have vendor management processes designed to help manage cybersecurity risks associated with our use of certain of these providers. For certain vendors, these processes include vendor risk assessments, security questionnaires, review of vendors' written security program, vulnerability scans related to the vendor, security assessment calls with the vendor's security personnel, and imposition of contractual obligations on certain vendors.

For a description of the risks from cybersecurity threats that may materially affect the Company and how they may do so, see our risk factors under Part 1. Item 1A. Risk Factors, including: "We and the third parties with whom we work are subject to stringent and evolving U.S. and foreign laws, regulations and rules, contractual obligations, industry standards, policies and other obligations related to data privacy and security. Our (or the third parties with whom we work) actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse business consequences."; and "If our information technology systems or data, or those of third parties with whom we work, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions, interruptions to operations or clinical trials, reputational harm, litigation, fines and penalties, disruptions of our business operations, and a loss of customers or sales."

Governance

Our board of directors addresses the Company's cybersecurity risk management as part of its general oversight function. The audit committee of the board of directors is responsible for overseeing the Company's cybersecurity risk management processes, including oversight of mitigation of risks from cybersecurity threats.

Our cybersecurity risk assessment and management processes are implemented and maintained by certain Company management, including our CIDO, who joined the Company in August 2025, and Senior Director of Information Security, who has led cybersecurity functions at the Company for over a decade, managed the Security Operations Center for a Fortune 500 company, and led cybersecurity efforts as the Director of IT at another organization.

The CIDO, along with management, is responsible for hiring appropriate personnel, helping to integrate cybersecurity risk considerations into the Company's overall risk management strategy, and communicating key priorities to relevant personnel. Management is responsible for approving budgets, helping prepare for cybersecurity incidents, approving cybersecurity processes, and reviewing security assessments and other security-related reports.

Our incident response policy is designed to escalate certain cybersecurity incidents to members of management depending on the circumstances, including our CIDO, Chief Legal Officer, Senior Vice President of Finance, Chief Compliance Officer, Senior Vice President of People and Performance, and Senior Director of Information Security. This team works with the Company's incident response team to help the Company mitigate and remediate cybersecurity incidents of which they are notified. In addition, the Company's incident response policy includes reporting to the audit committee of the board of directors for certain cybersecurity incidents.

The audit committee receives periodic reports from senior management concerning the Company's significant cybersecurity threats and risks and the processes the Company has implemented to address them.

Item 2. ***Properties.***

As of December 31, 2025, our primary facility consists of approximately 67,000 square feet of office space in San Diego, California, pursuant to a lease that expires in May 2031. We also lease a facility in Princeton, New Jersey that covers approximately 25,000 square feet of office space, which is leased on a month-to-month basis after it expired in January 2026. In addition, we lease a new facility in Princeton, New Jersey that covers approximately 53,000 square feet of office space, which is expected to commence in the second quarter of 2026. We believe that our existing facilities are adequate to meet our current needs, and that suitable additional alternative spaces will be available in the future on commercially reasonable terms.

Item 3. ***Legal Proceedings.***

Patent Infringement

On July 24, 2020, we filed complaints against (i) Aurobindo Pharma Limited and its affiliate Aurobindo Pharma USA, Inc. and (ii) Teva Pharmaceuticals USA, Inc. and its affiliate Teva Pharmaceutical Industries Ltd., and on July 30, 2020, we filed complaints against (i) Hetero Labs Limited and its affiliates Hetero Labs Limited Unit-V and Hetero USA Inc., (ii) MSN Laboratories Private Ltd. and its affiliate MSN Pharmaceuticals, Inc., and (iii) Zydus Pharmaceuticals (USA) Inc. and its affiliate Cadila Healthcare Limited. These complaints, which were filed in the United States District Court for the District of Delaware, allege infringement of certain of our Orange Book-listed patents covering NUPLAZID (Pimavanserin I Cases).

We entered into an agreement effective April 22, 2021 with Hetero settling all claims and counterclaims in the litigation. The agreement allows Hetero to launch its generic pimavanserin product on February 27, 2038, subject to certain triggers for earlier launch. The Hetero case was dismissed by joint agreement on May 3, 2021.

On September 30, 2022, we filed a stipulation and proposed order to stay the claims currently asserted against Teva and for Teva to be bound by the result of the litigation rendered against the remaining defendants Aurobindo and MSN, which was ordered by the Court on October 4, 2022.

On October 21, 2022, we filed additional complaints against Aurobindo, MSN and Zydus in the United States District Court for the District of Delaware alleging infringement of an additional Orange Book-listed patent covering NUPLAZID (Pimavanserin II Cases).

We entered into an agreement, effective March 31, 2023, with Zydus settling all claims and counterclaims in the Pimavanserin I Cases and Pimavanserin II Cases. The agreement allows Zydus to launch its generic pimavanserin 10 mg tablet products on September 23, 2036 and 34 mg capsule products on February 27, 2038, subject to certain triggers for earlier launch. The Zydus case was dismissed by joint agreement on April 5, 2023.

As a result of the above, only MSN remained as an active defendant in the Pimavanserin I Cases. On January 11, 2024, following summary judgment motions, the District Court entered final judgment in our favor that MSN's submission of ANDA No. 214925 was an act of infringement in the Pimavanserin I Case and the '740 patent was not invalid. On January 18, 2024, MSN filed a Notice of Appeal to the United States Court of Appeals for the Federal Circuit from the final judgment entered on January 11, 2024. On June 9, 2025, the Federal Circuit issued a decision affirming the final judgement of the District Court in our favor.

In connection with the Pimavanserin II cases, MSN and Aurobindo are the remaining defendants. A bench trial was conducted from December 3, 2024 to December 6, 2024 in the matter. Post-trial briefing was completed on February 12, 2025. On June 9, 2025, the District Court issued a final judgement in our favor that Aurobindo's ANDA infringes the asserted NUPLAZID patent and that the defendants failed to demonstrate such patent is invalid. On June 16, 2025, MSN and Aurobindo filed a Notice of Appeal to the United States Court of Appeals for the Federal Circuit from the final judgment entered on June 9, 2025. Briefing was completed on December 19, 2025. An oral argument has not been scheduled as yet.

On February 14, 2025, we filed a complaint against Zydus Lifesciences Limited, Zydus Worldwide DMCC, and Zydus Pharmaceuticals (USA) Inc. (collectively "Zydus") in the United States District Court for the District of Delaware, alleging infringement of certain of our Orange Book-listed patents covering NUPLAZID (Pimavanserin) by Zydus' proposed 34 mg pimavanserin tablet product. The case is scheduled for trial commencing November 2, 2026.

Securities Class Action

On April 19, 2021, a purported stockholder of us filed a putative securities class action complaint (captioned *City of Birmingham Relief Retirement Systems* v. Acadia Pharmaceuticals, Inc., Case No. 21-cv-0762) in the U.S. District Court for the Southern District of California against us and certain of our then-current executive officers. On September 29, 2021, the Court issued an order designating lead plaintiff and lead counsel. On December 10, 2021, lead plaintiff filed an amended complaint. The amended complaint generally alleges that defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, by failing to disclose that the materials submitted in support of its sNDA seeking approval of pimavanserin for the treatment of hallucinations and delusions associated with dementia-related psychosis contained statistical and design deficiencies and that the FDA was unlikely to approve the sNDA in its current form. The amended complaint seeks unspecified monetary damages and other relief. On March 11, 2024, the Court granted plaintiffs' motion for class certification and appointment of class representatives and class counsel. The parties concluded discovery on September 24, 2025. The parties submitted pretrial motions on November 12, 2025 and briefing for these motions will be complete on February 25, 2026. The Court has scheduled a pretrial motions hearing for April 10, 2026. Remaining pretrial deadlines will be determined pending the Court's rulings on the parties' pretrial motions.

Opt-Out Litigation

On March 7, 2024, a purported stockholder of us filed a complaint (captioned Alger Dynamic Opportunities Fund v. Acadia Pharmaceuticals, Inc., Case No. 24-cv-00451) in the U.S. District Court for the Southern District of California against us and one executive officer. The complaint is based on the same underlying allegations as the Securities Class Action described above, and alleged claims under federal and state securities laws, and for common law fraud and negligent misrepresentations. On May 24, 2024, Defendants moved to dismiss the complaint. On October 31, 2024, the Court granted in part and denied in part Defendants' motion to dismiss. The Court dismissed with leave to amend the purported stockholder's state and common law claims, as well as the claim brought under Section 18(a) of the Securities Exchange Act of 1934, as amended. Defendants filed their answer to the Sections 10(b) and 20(a) claims on December 16, 2024. On January 13, 2025, the Court stayed this suit pending the outcome of the Securities Class Action.

Derivative Suit

On December 15, 2023, a purported stockholder of us filed a derivative action (captioned *Kanner et al v. Biggar et al.*, Case No. 23-cv-2293) in the U.S. District Court for the Southern District of California against certain of our current directors. We are named as a nominal defendant. The complaint is based on the same alleged misconduct as the Securities Class Action, and asserts state law claims, on behalf of us, against the individual defendants for breach of fiduciary duty, unjust enrichment, abuse of control, waste of corporate assets, and insider trading. The complaint also asserts federal claims under sections 10(b), 21D, and 14(a) of the Securities Exchange Act of 1934, as amended. On December 27, 2023, the action was reassigned to District Judge William Q. Hayes and Magistrate Judge Michael S. Berg due to its relation to the Securities Class Action. On January 30, 2024, the parties jointly requested a stay of the action. The Court granted that request and the action was stayed on February 20, 2024, pending the outcome of our Demand Review Committee's investigation into the underlying claims. The stay was briefly lifted on September 5, 2025 but reinstated on October 17, 2025 and remains in place. On January 15, 2026, the parties informed the Court that they had reached a settlement in principle regarding the derivative claims. Pursuant to the proposed settlement, which is still subject to Court approval, defendants agreed to certain governance reforms and agreed to an award of $1.5 million in attorneys' fees to be paid by our insurance carrier.

We currently believe that none of the foregoing claims or other actions pending against us as of December 31, 2025 is likely to have, individually or in the aggregate, a material adverse effect on our business, liquidity, financial position, or results of operations. Given the unpredictability inherent in litigation, however, we cannot predict the outcome of these matters. We are unable to estimate possible losses or ranges of losses that may result from these matters, and therefore we have not accrued any amounts in connection with these matters other than attorneys' fees incurred to date.

Item 4. ***Mine Safety Disclosures.***

This item is 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 traded on the Nasdaq Global Select Market under the symbol "ACAD".

Holders

As of February 18, 2026, there were 170,494,613 shares of common stock outstanding held by approximately 29 stockholders of record.

Dividends

To date, we have not paid any cash dividends on our common stock, and we do not intend to pay any dividends in the foreseeable future. Instead, we intend to retain any future earnings to fund the development and growth of our business.

Securities Authorized for Issuance Under Equity Compensation Plans

The information required by this Item regarding equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report on Form 10-K.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

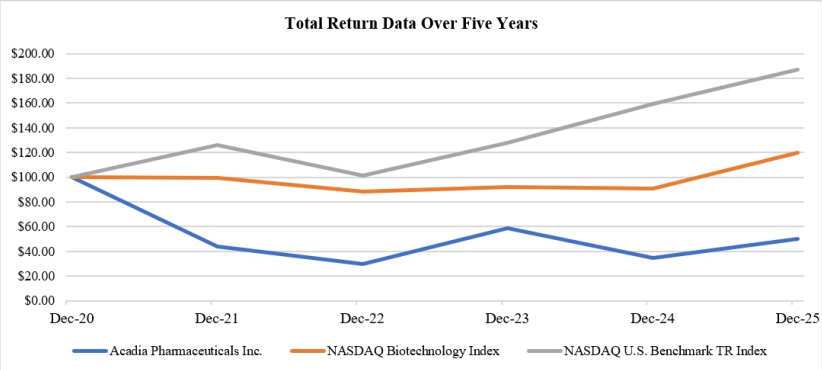
None.

Recent Sales of Unregistered Securities

Not applicable.

Performance Graph

The following graph shows a comparison of the total cumulative returns of an investment of $100 in cash from December 31, 2020 through December 31, 2025 in (i) our common stock, (ii) the Nasdaq Biotechnology Index, and (iii) the Nasdaq U.S. Benchmark TR Index. The comparisons in the graph are required by the SEC and are not intended to forecast or be indicative of the possible future performance of our common stock. The graph assumes that all dividends have been reinvested (to date, we have not declared any dividends).



	Dec-20	Dec-21	Dec-22	Dec-23	Dec-24	Dec-25
Acadia Pharmaceuticals Inc.	$ 100.00	$ 43.66	$ 29.78	$ 58.57	$ 34.32	$ 49.94
NASDAQ Biotechnology Index	$ 100.00	$ 99.37	$ 88.53	$ 91.84	$ 90.58	$ 119.92
NASDAQ U.S. Benchmark TR Index	$ 100.00	$ 125.89	$ 101.05	$ 127.76	$ 159.03	$ 186.96

Item 6. [Reserved]

Item 7. ***Management's Discussion and Analysis of Financial Condition and Results of Operations.***

The following discussion and analysis of our consolidated financial condition and results of operations should be read in conjunction with our consolidated financial statements and related notes included elsewhere in this report. Past operating results are not necessarily indicative of results that may occur in future periods. This discussion contains forward-looking statements, which involve a number of risks and uncertainties. Such forward-looking statements include statements about the benefits to be derived from our products and our product candidates, the potential market opportunities for our products and our product candidates, our strategy for the commercialization of our products, our plans for exploring and developing our products for additional indications, the commercialization of DAYBUE or trofinetide in jurisdictions other than the U.S., our plans and timing with respect to seeking regulatory approvals, the potential commercialization of any of our product candidates that receive regulatory approval, the progress, timing, results or implications of clinical trials and other development milestones and activities involving our products and our product candidates, our strategy for discovering, developing and, if approved, commercializing our product candidates, our existing and potential future collaborations, our estimates of future payments, revenues and profitability, our estimates regarding our capital requirements, future expenses and need for additional financing, the potential or expected impacts of geopolitical and macroeconomic developments, possible changes in legislation, and other statements that are not historical facts, including statements which may be preceded by the words "aims," "anticipates," "believes," "continue," "could," "estimates," "expects," "hopes," "intends," "may," "plans," "potential" "predicts," "pro forma," "projects," "seeks," "should," "will," "would," or similar words. In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain. For forward-looking statements, we claim the protection of the Private Securities Litigation Reform Act of 1995. Readers of this report are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date on which they are made. We undertake no obligation to update or revise publicly any forward-looking statements except as required by law. Forward-looking statements are not guarantees of performance. Actual results or events may differ materially from those anticipated in our forward-looking statements as a result of various factors, including those set forth under the section captioned "Risk Factors" elsewhere in this report. Information in the following discussion for a yearly period means for the year ended December 31 of the indicated year.

Overview

Background

We are a biopharmaceutical company focused on turning scientific promise into meaningful innovation that makes the difference for underserved neurological and rare disease communities around the world.

We have two core franchises in neurological and rare diseases. Our neurological disease franchise is anchored by the commercial product NUPLAZID (pimavanserin), which is the first and only drug approved by the FDA for the treatment of hallucinations and delusions associated with PDP. Our rare disease franchise is anchored by the commercial product DAYBUE, which is the first and only drug approved for the treatment of Rett syndrome. Net product sales from these two commercial products totaled $1,071.5 million for 2025, compared with $957.8 million for 2024.

In August 2018, we acquired an exclusive North American license to develop and commercialize DAYBUE for Rett syndrome and other indications from Neuren. Rett syndrome is a debilitating neurological disorder that occurs predominantly in females following apparently normal development for the first six months of life. Rett syndrome also occurs in boys, albeit far less frequently. Typically, between six to eighteen months of age, patients experience a period of rapid decline with loss of purposeful hand use and spoken communication and inability to independently conduct activities of daily living. Symptoms also include seizures, hand movements or stereotypies, disorganized breathing patterns, scoliosis and sleep disturbances, among others. The FDA approval of DAYBUE for the treatment of Rett syndrome was based on the positive results from our pivotal Phase 3 LAVENDER™ study which demonstrated statistically significant improvement over placebo for both co-primary endpoints as well as the key secondary endpoint.

Under the terms of the 2018 agreement, Neuren received an upfront payment of $10.0 million and is eligible to receive milestone payments of up to $400.0 million based on the achievement of certain development and sales milestones for Rett syndrome in North America, of which, $50 million has been paid as of December 31, 2025. Neuren is also eligible to receive up to $55.0 million in development and sales milestone for Fragile X syndrome in North America. In addition, Neuren is eligible to receive tiered, escalating, double-digit percentage royalties based on net sales in North America. The following tables provide a summary of milestone and royalty payments that Neuren remains eligible to receive based on the achievement of net sales of trofinetide in North America in any given year:

Sales Milestones Based on Annual Net Sales in North America	
Net Sales ≥$250 million	$50 million
Net Sales ≥$500 million	$50 million
Net Sales ≥$750 million	$100 million
Net Sales ≥$1 billion	$150 million

Tiered Royalty Rates Based on Annual Net Sales in North America	
≤$250 million	10%
>$250 million, but ≤$500 million	12%
>$500 million, but ≤$750 million	14%
>$750 million	15%

In July 2023, we expanded our current licensing agreement for trofinetide with Neuren to acquire rights to the drug outside of North America as well as global rights in Rett syndrome and Fragile X syndrome to Neuren's development candidate NNZ-2591. Under the terms of the expanded agreement, Neuren received an upfront payment of $100.0 million and is eligible to receive up to an additional $426.3 million in milestone payments based on the achievement of certain commercial and sales milestones for trofinetide outside of North America and up to $831.3 million in milestone payments based on the achievement of certain development and sales milestones for NNZ-2591. In addition, we will be required to pay Neuren tiered royalties from the mid-teens to low-twenties percent based on net sales of trofinetide and NNZ-2591. The following table provides a summary of milestone payments that Neuren is eligible to receive based on the achievement of certain sales milestones under the terms of the expanded agreement:

Territory	First Commercial Sales Milestones	Total Sales Milestones
Europe	$35 million (Rett syndrome) $10 million (2nd indication)	Up to $170 million
Japan	$15 million (Rett syndrome) $4 million (2nd indication)	Up to $110 million
Rest of World	—	Up to $83 million

In addition to these commercial products, we have a portfolio of product candidates and research programs that are designed to address significant unmet medical needs in neurological and rare diseases. In order to achieve significant long-term growth, we plan to develop our current portfolio, expand our pipeline of early- and late-stage product candidates and expand into areas of rare disease that are adjacent to our existing franchises, including through strategic business development, and make use of our internal capabilities and knowledge.

Our most advanced current product candidate is remlifanserin for the treatment of ADP and LBDP. In November 2023, we initiated a Phase 2 study evaluating the efficacy and safety of remlifanserin for the treatment of hallucinations and delusions associated with ADP. We initiated an additional Phase 2 study of remlifanserin in LBDP in September 2025. In the fourth quarter of 2025, we initiated a Phase 2 study of ACP-211 for the treatment of major depressive disorder.

Until September 2025 we had been developing the product candidate ACP-101 (intranasal carbetocin) for the treatment of hyperphagia in PWS, a neuro rare disease. In September 2025, we announced top-line results from our COMPASS PWS study, a Phase 3 study evaluating the efficacy and safety of ACP-101 for the treatment of hyperphagia in PWS. In the study, ACP-101 did not demonstrate a statistically significant improvement over placebo on the study's primary endpoint, change from baseline to Week 12 on the Hyperphagia Questionnaire for Clinical Trials (HQ-CT), nor was there separation from placebo on any secondary endpoint. As a result, we do not intend to investigate ACP-101 any further.

We have several product candidates in earlier stages of development for the treatment of neurological and rare diseases. These include ACP-711 for the treatment of essential tremor, with a Phase 2 study expected to begin in 2026; and ACP-271, a GPR88 agonist, with a first-in-human study in healthy volunteers planned for the first quarter of 2026.

We have incurred substantial operating losses since our inception due in large part to expenditures for our research and development activities. As of December 31, 2025, we had an accumulated deficit of approximately $1.8 billion. Contingent on the level of business development activities we may complete as well as pipeline programs we may advance, we may incur operating losses as we incur significant research and development costs and costs for continued commercialization of our products.

Financial Operations Overview

Product Revenues

Net product sales consist of sales of our products. The FDA approved NUPLAZID in April 2016 for the treatment of hallucinations and delusions associated with PDP and we launched the product in the United States in May 2016. The FDA approved DAYBUE in March 2023 for the treatment of Rett syndrome and we launched the product in the United States in April 2023. Health Canada granted marketing authorization of DAYBUE for the treatment of Rett syndrome in adult and pediatric patients 2 years of age and older in October 2024. The FDA approved DAYBUE STIX in December 2025 for the treatment of Rett syndrome and we made the product available on a limited basis in the first quarter of 2026, with a broader launch planned for Q2 2026. The Ministry of Health in Israel recently approved DAYBUE for the treatment of Rett syndrome in adults and pediatric patients 2 years of age and older and weighing at least 9 kg in December 2025.

Cost of Product Sales

Cost of product sales consists of third-party manufacturing costs, freight, duties, and indirect overhead costs associated with sales of our products. Cost of product sales may also include period costs related to certain inventory manufacturing services, excess or obsolete inventory adjustment charges, unabsorbed manufacturing and overhead costs, and manufacturing variances. In addition, cost of product sales may include license fees and royalties. License fees and royalties currently consist of milestone payments capitalized and subsequently amortized under our 2018 license agreement with Neuren. License fees and royalties also include royalties of tiered, escalating, double-digit percentages due to Neuren based upon net sales of DAYBUE.

Cost of sales for a newly launched product does not include the full cost of manufacturing until the initial pre-launch inventory is depleted, and additional inventory is manufactured and sold. Thus the cost of sales as a percentage of net sales of DAYBUE for the year ended December 31, 2025, 2024 and 2023 were affected by use of the initial pre-launch inventory, which was previously expensed as research and development expense, and is referred to as zero cost inventories. However, we do not expect that the cost of sales as a percentage of net sales of DAYBUE will increase significantly once we commence the sales of full cost inventories.

Research and Development Expenses

Our research and development expenses have consisted primarily of fees paid to external service providers, salaries and related personnel expenses, facilities and equipment expenses, and other costs incurred related to pre-commercial product candidates. We charge all research and development expenses to operations as incurred. Our research and development activities have focused on pimavanserin, trofinetide, remlifanserin and other earlier-stage product candidates. In connection with the FDA approval of DAYBUE, we are required to conduct post-marketing work, including a clinical study of renal impairment in healthy volunteers, nonclinical carcinogenicity studies, and nonclinical in vitro and clinical in vivo drug interaction studies. The FDA has released us from one of the five PMRs. In addition, we have fulfilled three of the five PMRs. We will be responsible for all costs incurred for these PMRs. In addition, we expect to incur increased research and development expenses as a result of advancement of our early-stage product candidates.

We use external service providers to manufacture our product candidates and for the majority of the services performed in connection with the preclinical and clinical development of our product candidates. Historically, we have used our internal research and development resources, including our employees and discovery infrastructure, across several projects and many of our costs have not been attributable to a specific project. Accordingly, we have not reported our internal research and development costs on a project-by-project basis. To the extent that external expenses are not attributable to a specific project, they are allocated proportionally to each of the projects.

The following table summarizes our research and development expenses for the years ended December 31, 2025, 2024, and 2023 (in thousands):

	Years Ended December 31,		
	2025	2024	2023
Costs of external service providers:			
NUPLAZID (pimavanserin)	$ 3,706	$ 34,369	$ 55,527
DAYBUE (trofinetide)	34,083	30,677	32,065
ACP-101	44,412	30,401	11,887
Remlifanserin	85,598	54,389	43,768
Early-stage product candidates	52,272	44,703	26,789
Upfront and milestone payments*	12,000	34,500	102,500
Subtotal	232,071	229,039	272,536
Internal costs	80,295	60,110	61,675
Stock-based compensation	16,436	14,100	17,408
Total research and development expenses	$ 328,802	$ 303,249	$ 351,619

* Includes upfront and milestone consideration as well as transaction costs associated with acquired in-process research and development.

At this time, due to the risks inherent in regulatory requirements and clinical development, we are unable to estimate with certainty the costs we will incur to support the commercialization of DAYBUE or DAYBUE STIX, as well as the further development of our early-stage product candidates. Likewise, we are unable to determine with certainty the anticipated completion dates for our current research and development programs. Clinical development and regulatory approval timelines, probability of success, and development costs vary widely across our development programs. While our current development efforts are primarily focused on advancing the development of remlifanserin and other early-stage product candidates, we anticipate that we will make determinations as to which programs to pursue and how much funding to direct to each program on an ongoing basis in response to the scientific and clinical success of each product candidate, as well as an ongoing assessment of the commercial potential of each candidate and our financial position. We cannot forecast with any degree of certainty which product candidates will be subject to future collaborative or licensing arrangements, when such arrangements will be secured, if at all, and to what degree any such arrangements would affect our development plans and capital requirements. Similarly, we are unable to estimate with certainty the costs we will incur for post-marketing studies that we committed to conduct in connection with FDA approval of DAYBUE.

We expect our research and development expenses will continue to be substantial as we conduct studies pursuant to our PMRs and pursue the further development of remlifanserin and other early-stage product candidates. The lengthy process of completing clinical trials and supporting development activities and seeking regulatory approval for our product candidates requires the expenditure of substantial resources. Any failure by us or delay in completing clinical trials, or in obtaining regulatory approvals, could cause our research and development expenses to increase and, in turn, have a material adverse effect on our results of operations.

Selling, General and Administrative Expenses

Our selling, general and administrative expenses consist of salaries and other related costs, including stock-based compensation expense, for our commercial personnel, including our specialty sales forces, our medical education professionals, and our personnel serving in executive, finance, business development, and business operations functions. Also included in selling, general and administrative expenses are fees paid to external service providers to support our commercial activities associated with our products, professional fees associated with legal and accounting services, costs associated with patents and patent applications for our intellectual property and charitable donations to independent charitable foundations that support Parkinson's disease patients generally. Changes in selling, general and administrative expenses in future periods are subject to the evolving PDP market dynamics and the Rett syndrome market.

Gain on Sale of Non-Financial Asset

Following the FDA approval of DAYBUE, we were granted a Rare Pediatric Disease PRV. During the year ended December 31, 2024, we sold the PRV to a third party for the aggregate net proceeds of $146.5 million.

Income Tax Expense

Our provision for income taxes, deferred tax assets and liabilities, and reserves for unrecognized tax benefits reflect our best assessment of estimated future taxes to be paid. Judgments and estimates based on interpretations of existing tax laws or regulations are required in determining our provision for income taxes. Changes in tax laws, regulations, or statutory tax rates, and estimates of our future taxable income could impact the deferred tax assets and liabilities provided for in the consolidated financial statements and would require an adjustment to the provision for income taxes. Prior to fiscal year 2025, we maintained a full valuation allowance against our net deferred tax assets (DTAs) due to a history of cumulative losses. However, during the fiscal year ended December 31, 2025, we achieved cumulative three-year profitability. Management determined there is sufficient positive evidence to conclude it is "more likely than not" that deferred taxes are realizable. We therefore reduced the valuation allowance accordingly.

On July 4, 2025, President Trump signed into law the OBBBA. The OBBBA made permanent key elements of the Tax Cuts and Jobs Act, including domestic research cost expensing, the business interest limitation, and 100% bonus depreciation. We evaluated the enacted effects of the legislation on our estimated annual effective tax rate and cash tax position. We expect to realize significant cash tax savings in tax year 2025 as we are no longer required to capitalize our domestic research and experimental costs under Section 174 of the Internal Revenue Code beginning with the tax year ending December 31, 2025.

Critical Accounting Policies and Estimates

A summary of the significant accounting policies is provided in Note 2 to our Consolidated Financial Statements.

The preparation of financial statements in accordance with GAAP requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. We evaluate our estimates on an ongoing basis. Our estimates are based on historical experience and on various other assumptions and factors 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 and liabilities and the reported amounts of revenues and expenses that are not readily apparent from other sources. Actual results may differ from those estimates under different assumptions and conditions.

Management considers an accounting estimate to be critical if:

- it requires a significant level of estimation uncertainty; and
- changes in the estimate are reasonably likely to have a material effect on our financial condition or results of operations.

We believe the following critical accounting policies and estimates describe the more significant judgments and estimates used in the preparation of our consolidated financial statement.

Product Sales, Net

We sell NUPLAZID through SPs and SDs. SPs dispense product to a patient based on the fulfillment of a prescription and SDs sell product to government facilities, long-term care pharmacies, or in-patient hospital pharmacies. We sell DAYBUE in the U.S. through a single wholesale distributor. We sell DAYBUE outside of the U.S. through third party distributors. Product shipping and handling costs are included in cost of product sales.

We recognize revenue from product sales at the net sales price (the "transaction price") which includes estimates of variable consideration for which reserves are established and reflects each of these as either a reduction to the related account receivable or as an accrued liability, depending on how the amount payable is settled. Overall, these reserves reflect our best estimates of the amount of consideration to which we are entitled based on the terms of the contract. Actual amounts of consideration ultimately received may differ from our estimates. If actual results in the future vary from estimates, we may need to adjust our estimates, which would affect net revenue in the period of adjustment. The following sales discounts and allowances involve a substantial degree of judgment:

Rebates: Allowances for rebates include mandated discounts under the Medicaid Drug Rebate Program and the Medicare Part D prescription drug benefit. Rebates are amounts owed after the final dispensing of the product to a benefit plan participant and are based upon contractual agreements with, or statutory requirements pertaining to, Medicaid and

Medicare benefit providers. The allowance for rebates is based on statutory discount rates and expected utilization. Our estimates for expected utilization of rebates is based on historical data received from the SPs, SDs and the single wholesale distributor since product launch. Rebates are generally invoiced and paid in arrears so that the accrual balance consists of an estimate of the amount expected to be incurred for the current quarter's activity, plus an accrual balance for prior quarters' unpaid rebates still estimated to be incurred. Allowances for rebates also include amounts due under the Inflation Reduction Act of 2022 (IRA) for Medicare Part D unit sales with applicable period AMP increases that outpace inflation over the benchmark period. The applicable period will be twelve months on October 1 of each year, with the initial applicable period beginning on October 1, 2022. The benchmark period AMP price is January 1, 2021 through September 30, 2021 for NUPLAZID and January 1, 2024 through December 31, 2024 for DAYBUE. Our estimates are based Medicare Part D sales as a percentage of gross sales and the rate AMP for the current period will be in excess the benchmark period. We regularly monitor our estimates and record adjustments when rebate trends, rebate programs and contract terms, legislative changes, or other significant events indicate that a change in the estimates is appropriate. Prior to 2025, our estimates had not differed materially from actual rebates. However, in December 2025, we received our first invoices for Medicare inflation cap rebates from CMS for the applicable periods beginning on October 1, 2022 through September 30, 2024, which were higher than expected and material to our product revenue. The variances between the actual invoices received and our accruals were from the higher units billed. While we have been accruing for Medicare inflation cap rebates since the implementation of the IRA, the historical data we had from the federal government and our customers indicated that our Medicare volume mix for NUPLAZID was lower than the ultimate Medicare volume we received from CMS in our IRA invoices. We adjusted our Medicare rebate accruals to reflect actual invoices received and updated expectations. This unfavorable change of approximately $20.1 million related to the sales from October 1, 2022 to December 31, 2025, which increased our gross-to-net adjustments and reduced our net product sales of NUPLAZID. The adjustment does not impact underlying demand trends, which demonstrated strong volume growth in 2025. Of the $20.1 million, $11.8 million was classified as a change in estimate for the impact through December 31, 2024, and $8.3 million was captured within the current financial statements for the period ending December 31, 2025.

Chargebacks: Chargebacks are discounts and fees that relate to contracts with government and other entities purchasing from the SDs at a discounted price. The SDs charge back to us the difference between the price initially paid by the SDs and the discounted price paid to the SDs by these entities. We also incur group purchasing organization fees for transactions through certain purchasing organizations. We estimate sales with these entities and accrue for anticipated chargebacks and organization fees, based on the applicable contractual terms. To date, our estimates have not differed materially from the actual chargebacks and organization fees. However, subsequent changes in estimates may result in a material change in our accruals, which could also materially affect our balance sheet and results of operations.

Research and Development Accruals

We estimate certain costs and expenses and accrue for these liabilities as part of our process of preparing financial statements. Examples of areas in which subjective judgments may be required include, among other things, costs associated with services provided by contract organizations for preclinical development, manufacturing of our product candidates and clinical trials, and personnel related expenses. We accrue for costs incurred as the services are being provided by monitoring the status of the trial or services provided, and the invoices received from our external service providers. In the case of clinical trials, a portion of the estimated cost normally relates to the projected cost to treat a patient in the trials, and this cost is recognized based on the number of patients enrolled in the trial. Other indirect costs are generally recognized on a straight-line basis over the estimated period of the study. As actual costs become known to us, we adjust our accruals. To date, our estimates have not differed materially from the actual costs incurred. However, subsequent changes in estimates may result in a material change in our accruals, which could also materially affect our balance sheet and results of operations.

Stock-Based Compensation

The fair value of each employee stock option and each employee stock purchase plan right granted is estimated on the grant date under the fair value method using the Black-Scholes valuation model, which requires us to make a number of assumptions including the estimated expected life of the award and related volatility. The fair value of restricted stock units is estimated based on the market price of our common stock on the date of grant. The estimated fair values of stock options, purchase plan rights, and regular restricted stock units are then expensed over the vesting period. For restricted stock units requiring satisfaction of both market and service conditions, the estimated fair values are generally expensed over the longest of the explicit, implicit and derived service periods. The fair value of performance-based stock awards (PSUs) that vest upon the achievement of certain pre-defined company-specific performance-based criteria is estimated based on the closing market price of our common stock on the date of grant. Expense related to these PSUs is recognized ratably over the expected performance period once the pre-defined performance-based criteria for vesting becomes probable and can vest up to 200 percent of the target number of shares granted. Beginning in 2024, the structure of the PSU design was revised with a relative total shareholder return (rTSR) approach such that awards are earned for our rTSR performance over three-year measurement periods relative to a peer group of companies and the actual numbers of PSUs that will vest at the end of the performance period may be anywhere from zero to 150 percent of the target number of shares granted. The fair value of these PSUs is estimated using a Monte Carlo model. Expense related to these PSUs is recognized ratably over the three-year measurement period. See also Item 15 of Part IV, "Notes to Consolidated Financial Statements—Note 2—Summary of Significant Accounting Policies" for further discussion of our assumptions and estimates related to our stock-based compensation.

Income Taxes

Our provision for income taxes, deferred tax assets and liabilities, and reserves for unrecognized tax benefits reflect our best assessment of estimated future taxes to be paid. Judgments and estimates based on interpretations of existing tax laws or regulations in the United States and the numerous foreign jurisdictions where we are subject to income tax are required in determining our provision for income taxes. Changes in tax laws, regulations, or statutory tax rates, and estimates of our future taxable income could impact the deferred tax assets and liabilities provided for in the consolidated financial statements and would require an adjustment to the provision for income taxes.

The company evaluates the realizability of DTAs on a quarterly basis, weighing positive and negative evidence to determine if it is "more likely than not" that all or some portion of the DTAs will be realized. The weight given to evidence is based on the extent to which it can be objectively verified.

Prior to fiscal year 2025, we maintained a full valuation allowance against our net DTAs due to a history of cumulative losses. However, during the fiscal year ended December 31, 2025, we achieved cumulative three-year profitability. Management determined there is sufficient positive evidence to conclude it is "more likely than not" that deferred taxes of $249.9 million are realizable. We therefore reduced the valuation allowance accordingly.

The Company recognizes the impact of a tax position in the financial statements only if that position is more likely than not to be sustained upon examination by taxing authorities, based on the technical merits of the position. Any interest and penalties related to uncertain tax positions will be reflected in income tax expense.

Results of Operations

Fluctuations in Operating Results

Our results of operations have fluctuated significantly from period to period in the past and are likely to continue to do so in the future. We anticipate that our quarterly and annual results of operations will be impacted for the foreseeable future by several factors, including the progress and timing of expenditures related to our commercial activities associated with our products and the extent to which we generate revenue from product sales, our further development of our early-stage product candidates and the progress and timing of expenditures related to studies of DAYBUE pursuant to our PMRs. Further, we expect our sales allowances to vary from quarter to quarter due to fluctuations in our Medicare Part D liability and the volume of purchases eligible for government mandated discounts and rebates, as well as changes in discount percentages that may be impacted by potential future price increases and other factors. We cannot predict with certainty what the full impact that geopolitical and macroeconomic developments, including the ongoing military conflict between Ukraine and Russia and in the Middle East, and tariffs and trade tensions may have on our business, results of operations, financial condition and prospects. Due to these fluctuations, we believe that the period-to-period comparisons of our operating results are not a good indication of our future performance.

Comparison of the Years Ended December 31, 2025 and 2024

Product Sales, Net

Net product sales, comprised of our products, were $1,071.5 million and $957.8 million for the years ended December 31, 2025 and 2024, respectively.

Net product sales of NUPLAZID were $680.1 million and $609.4 million in 2025 and 2024, respectively. The increase in net product sales of NUPLAZID of $70.7 million was due to the growth in NUPLAZID unit sales as well as a higher average net selling price of NUPLAZID in 2025 compared to 2024, partially offset by an unfavorable gross-to-net adjustments of approximately $11.8 million related to Medicare inflation cap rebates for the sales related to October 1, 2022 to December 31, 2024. This adjustment does not impact underlying demand trends, which continue to be demonstrated by strong volume growth. Net product sales of DAYBUE were $391.4 million and $348.4 million in 2025 and 2024, respectively. The increase in net product sales of DAYBUE of $43.0 million was due to the growth in DAYBUE unit sales as well as a higher average net selling price of DAYBUE in 2025 compared to 2024.

The following table provides a summary of activity with respect to our sales allowances and accruals for the year ended December 31, 2025 (in thousands):

	Distribution Fees, Discounts & Chargebacks	Co-Pay Assistance	Rebates, Data Fees & Returns	Total
Balance at December 31, 2024	$ 11,883	$ (114)	$ 148,106	$ 159,875
Provision related to current period sales	145,584	6,779	197,113	349,476
Credits/payments for current period sales	(129,127)	(6,816)	(69,589)	(205,532)
Credits/payments for prior period sales	(11,883)	114	(135,190)	(146,959)
Balance at December 31, 2025	$ 16,457	$ (37)	$ 140,440	$ 156,860

Cost of Product Sales

Cost of product sales was $89.0 million and $81.8 million for the years ended December 31, 2025 and 2024, respectively, or approximately 8% and 9% of net product sales, respectively. Cost of product sales as a percentage of net product sales for both NUPLAZID and DAYBUE remained relatively flat in 2025 as compared to 2024. The increase in cost of product sales was primarily due to the increased standard per unit manufacturing cost for DAYBUE as we substantially finished the zero cost inventories.

Certain manufacturing related expenses incurred prior to DAYBUE receiving FDA approval were classified as research and development expenses, resulting in zero cost inventory. Prior to receiving FDA approval for DAYBUE in March 2023, we manufactured inventory and recorded approximately $29.9 million related to the zero cost inventory as research and development expense. If the previously expensed inventory been capitalized and recognized when sold, the total cost of sales with these manufacturing costs included for the year ended December 31, 2025 would have increased by approximately $6.3 million based on the actual direct costs to manufacture DAYBUE prior to receiving FDA approval. We do not expect our cost of product sales for DAYBUE to increase significantly as a percentage of net product sales in future periods as we continue to produce inventory for future sales. We sold substantially all of the zero cost inventories of DAYBUE through the year ended December 31, 2025.

Subsequent to using our entire zero cost inventories, we estimate our overall cost of product sales as a percentage of total net product sales will be in the range of a mid-single digit to high single digit percentage.

Research and Development Expenses

Research and development expenses increased to $328.8 million for the year ended December 31, 2025 from $303.2 million for the year ended December 31, 2024. The increase in research and development expenses during 2025 was primarily related to increased expenditures for remlifanserin and other early-stage product candidates as well as increased personnel expenses, offset by reduced expenditures for ending studies that took place in 2025.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased to $548.9 million for the year ended December 31, 2025 from $488.4 million for the year ended December 31, 2024. The increase in selling, general and administrative expenses was primarily driven by costs related to our consumer activation program to support NUPLAZID and the planned expansion of the DAYBUE team.

Gain on Sale of Non-Financial Asset

Following the FDA approval of DAYBUE, we were granted a Rare Pediatric Disease PRV. During the year ended December 31, 2024, we sold the PRV to a third party for the aggregate net proceeds of $146.5 million. There were no non-financial asset sales during the year ended December 31, 2025.

Comparison of the Years Ended December 31, 2024 and 2023

Product Sales, Net

Product sales, net, comprised of our products, were $957.8 million and $726.4 million in the years ended December 31, 2024 and 2023, respectively.

Net product sales of NUPLAZID were $609.4 million and $549.2 million in 2024 and 2023, respectively. The increase in net product sales of NUPLAZID of $60.2 million was due to the growth in NUPLAZID unit sales as well as a higher average net selling price in NUPLAZID in 2024 compared to 2023. Net product sales of DAYBUE were $348.4 million and $177.2 million in 2024 and 2023, respectively. The increase in net product sales of DAYBUE of $171.2 million was mainly due to the growth in DAYBUE unit sales in 2024 compared to 2023.

The following table provides a summary of activity with respect to our sales allowances and accruals for the year ended December 31, 2024 (in thousands):

	Distribution Fees, Discounts & Chargebacks	Co-Pay Assistance	Rebates, Data Fees & Returns	Total
Balance at December 31, 2023	$ 12,156	$ (520)	$ 86,054	$ 97,690
Provision related to current period sales	122,083	5,148	168,868	296,099
Credits/payments for current period sales	(110,200)	(5,262)	(20,762)	(136,224)
Credits/payments for prior period sales	(12,156)	520	(86,054)	(97,690)
Balance at December 31, 2024	$ 11,883	$ (114)	$ 148,106	$ 159,875

Cost of Product Sales

Cost of product sales was $81.8 million and $41.6 million in 2024 and 2023, respectively, or approximately 9% and 6% of net product sales, respectively. Cost of product sales as a percentage of net product sales for NUPLAZID remained flat in 2024 as compared to 2023. The increase in cost of product sales was primarily due to the $51.8 million in license fees and royalties expensed during 2024 as compared to $21.8 million in the same period of 2023 for DAYBUE, including royalties due to Neuren based on net sales of DAYBUE and the amortization of the milestone payments capitalized under our 2018 license agreement with Neuren.

Certain manufacturing related expenses incurred prior to DAYBUE receiving FDA approval were classified as research and development expenses, resulting in zero cost inventory. Prior to receiving FDA approval for DAYBUE in March 2023, we manufactured inventory and recorded approximately $29.9 million related to the zero cost inventory as research and development expense. Utilizing the actual direct costs to manufacture DAYBUE prior to receiving FDA approval, had the previously expensed inventory been capitalized and recognized when sold, the total cost of sales with these manufacturing costs included for the year ended December 31, 2024 would have increased by approximately $14.9 million. We do not expect our cost of product sales for DAYBUE to increase significantly as a percentage of net product sales in future periods as we continue to produce inventory for future sales.

Subsequent to using our entire zero cost inventories, we estimate our overall cost of product sales as a percentage of total net product sales will be in the range of a mid-single digit to high single digit percentage.

Research and Development Expenses

Research and development expenses decreased to $303.2 million in 2024, including $14.1 million in stock-based compensation expense, from $351.6 million in 2023, including $17.4 million in stock-based compensation expense. The decrease in research and development expenses during 2024 was due to decreased business development payments, which in the period ending December 31, 2023 included the $100.0 million payment to Neuren under the expanded license agreement for trofinetide, partially offset by increased costs from clinical stage programs.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased to $488.4 million in 2024, including $51.6 million in stock-based compensation expense, from $406.6 million in 2023, including $48.0 million in stock-based compensation expense. The increase in selling, general and administrative expenses was primarily driven by increased marketing costs to support the NUPLAZID and DAYBUE franchises in the U.S. and investments to support commercialization of DAYBUE outside the U.S.

Gain on Sale of Non-Financial Asset

Following the FDA approval of DAYBUE, we were granted a Rare Pediatric Disease PRV. During the year ended December 31, 2024, we sold the PRV to a third party for the aggregate net proceeds of $146.5 million. No non-financial asset sale happened during the year ended December 31, 2023.

Liquidity and Capital Resources

We have funded our operations primarily with revenues from sales of our products since their approvals, and through sales of our equity securities and interest income. We anticipate that the level of cash used in our operations will fluctuate in future periods depending on the levels of spending required for our ongoing and planned commercial activities for our products, our ongoing and planned development activities for remlifanserin as a treatment for ADP and LBDP, studies to be conducted pursuant to our PMRs, our ongoing and planned development activities for other early- and late-stage product candidates and strategic business development to further expand our portfolio. We expect that our cash, cash equivalents and investment securities, as well as funds generated by anticipated sales of our products, will be sufficient to fund our planned operations through and beyond the next 12 months.

We may require additional financing in the future to fund our operations. Our future capital requirements will depend on, and could increase significantly as a result of, many factors, including:

- the costs of acquiring additional product candidates or research and development programs;
- the scope, prioritization and number of our research and development programs;
- the ability of our collaborators and us to reach the milestones and other events or developments triggering payments under our collaboration or license agreements, or our collaborators' ability to make payments under these agreements;
- our ability to enter into new collaboration and license agreements;
- the progress in, and the costs of, our ongoing and planned development activities for pimavanserin, post-marketing studies for DAYBUE to be conducted over the next several years, and ongoing and planned commercial activities for our products;
- the costs of our development activities for our product candidates;
- the costs of commercializing our products, including the maintenance and development of our sales and marketing capabilities;
- the costs of establishing, or contracting for, sales and marketing capabilities for our product candidates;
- the amount of U.S. product sales from our products;

- the costs of preparing applications for regulatory approvals for DAYBUE in jurisdictions other than the U.S., for NUPLAZID in additional indications other than PDP and for other product candidates, as well as the costs required to support review of such applications;
- the costs of manufacturing and distributing our products for commercial use in the U.S.;
- our ability to obtain regulatory approval for, and subsequently generate product sales from, our product candidates;
- the extent to which we are obligated to reimburse collaborators or collaborators are obligated to reimburse us for costs under collaboration agreements;
- the costs involved in filing, prosecuting, enforcing, and defending patent claims and other intellectual property rights;
- the costs of maintaining or securing manufacturing arrangements for clinical or commercial production of pimavanserin, trofinetide or other product candidates; and
- the costs associated with litigation, including the costs incurred in defending against any product liability claims that may be brought against us related to our products.

In the past, periods of turmoil and volatility in the financial markets have adversely affected the market capitalizations of many biotechnology companies, and generally made equity and debt financing more difficult to obtain. For example, due to geopolitical and macroeconomic developments, including the Ukraine-Russia military conflict and related sanctions, the ongoing conflicts in the Middle East, tariffs and trade tensions, the global credit and financial markets have experienced extreme volatility and disruptions, including diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. These events, coupled with other factors, may limit our access to additional financing in the future. We cannot be certain that additional funding will be available to us on acceptable terms, or at all. If adequate funds are not available when needed, we will be required to delay, reduce the scope of, or eliminate one or more of our research or development programs or our commercialization efforts. We also may be required to relinquish greater or all rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose. Additional funding, if obtained, may significantly dilute existing stockholders and could negatively impact the price of our stock.

We have invested a substantial portion of our available cash in money market funds, municipal bonds, and government sponsored enterprises in accordance with our investment policy. Our investment policy defines allowable investments and establishes guidelines relating to credit quality, diversification, and maturities of our investments to preserve principal and maintain liquidity. All investment securities have a credit rating of at least Aa3/AA- or better, or P-1/A-1 or better, as determined by Moody's Investors Service or Standard & Poor's. Our investment portfolio has not been adversely impacted by the disruptions in the credit markets that have occurred in the past. However, if there are future disruptions in the credit markets, there can be no assurance that our investment portfolio will not be adversely affected.

Material Cash Requirements

Our material cash requirements in the short and long term consist of the operational, manufacturing, and capital expenditures, a portion of which contain contractual or other obligations. We plan to fund our material cash requirements with our current financial resources together with our anticipated receipts from product sales. On a long-term basis, we manage future cash requirements relative to our long-term business plans.

Our primary uses of cash and operating expenses relate to paying employees and consultants, administering clinical trials, marketing our products, and providing technology and facility infrastructure to support our operations. We also make investments in our office and laboratory facilities to enable continued expansion of our business.

As of December 31, 2025 we have long-term contractual obligations related to our operating leases of $58.5 million. In May 2023, we subleased our 2nd floor of corporate office space in San Diego with a total minimum sublease income of $18.4 million. In addition to operating leases, we enter into certain other long-term commitments for goods and services that are outstanding for periods greater than one year. We also enter into short-term agreements with various vendors and suppliers of goods and services in the normal course of operations through purchase orders or other documentation, or that are undocumented except for an invoice. Such short-term agreements are generally outstanding for periods less than a year and are settled by cash payments upon delivery of goods and services. The nature of the work being conducted under these agreements is such that, in most cases, the services may be stopped on short notice. In such event, we would not be liable for the full amount of the agreement.

We have entered into various collaboration, licensing and merger agreements which generally include upfront license fees, development and commercial milestone payments upon achievement of certain clinical and commercial development and annual net sales milestones, as well as royalties calculated as a percentage of net product sales, with rates that vary by agreement. As of December 31, 2025, we may be required to make milestone payments up to $3.5 billion in the aggregate. $0.9 billion payments are contingent upon achieving future development and regulatory milestones, and $2.6 billion payments are contingent upon achieving future commercial milestones.

We expect to receive an invoice for rebates under the IRA from Medicare Part D unit sales for applicable period of October 1, 2024 to September 30, 2025 in June 2026. Payment is due 30 days after receiving such invoice; the payment will be set off against the allowance for such rebate that we have accrued up to the date of payment.

Cash Flows

At December 31, 2025, we had $819.7 million in cash, cash equivalents, and investment securities, compared to $756.0 million at December 31, 2024. This $63.7 million increase in cash, cash equivalents, and investment securities during 2025 was primarily due to net cash provided by operating activities.

Net cash provided by operating activities was $109.8 million in 2025 compared to $157.7 million in 2024 and $16.7 million in 2023. The decrease in net cash provided by operating activities in 2025 relative to 2024 was primarily due to increased research and development costs and sales and marketing costs, partially offset by an increase in our net revenues. The increase in net cash provided by operating activities in 2024 relative to 2023 was primarily due to an increase in our net revenues and decreased research and development costs, partially offset by increased sales and marketing costs.

Net cash used in investing activities totaled $302.6 million in 2025 compared to net cash used in investing activities of $30.5 million in 2024 and net cash provided by investing activities of $32.0 million in 2023. The increase in net cash used in investing activities in 2025 compared to 2024 was primarily due to no proceeds from sale of a non-financial asset and increased net payments made to Neuren for our sale of the PRV and an annual net sales milestone. The increase in net cash used in investing activities in 2024 compared to 2023 was primarily due to increased net purchases of investment securities.

Net cash provided by financing activities was $49.9 million in 2025 compared to $6.8 million in 2024 and $25.1 million in 2023. This increase in net cash provided by financing activities in 2025 relative to 2024 was attributable primarily to an increase in proceeds resulting from the exercise of employee stock options. The decrease in net cash provided by financing activities in 2024 relative to 2023 was primarily due to a decrease in proceeds resulting from the exercise of employee stock options.

Off-Balance Sheet Arrangements

To date, we have not had any relationships with unconsolidated entities or financial partnerships, such as entities referred to as structured finance or special purpose entities, which are established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. As such, we are not materially exposed to any financing, liquidity, market, or credit risk that could arise if we had engaged in these relationships.

Recent Accounting Pronouncements

See Item 15 of Part IV, “Notes to Consolidated Financial Statements—Note 2—Summary of Significant Accounting Policies.”

Item 7A. ***Quantitative and Qualitative Disclosures About Market Risk***

Interest Rate Risk

We invest our excess cash in investment-grade, interest-bearing securities. The primary objective of our investment activities is to preserve principal and liquidity. To achieve this objective, we invest in money market funds. U.S. treasury notes, and high quality marketable debt instruments of corporations and government sponsored enterprises with contractual maturity dates of generally less than one year. All investment securities have a credit rating of at least Aa3/AA- or better, or P-1/A-1 or better, as determined by Moody's Investors Service or Standard & Poor's. We do not have any direct investments in auction-rate securities or securities that are collateralized by assets that include mortgages or subprime debt. If a 10 percent change in interest rates were to have occurred on December 31, 2025 and 2024, this change would not have had a material effect on the fair value of our investment portfolio as of that date. Due to our investment in investment-grade, interest-bearing securities, as of the date of this Annual Report on Form 10-K, we do not expect anticipated changes in interest rates to have a material effect on our interest rate risk in future reporting periods.

Item 8. ***Financial Statements and Supplementary Data.***

The consolidated financial statements required pursuant to this item are included in Item 15 of this report and are presented beginning on page F-1.

Item 9. ***Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.***

None.

Item 9A. ***Controls and Procedures.***

Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our periodic and current reports that we file with the SEC 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 our management, including our Chief Executive Officer and Chief Financial Officer (our principal executive officer and principal financial officer, respectively), as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable and not absolute assurance of achieving the desired control objectives. In reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. In addition, the design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

As of December 31, 2025, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level 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. Internal control over financial reporting is a process designed by, or under the supervision and with the participation of, our Chief Executive Officer and Chief Financial Officer, and effected by our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America.

As of December 31, 2025, our management assessed the effectiveness of our internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act of 1934, as amended, using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework (2013). Based on this assessment, management, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, concluded that, as of December 31, 2025, our internal control over financial reporting was effective based on those criteria.

The effectiveness of our internal control over financial reporting as of December 31, 2025 has been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in its report, which is included herein.

Changes in Internal Control Over Financial Reporting

An evaluation was also performed under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of any changes in our internal control over financial reporting that occurred during our last fiscal quarter and that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. That evaluation did not identify any change in our internal control over financial reporting that occurred during our latest fiscal quarter and that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Acadia Pharmaceuticals Inc.

Opinion on Internal Control Over Financial Reporting

We have audited Acadia Pharmaceuticals Inc.'s 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 (2013 framework) (the COSO criteria). In our opinion, Acadia Pharmaceuticals Inc. (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2025, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2025 and 2024, the related consolidated statements of operations, comprehensive income (loss), cash flows and stockholders' equity for each of the three years in the period ended December 31, 2025, and the related notes and financial statement schedule listed in the Index at Item 15(a)2 and our report dated February 25, 2026 expressed an unqualified opinion thereon.

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 included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and 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 its 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 the degree of compliance with the policies or procedures may deteriorate.

/s/ Ernst & Young LLP

San Diego, California
February 25, 2026

Item 9B. ***Other Information.***

Insider Trading Arrangements

During the Company's last fiscal quarter, the following officer (as defined in Rule 16a-1(f) under the Securities Exchange Act of 1934, as amended (the Exchange Act)) adopted or terminated a "Rule 10b5-1 trading arrangement" as defined in Item 408 of Regulation S-K, as follows:

- On December 9, 2025, James Kihara, Senior Vice President, Finance, adopted a Rule 10b5-1 trading arrangement providing for the sale of up to 41,421 shares of our common stock. The trading arrangement is intended to satisfy the affirmative defense in Rule 10b5-1(c). The duration of the trading arrangement is from March 9, 2026 until March 9, 2027, or earlier if and when all transactions under the trading arrangement are completed.

Registration Rights Agreement

On February 24, 2026, we entered into a registration rights agreement (the "Registration Rights Agreement") with 667, L.P. and Baker Brothers Life Sciences, L.P] (the "Baker Entities"), both of which are existing stockholders of our company and are affiliated with our directors, Julian C. Baker and Stephen R. Biggar. The Registration Rights Agreement replaces the registration rights agreement we entered into with the Baker Entities in January 2016 that continued in effect for 10 years. Under the Registration Rights Agreement, we agreed that, if requested by the Baker Entities, we would register our securities held by the Baker Entities for resale under the Securities Act of 1933, as amended. Our registration obligations under the Registration Rights Agreement cover all of our securities now held or later acquired by the Baker Entities, will continue in effect for up to 10 years, and include our obligation to facilitate certain underwritten public offerings and block trades of our securities by the Baker Entities in the future. We and the Baker Entities granted each other customary indemnification rights in connection with our registration obligations. The Registration Rights Agreement is filed as Exhibit 10.25 to this report and the description of the terms of the Registration Rights Agreement does not purport to be complete and is qualified in its entirety by reference to the full text of such exhibit.

Item 9C. ***Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.***

Not applicable.

PART III

Item 10. ***Directors, Executive Officers and Corporate Governance*****.**

The remaining information required by this Item and not set forth below will be set forth under the proposal captioned "Election of Directors" and the sections captioned "Information Regarding the Board of Directors and Corporate Governance," "Executive Officers" and "Delinquent Section 16(a) Reports," if any, in our definitive Proxy Statement for our 2026 Annual Meeting of Stockholders to be filed with the SEC by April 30, 2026 (our Proxy Statement) and is incorporated in this report by reference.

The information required by Item 408(b) of Regulation S-K will be set forth in the section captioned "Insider Trading Arrangements and Policies" in our Proxy Statement and is incorporated in this report by reference.

We have adopted a code of ethics for directors, officers (including our principal executive officer, principal financial officer and principal accounting officer or controller) and employees, known as the Code of Business Conduct and Ethics. The Code of Business Conduct and Ethics is available on our website at *http://www.acadia.com* under the Governance Documents section of our Investors page. Information contained in our website does not constitute a part of this report or our other filings with the SEC. We will promptly disclose on our website, as required, (i) the nature of any amendment to the policy that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions and (ii) the nature of any waiver, including an implicit waiver, from a provision of the policy that is granted to one of these specified individuals, the name of such person who is granted the waiver and the date of the waiver. Stockholders may request a free copy of the Code of Business Conduct and Ethics from our compliance department c/o Acadia Pharmaceuticals Inc., 12830 El Camino Real, Suite 400, San Diego, CA 92130.

Item 11. ***Executive Compensation*****.**

The information required by this Item will be set forth in the sections headed "Executive Compensation—Compensation Disclosure and Analysis," "Director Compensation," "Compensation Committee Interlocks and Insider Participation" and "Compensation Committee Report" in our Proxy Statement and is incorporated in this report by reference.

The information required by Item 402(x) of Regulation S-K shall be set forth in the section headed "Policies and practices related to the grant of certain equity awards close in time to the release of material nonpublic information" in our Proxy Statement and is incorporated in this report by reference.

Item 12. ***Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters*****.**

The information required by this Item will be set forth in the section headed "Security Ownership of Certain Beneficial Owners and Management" in our Proxy Statement and is incorporated in this report by reference.

Information regarding our equity compensation plans will be set forth in the section headed "Equity Compensation Plan Information" in our Proxy Statement and is incorporated in this report by reference.

Item 13. ***Certain Relationships and Related Transactions, and Director Independence*****.**

The information required by this Item will be set forth in the section headed "Transactions With Related Persons" in our Proxy Statement and is incorporated in this report by reference.

Item 14. ***Principal Accountant Fees and Services*****.**

The information required by this Item will be set forth under the proposal captioned "Ratification of Selection of Independent Registered Public Accounting Firm" in our Proxy Statement and is incorporated in this report by reference.

PART IV

Item 15. ***Exhibits and Financial Statement Schedules.***

(a) Documents filed as part of this report.

1. The following financial statements of Acadia Pharmaceuticals Inc. and Report of Ernst & Young LLP, Independent Registered Public Accounting Firm, are included in this report:

2. List of financial statement schedules:

Schedule II – Valuation and Qualifying Accounts

Schedules not listed above have been omitted because they are not applicable or the required information is shown in the financial statements or notes thereto.

3. List of Exhibits required by Item 601 of Regulation S-K. See part (b) below.

(b) Exhibits.

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation, as Amended (incorporated by reference to Exhibit 3.1 to the Registrant's Quarterly Report on Form 10-Q, filed August 6, 2015).
3.2	Certificate of Amendment of Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.2 to the Registrant's Annual Report on Form 10-K, filed February 25, 2021).
3.3	Amended and Restated Bylaws of Acadia Pharmaceuticals Inc. (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed April 16, 2025).
4.1	Form of common stock certificate of the Registrant (incorporated by reference to Exhibit 4.1 to Registration Statement No. 333-52492).
4.2	Form of Amended and Restated Warrant to Purchase Common Stock (incorporated by reference to Exhibit 4.2 to the Registrant's Annual Report on Form 10-K, filed February 26, 2019).
4.3	Description of the Registrant's Common Stock (incorporated by reference to Exhibit 4.3 to the Registrant's Annual Report on Form 10-K, filed February 27, 2020).
10.1[a]	Form of Indemnity Agreement for directors and officers (incorporated by reference to Exhibit 10.1 to Registration Statement No. 333-113137).
10.2[a]	2004 Equity Incentive Plan and forms of agreement thereunder (incorporated by reference to Exhibit 10.3 to Registration Statement No. 333-113137).
10.3[a]	2010 Equity Incentive Plan, as amended (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-K, filed August 9, 2022).
10.4[a]	Forms of Nonstatutory Stock Option Grant Notice and Stock Option Agreement under Acadia Pharmaceuticals Inc. 2010 Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, filed May 9, 2024).

10.5[a]	Forms of Restricted Stock Unit Grant Notice and Restricted Stock Unit Award Agreement under Acadia Pharmaceuticals Inc. 2010 Equity Incentive Plan (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q, filed May 9, 2024).
10.6[a]	Forms of Performance Stock Unit Grant Notice and Performance Stock Unit Award Agreement under Acadia Pharmaceuticals Inc. 2010 Equity Incentive Plan (incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q, filed May 9, 2024).
10.7[a]	2004 Employee Stock Purchase Plan, as amended (incorporated by reference to Exhibit 99.1 to the Registrant's Current Report on Form 8-K, filed June 29, 2020).
10.8[a]	Offerings under the 2004 Employee Stock Purchase Plan, as amended (incorporated by reference to Exhibit 10.6 to the Registrant's Annual Report on Form 10-K, filed February 28, 2017).
10.9[a]	Employment Agreement, dated September 23, 2024, by and between the Registrant and Catherine Owen Adams (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K, filed on September 23, 2024).
10.10[a]	Employment Offer Letter, dated April 28, 2020, between the Registrant and Mark Schneyer (incorporated by reference to Exhibit 10.11 to the Registrant's Annual Report on Form 10-K, filed March 1, 2022).
10.11[a]	Employment Offer Letter, dated February 22, 2024, between the Registrant and Elizabeth H. Z. Thompson. (incorporated by reference to Exhibit 10.9 of the Registrant's Quarterly Report on Form 10-Q, filed August 7, 2024).
10.12[a]	Employment Offer Letter, dated January 12, 2024, between the Registrant and Jennifer Rhodes (incorporated by reference to Exhibit 10.13 to the Registrant's Annual Report on Form 10-K, filed February 28, 2024).
10.13[a, b]	Employment Offer Letter, dated November 15, 2024, by and between the Registrant and Thomas Garner (incorporated by reference to Exhibit 10.16 to the Registrant's Annual Report on Form 10-K, filed February 27, 2025).
10.14[a]	Non-Employee Director Compensation Policy, effective April 14, 2025 (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, filed May 8, 2025).
10.15[a]	Management Severance Benefit Plan (incorporated by reference to Exhibit 99.1 to the Registrant's Current Report on Form 8-K, filed December 15, 2015).
10.16[a]	Amended and Restated Change in Control Severance Benefit Plan (incorporated by reference to Exhibit 99.2 to the Registrant's Current Report on Form 8-K, filed December 15, 2015).
10.17[b]	Master Manufacturing Services Agreement and Product Agreement, dated August 3, 2015, by and between the Registrant and Patheon Pharmaceuticals Inc. (incorporated by reference to Exhibit 10.17 to the Registrants Annual Report on Form 10-K, filed February 28, 2024).
10.18[b]	First Amendment to Product Agreement, dated April 25, 2016, by and between the Registrant and Patheon Pharmaceuticals Inc. (incorporated by reference to Exhibit 10.18 to the Registrants Annual Report on Form 10-K, filed February 28, 2024).
10.19[b]	Second Amendment to Product Agreement, dated October 6, 2016, by and between the Registrant and Patheon Pharmaceuticals Inc. (incorporated by reference to Exhibit 10.19 to the Registrants Annual Report on Form 10-K, filed February 28, 2024).
10.20[b]	Third Amendment to Product Agreement, dated December 11, 2017, by and between the Registrant and Patheon Pharmaceuticals Inc. (incorporated by reference to Exhibit 10.20 to the Registrants Annual Report on Form 10-K, filed February 28, 2024).
10.21[b]	Master Services Agreement, dated December 15, 2016, by and between Acadia Pharmaceuticals GmbH and Siegfried AG and its affiliates, and Attachment #1, Attachment #2 and Attachment #3 (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, filed November 3, 2022).
10.22[b]	Change Order #1 to Master Services Agreement Attachment #1, dated January 3, 2017, by and between Acadia Pharmaceuticals GmbH and Siegfried AG (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q, filed November 3, 2022).

10.23[b]	Attachment #4, Attachment #5 and Attachment #6, each dated May 12, 2017, to the Master Services Agreement, dated December 15, 2016, by and between Acadia Pharmaceuticals GmbH and Siegfried AG and its affiliates (incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q, filed November 3, 2022).
10.24[b]	Attachment #7, dated September 30, 2020, to the Master Services Agreement, dated December 15, 2016, by and between Acadia Pharmaceuticals GmbH and Siegfried AG and its affiliates (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly report on Form 10-Q, filed November 4, 2020).
10.25	Registration Rights Agreement, dated February 24, 2026, among the Registrant and the investors listed on Schedule A thereto.
10.26	Assignment of Brann Intellectual Property Rights, dated January 29, 1997, by Mark R. Brann in favor of the Registrant (incorporated by reference to Exhibit 10.17 to Registration Statement No. 333-52492).
10.27[b]	License Agreement, dated August 6, 2018, by and between the Registrant and Neuren Pharmaceuticals Ltd. (incorporated by reference to Exhibit 10.30 to the Registrant's Annual Report on Form 10-K, filed February 27, 2025).
10.28[b]	Lease Agreement, effective October 4, 2018, by and between the Registrant and Kilroy Realty, L.P (incorporated by reference to Exhibit 10.31 to the Registrant's Annual Report on Form 10-K, filed February 27, 2025).
10.29[b]	First Amendment to Office Lease, dated December 23, 2019, between the Registrant and Kilroy Realty, L.P. (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly report on Form 10-Q, filed May 8, 2020).
10.30[b]	Second Amendment to Office Lease, dated March 12, 2020, between the Registrant and Kilroy Realty, L.P. (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly report on Form 10-Q, filed May 8, 2020).
10.31[a]	Acadia Pharmaceuticals Inc. 2023 Inducement Plan (incorporated by reference to Exhibit 99.1 to Registration Statement No. 333-269611).
10.32[a]	Forms of Stock Option Grant Notice and Stock Option Agreement under Acadia Pharmaceuticals Inc. 2023 Inducement Plan (incorporated by reference to Exhibit 99.2 to Registration Statement No. 333-269611).
10.33[a]	Forms of Restricted Stock Unit Grant Notice and Restricted Stock Unit Agreement under Acadia Pharmaceuticals Inc. 2023 Inducement Plan (incorporated by reference to Exhibit 99.3 to Registration Statement No. 333-269611).
10.34[b]	Lease Agreement, effective May 15, 2018, by and between the Registrant and Boston Properties Limited Partnership (incorporated by reference to Exhibit 10.33 to the Registrant's Annual Report on Form 10-K, filed February 28, 2023).
10.35[b]	Master Commercial Supply Agreement, dated November 16, 2022, by and between the Registrant and Corden Pharma Bergamo S.p.A. (incorporated by reference to Exhibit 10.36 to the Registrants Annual Report on Form 10-K, filed February 28, 2024).
10.36[b]	Commercial Supply Agreement, dated December 15, 2021, by and between the Registrant and F.I.S. Fabbrica Italiana Sintetici S.p.A. (incorporated by reference to Exhibit 10.36 to the Registrants Annual Report on Form 10-K, filed February 28, 2024).
10.37[b]	Product Agreement, effective May 1, 2022, by and between the Registrant and Patheon Pharmaceuticals Inc. (incorporated by reference to Exhibit 10.37 to the Registrants Annual Report on Form 10-K, filed February 28, 2024).
10.38[b]	Commercial Supply Agreement, dated March 1, 2023, by and between the Registrant and Bend Biosciences (formerly known as CoreRx Inc.) as amended by Amendment No. 1, dated August 1, 2023 (incorporated by reference to Exhibit 10.38 to the Registrants Annual Report on Form 10-K, filed February 28, 2024).
10.39[b]	Joint Venture and License Agreement, dated July 13, 2023, by and between the Registrant and Neuren Pharmaceuticals Ltd. (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, filed August 3, 2023).
10.40[a]	Acadia Pharmaceuticals Inc. 2024 Equity Incentive Plan (incorporated by reference to Exhibit 99.1 to Registration Statement No. 333-279784).

10.41[a]	Forms of Standard Stock Option Grant Notice and Stock Option Agreement under the Acadia Pharmaceuticals Inc. 2024 Equity Incentive Plan (incorporated by reference to Exhibit 99.2 to Registration Statement No. 333-279784).
10.42[a]	Forms of Standard Restricted Stock Unit Grant Notice and Restricted Stock Unit Agreement under the Acadia Pharmaceuticals Inc. 2024 Equity Incentive Plan (incorporated by reference to Exhibit 99.3 to Registration Statement No. 333-279784).
10.43[a]	Forms of Director Stock Option Grant Notice and Stock Option Agreement under the Acadia Pharmaceuticals Inc. 2024 Equity Incentive Plan (incorporated by reference to Exhibit 99.4 to Registration Statement No. 333-279784).
10.44[a]	Forms of Director Restricted Stock Unit Grant Notice and Restricted Stock Unit Agreement under the Acadia Pharmaceuticals Inc. 2024 Equity Incentive Plan (incorporated by reference to Exhibit 99.5 to Registration Statement No. 333-279784).
10.45[a]	Acadia Pharmaceuticals Inc. 2024 Inducement Plan (incorporated by reference to Exhibit 99.1 to Registration Statement No. 333-282295).
10.46[a]	Forms of Standard Stock Option Grant Notice and Stock Option Agreement under the Acadia Pharmaceuticals Inc. 2024 Inducement Plan (incorporated by reference to Exhibit 99.2 to Registration Statement No. 333-282295).
10.47[a]	Forms of Standard Restricted Stock Unit Grant Notice and Restricted Stock Unit Agreement under the Acadia Pharmaceuticals Inc. 2024 Inducement Plan (incorporated by reference to Exhibit 99.3 to Registration Statement No. 333-282295).
10.48[a]	Forms of Standard Performance Stock Unit Grant Notice and Performance Stock Unit Agreement under the Acadia Pharmaceuticals Inc. 2024 Inducement Plan (incorporated by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q, filed August 7, 2025).
10.49[a]	Lease and Lease Agreement, dated May 15, 2025, between the Company and 210 Associates Limited Partnership (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q, filed August 7, 2025).
10.50[a]	Amendment No. 1 to Lease and Lease Agreement, dated May 15, 2025, between the Company and Boston Properties Limited Partnership (incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q, filed August 7, 2025).
10.51[a]	Forms of Standard Performance Stock Unit Grant Notice and Performance Stock Unit Agreement under the Acadia Pharmaceuticals Inc. 2024 Equity Incentive Plan (incorporated by reference to Exhibit 10.5 to the Registrant's Quarterly Report on Form 10-Q, filed August 7, 2025).
10.52[b]	Commercial Supply Agreement, dated February 22, 2018, by and between the Registrant and Catalent Pharma Solutions, LLC, as amended by Amendment No. 1 dated May 1, 2019 and Amendment No. 2 dated May 29, 2020.
10.53[b]	Master Commercial Manufacturing Services Agreement, dated December 10, 2025, by and between the Registrant and Halo Pharmaceutical, Inc.
19.1	Acadia Pharmaceuticals Inc. Insider Trading Policy (incorporated by reference to Exhibit 19.1 to the Registrant's Annual Report on Form 10-K, filed February 27, 2025).
21.1	List of subsidiaries of the Registrant.
23.1	Consent of Independent Registered Public Accounting Firm.
24.1	Power of Attorney (see signature page hereto).
31.1	Certification of Catherine Owen Adams, Chief Executive Officer, pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Mark Schneyer, Executive Vice President and Chief Financial Officer, pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

32.1[c]	Certification of Catherine Owen Adams, Chief Executive Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2[c]	Certification of Mark Schneyer, Executive Vice President and Chief Financial Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
97.1	Acadia Pharmaceuticals Inc. Dodd-Frank Clawback Policy (incorporated by reference to Exhibit 97.1 to the Registrants Annual Report on Form 10-K, filed February 28, 2024).
101	The following financial statements from this Annual Report, formatted in iXBRL (Inline Extensible Business Reporting Language), are filed herewith: (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Operations, (iii) Consolidated Statements of Comprehensive Loss, (iv) Consolidated Statements of Cash Flows, (v) Consolidated Statements of Stockholders' Equity, and (vi) Notes to Consolidated Financial Statements.
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)

[a] Indicates management contract or compensatory plan or arrangement.

[b] Pursuant to Item 601(b)(10) of Regulation S-K, certain portions of this exhibit have been omitted (indicated by "[***]" or "[…***…]") because the Company has determined that the information is both not material and is the type that the Company treats as private or confidential.

[c] The information in Exhibits 32.1 and 32.2 shall not be deemed "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act or the Exchange Act (including this Annual Report), unless the Registrant specifically incorporates the foregoing information into those documents by reference.

Item 16. ***Form 10-K Summary***

None.

SIGNATURES

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

ACADIA PHARMACEUTICALS INC.

Date: February 25, 2026

/s/ CATHERINE OWEN ADAMS

Catherine Owen Adams
Chief Executive Officer
(on behalf of the registrant and as the registrant's Principal Executive Officer)

KNOW ALL PERSONS BY THESE PRESENTS, that each individual whose signature appears below constitutes and appoints each of Catherine Owen Adams and Mark C. Schneyer his or her true and lawful attorney-in-fact and agent, with full power of substitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto and all documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that each said attorney-in-fact and agent, or his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities and 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/ Catherine Owen Adams **Catherine Owen Adams**	Chief Executive Officer and Director (Principal Executive Officer)	February 25, 2026
/s/ Mark C. Schneyer **Mark C. Schneyer**	Executive Vice President and Chief Financial Officer (Principal Financial Officer)	February 25, 2026
/s/ James K. Kihara **James K. Kihara**	Senior Vice President, Finance (Principal Accounting Officer)	February 25, 2026
/s/ Stephen R. Biggar **Stephen R. Biggar**	Chairman of the Board	February 25, 2026
/s/ Julian C. Baker **Julian C. Baker**	Director	February 25, 2026
/s/ Laura A. Brege **Laura A. Brege**	Director	February 25, 2026
/s/ James M. Daly **James M. Daly**	Director	February 25, 2026
/s/ Elizabeth A. Garofalo **Elizabeth A. Garofalo**	Director	February 25, 2026
/s/ Edmund P. Harrigan **Edmund P. Harrigan**	Director	February 25, 2026
/s/ Adora Ndu **Adora Ndu**	Director	February 25, 2026

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Acadia Pharmaceuticals Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Acadia Pharmaceuticals Inc. (the Company) as of December 31, 2025 and 2024, the related consolidated statements of operations, comprehensive income (loss), cash flows and stockholders' equity for each of the three years in the period ended December 31, 2025, and the related notes and financial statement schedule listed in the Index at Item 15(a)2 (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2025 and 2024, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2025, in conformity with U.S. generally accepted accounting principles.

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 criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework), and our report dated February 25, 2026 expressed an unqualified opinion thereon.

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 audit 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 Matter

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

Medicare Part D sales rebate accruals

Description of the Matter	As described in Note 2 to the consolidated financial statements under the caption "Revenue Recognition" the Company establishes provisions for sales rebates and discounts in the same period as the related sales occur. Estimated sales rebates for the purchase of NUPLAZID covered by Medicare Part D are included within accrued liabilities on the consolidated balance sheet. In order to establish these sales rebate accruals, the Company estimated its rebates based upon the identification of the product subject to a rebate, the historical and expected payor mix, the applicable price, rebate terms and the estimated lag time between the sale and payment of the rebate. Auditing the Medicare Part D sales rebate is complex because of certain assumptions required to estimate the rebate liabilities and the amounts involved are material to the financial statements taken as a whole. In calculating the appropriate accrual amount, the Company considered historical Medicare Part D rebate payments as well as any significant changes in sales trends, the lag in payment timing, an evaluation of the current Medicare Part D laws and interpretations, the percentage of products that are sold via Medicare Part D, and product pricing. In deriving these estimates and assumptions, the Company used both internal and external sources of information to estimate product in the distribution channels, payor mix, prescription volumes and historical experience. Management supplemented its historical data analysis with qualitative adjustments based upon changes in rebate trends, rebate programs and contract terms, legislative changes, or other significant events which indicate a change in the reserve is appropriate.
How We Addressed the Matter in Our Audit	We obtained an understanding, evaluated the design, and tested the operating effectiveness of controls over the Company's sales rebate accruals for Medicare Part D rebates. This included testing controls over management's review of the significant assumptions described above and inputs into the rebate calculations. For example, we tested controls over actual sales and the accuracy of forecasting expected utilization and payor mix. The testing was inclusive of management's controls to evaluate the accuracy of its reserve judgments to actual rebates paid, rebate validation and processing, and controls to ensure that the data used to evaluate and support the significant assumptions was complete, accurate and, where applicable, verified to external data sources. To test the sales rebate accruals for Medicare Part D, our audit procedures included, among others, understanding and evaluating the significant assumptions and underlying data used in management's calculations. Our testing of significant assumptions included a lookback analysis to evaluate the historical accuracy of management's estimates by comparing actual rebates to previous estimates and performed sensitivity analyses over certain assumptions to evaluate the completeness of the reserves. As a part of our procedures, we evaluated the reasonableness of the Company's assumptions considering recent sales trends and regulatory factors.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2015.

San Diego, California
February 25, 2026

ACADIA PHARMACEUTICALS INC.
CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share amounts)

	December 31, 2025	December 31, 2024
Assets		
Cash and cash equivalents	$ 177,695	$ 319,589
Investment securities, available-for-sale	641,991	436,404
Accounts receivable, net	121,457	98,739
Interest and other receivables	26,774	5,956
Inventory	34,670	21,949
Prepaid expenses	59,526	55,681
Total current assets	1,062,113	938,318
Property and equipment, net	7,511	4,215
Operating lease right-of-use assets	47,354	46,571
Intangible assets, net	108,893	119,782
Restricted cash	7,845	8,770
Long-term inventory	76,704	69,741
Deferred tax assets	249,879	—
Other assets	3,896	359
Total assets	$ 1,564,195	$ 1,187,756
Liabilities and stockholders' equity		
Accounts payable	$ 10,903	$ 16,192
Accrued liabilities	266,211	378,678
Total current liabilities	277,114	394,870
Operating lease liabilities	40,554	42,037
Other long-term liabilities	19,137	18,056
Total liabilities	336,805	454,963
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 5,000,000 shares authorized at December 31, 2025 and 2024; no shares issued and outstanding at December 31, 2025 and 2024	—	—
Common stock, $0.0001 par value; 225,000,000 shares authorized at December 31, 2025 and 2024; 170,309,376 shares and 166,708,856 shares issued and outstanding at December 31, 2025 and 2024, respectively	16	16
Additional paid-in capital	3,039,315	2,936,871
Accumulated deficit	(1,813,386)	(2,204,386)
Accumulated other comprehensive income	1,445	292
Total stockholders' equity	1,227,390	732,793
Total liabilities and stockholders' equity	$ 1,564,195	$ 1,187,756

The accompanying notes are an integral part of these consolidated financial statements.

ACADIA PHARMACEUTICALS INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share amounts)

	Years Ended December 31,		
	2025	2024	2023
Revenues			
Product sales, net	$ 1,071,505	$ 957,797	$ 726,437
Total revenues	1,071,505	957,797	726,437
Operating expenses			
Cost of product sales	88,998	81,841	41,638
Research and development	328,802	303,249	351,619
Selling, general and administrative	548,894	488,428	406,559
Gain on sale of non-financial asset	—	(146,515)	—
Total operating expenses	966,694	727,003	799,816
Income (loss) from operations	104,811	230,794	(73,379)
Interest income, net	31,722	25,458	17,234
Other income	2,371	1,823	5,109
Income (loss) before income taxes	138,904	258,075	(51,036)
Income tax (benefit) expense	(252,096)	31,624	10,250
Net income (loss)	$ 391,000	$ 226,451	$ (61,286)
Earnings (net loss) per share:			
Basic	$ 2.32	$ 1.37	$ (0.37)
Diluted	$ 2.30	$ 1.36	$ (0.37)
Weighted average common shares outstanding:			
Basic	168,356	165,717	163,819
Diluted	169,919	166,362	163,819

The accompanying notes are an integral part of these consolidated financial statements.

ACADIA PHARMACEUTICALS INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)
(in thousands)

	Years Ended December 31,		
	2025	2024	2023
Net income (loss)	$ 391,000	$ 226,451	$ (61,286)
Other comprehensive income (loss):			
Unrealized gain on investment securities	1,127	362	1,017
Foreign currency translation adjustments	26	(94)	(18)
Comprehensive income (loss)	$ 392,153	$ 226,719	$ (60,287)

The accompanying notes are an integral part of these consolidated financial statements.

ACADIA PHARMACEUTICALS INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Years Ended December 31,		
	2025	2024	2023
Cash flows from operating activities			
Net income (loss)	$ 391,000	$ 226,451	$ (61,286)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:			
Stock-based compensation	52,135	67,049	66,421
Amortization of premiums and accretion of discounts on investment securities	(5,424)	(9,304)	(7,533)
Amortization of intangible assets	10,889	14,963	4,093
Gain on sale of non-financial asset	—	(146,515)	—
Gain on strategic investment	—	—	(5,109)
Depreciation	871	920	1,459
Loss on sale of investment securities	—	—	524
Deferred income taxes (including benefit from valuation allowance)	(249,879)	—	—
Changes in operating assets and liabilities:			
Accounts receivable, net	(22,718)	(472)	(36,072)
Interest and other receivables	(20,818)	(1,873)	(3,198)
Inventory	(18,197)	(49,550)	(28,808)
Prepaid expenses and other current assets	(3,845)	(16,590)	(17,693)
Operating lease right-of-use assets	8,667	7,502	5,769
Other assets	(2,856)	117	(33)
Accounts payable	(5,289)	(1,351)	4,797
Accrued liabilities	(19,265)	71,061	93,170
Operating lease liabilities	(6,516)	(7,598)	(5,872)
Long-term liabilities	1,081	2,909	6,073
Net cash provided by operating activities	109,836	157,719	16,702
Cash flows from investing activities			
Purchases of investment securities	(692,565)	(505,095)	(369,985)
Sale and maturity of investment securities	493,529	328,565	429,780
Proceeds from sale of non-financial asset	—	146,515	—
Proceeds from sale of strategic investment	—	—	12,253
Net purchases of property and equipment	(4,690)	(523)	(50)
Payment of milestone and contingent payments in connection with asset acquisition	(98,838)	—	(40,000)
Net cash (used in) provided by investing activities	(302,564)	(30,538)	31,998
Cash flows from financing activities			
Proceeds from issuance of common stock, net of issuance costs	49,883	6,845	25,129
Net cash provided by financing activities	49,883	6,845	25,129
Effect of exchange rate changes on cash	26	(94)	(18)
Net (decrease) increase in cash, cash equivalents and restricted cash	(142,819)	133,932	73,811
Cash, cash equivalents and restricted cash			
Beginning of year	328,359	194,427	120,616
End of year	$ 185,540	$ 328,359	$ 194,427
Supplemental disclosure of cash flow information:			
Cash paid for income taxes	$ 25,170	$ 19,521	$ 5,850
Supplemental disclosure of noncash information:			
Accrued inventory purchases	$ 1,219	$ 1,268	$ —
Stock based compensation capitalized	$ 426	$ 425	$ 79
Accrued milestone and contingent payments in connection with asset acquisition	$ —	$ 98,838	$ 29,583

The accompanying notes are an integral part of these consolidated financial statements.

ACADIA PHARMACEUTICALS INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands, except share amounts)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
	Shares	Amount				
Balances at December 31, 2022	162,064,872	$ 16	$ 2,770,923	$ (2,369,551)	$ (975)	$ 400,413
Issuance of common stock from exercise of stock options and units	2,236,849	—	20,309	—	—	20,309
Issuance of common stock pursuant to employee stock purchase plan	348,498	—	4,820	—	—	4,820
Net loss	—	—	—	(61,286)	—	(61,286)
Stock-based compensation	—	—	66,500	—	—	66,500
Other comprehensive income	—	—	—	—	999	999
Balances at December 31, 2023	164,650,219	16	2,862,552	(2,430,837)	24	431,755
Issuance of common stock from exercise of stock options and units	1,641,013	—	1,572	—	—	1,572
Issuance of common stock pursuant to employee stock purchase plan	417,624	—	5,273	—	—	5,273
Net income	—	—	—	226,451	—	226,451
Stock-based compensation	—	—	67,474	—	—	67,474
Other comprehensive income	—	—	—	—	268	268
Balances at December 31, 2024	166,708,856	16	2,936,871	(2,204,386)	292	732,793
Issuance of common stock from exercise of stock options and units	3,180,888	—	44,370	—	—	44,370
Issuance of common stock pursuant to employee stock purchase plan	419,632	—	5,513	—	—	5,513
Net income	—	—	—	391,000	—	391,000
Stock-based compensation	—	—	52,561	—	—	52,561
Other comprehensive income	—	—	—	—	1,153	1,153
Balances at December 31, 2025	170,309,376	$ 16	$ 3,039,315	$ (1,813,386)	$ 1,445	$ 1,227,390

The accompanying notes are an integral part of these consolidated financial statements.

ACADIA PHARMACEUTICALS INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Organization and Business

Acadia Pharmaceuticals Inc. (the Company), based in San Diego, California, is a biopharmaceutical company focused on turning scientific promise into meaningful innovation that makes the difference for underserved neurological and rare disease communities around the world.

In April 2016, the FDA approved the Company's first drug, NUPLAZID® (pimavanserin), for the treatment of hallucinations and delusions associated with PDP. NUPLAZID became available for prescription in the United States in May 2016.

In March 2023, the FDA approved the Company's second drug, DAYBUE® (trofinetide), for the treatment of Rett syndrome. DAYBUE became available for prescription in the United States in April 2023.

In October 2024, Health Canada granted marketing authorization of DAYBUE® (trofinetide) for the treatment of Rett syndrome in adult and pediatric patients 2 years of age and older.

In December 2025, the FDA approved DAYBUE® STIX (trofinetide), a dye- and preservative-free powder formulation, for the treatment of Rett syndrome in adult and pediatric patients 2 years and older. DAYBUE STIX will be available on a limited basis starting in the first quarter of 2026, with a broader launch planned for the second quarter of 2026.

In December 2025, the Ministry of Health in Israel approved DAYBUE® (trofinetide) for the treatment of Rett syndrome in adults and pediatric patients 2 years of age and older and weighing at least 9 kg.

2. Summary of Significant Accounting Policies

Significant accounting policies followed in the preparation of these financial statements are as follows:

Principles of Consolidation

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

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from these estimates.

Cash and Cash Equivalents

The Company considers all highly liquid investments with a maturity date at the date of purchase of three months or less to be cash equivalents.

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported in the consolidated balance sheets that sum to the total of the same such amounts shown in the consolidated statements of cash flows (in thousands):

	Twelve Months Ended December 31,2025		Twelve Months Ended December 31,2024	
	Beginning of period	End of period	Beginning of period	End of period
Cash and cash equivalents	$ 319,589	$ 177,695	$ 188,657	$ 319,589
Restricted cash	8,770	7,845	5,770	8,770
Total cash, cash equivalents and restricted cash shown in the statements of cash flows	$ 328,359	$ 185,540	$ 194,427	$ 328,359

Investment Securities

Currently, all of the Company's investment securities are debt securities. The Company has classified all of its investment securities as available-for-sale as the sale of such securities may be required prior to maturity to implement management strategies, and accordingly, carries these investments at fair value. Unrealized gains and losses, if any, are reported as a separate component of stockholders' equity. The cost of investment securities classified as available-for-sale is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization and accretion are included in interest income. Realized gains and losses, if any, are also included in interest income. The cost of securities sold is based on the specific identification method.

Fair Value of Financial Instruments

The carrying values of the Company's financial instruments, consisting of cash and cash equivalents, trade receivables, interest and other receivables, restricted cash, and accounts payable and accrued liabilities, approximate fair value due to the relative short-term nature of these instruments.

As disclosed in Note 4, the Company classifies its cash equivalents and available-for-sale investment securities within the fair value hierarchy as defined by authoritative guidance:

Level 1 Inputs — Quoted prices for identical instruments in active markets.

Level 2 Inputs — Quoted prices for similar instruments in active markets; quoted prices for identical or similar instruments in markets that are not active; and model-derived valuations in which all significant inputs and significant value drivers are observable.

Level 3 Inputs — Valuation derived from valuation techniques in which one or more significant inputs or significant value drivers are unobservable.

Accounts Receivable

Accounts receivable are recorded net of customer allowances for distribution fees, prompt payment discounts, chargebacks, and credit losses. Allowances for distribution fees, prompt payment discounts and chargebacks are based on contractual terms. The Company estimated the current expected credit losses of its accounts receivable by assessing the risk of loss and available relevant information about the collectability, including historical credit losses, existing contractual payment terms, actual payment patterns of its customers, individual customer circumstances, and reasonable and supportable forecast of economic conditions expected to exist throughout the contractual life of the receivable. Based on its assessment, as of December 31, 2025 and 2024, the Company has determined that an allowance for credit loss was not required.

Inventory

Inventory is stated at the lower of cost or net realizable value under the first-in, first-out method (FIFO). The Company uses a combination of standard and actual costing methodologies to determine the cost basis for its inventories which approximates actual costs. Inventory consists of raw material, work in process, and finished goods, including third-party manufacturing costs, freight, and indirect overhead costs. The Company capitalizes inventory costs associated with its products upon regulatory approval when, based on management's judgment, future commercialization is considered probable and the future economic benefit is expected to be realized; otherwise, such costs are expensed. Prior to FDA approval of NUPLAZID in April 2016 and DAYBUE in March 2023, all costs related to the manufacturing of NUPLAZID and DAYBUE were charged to research and development expense in the period incurred.

The Company periodically reviews inventory and reduces the carrying value of items to net realizable value for potentially excess, dated or obsolete inventory based on an analysis of forecasted demand compared to quantities on hand and any firm purchase orders, as well as product shelf life. During the years ended December 31, 2025, 2024 and 2023, the Company recorded charges of $2.3 million, $0.5 million and $0.9 million, respectively, to reduce certain finished goods and work in process inventory to its net realizable value.

Property and Equipment

Property and equipment are recorded at cost and depreciated over their estimated useful lives using the straight-line method. Leasehold improvements are amortized over the shorter of their estimated useful lives or the term of the lease by use of the straight-line method. Construction-in-process reflects amounts incurred for property, equipment or improvements that have not been placed in service. Maintenance and repair costs are expensed as incurred. When assets are retired or sold, the assets and accumulated depreciation are removed from the respective accounts and any gain or loss is recognized. Estimated useful lives by major asset category are as follows:

	Useful Lives
Machinery and equipment	5 to 7 years
Computers and software	3 years
Furniture and fixtures	10 years

Impairment of Long-Lived Assets

The Company reviews its long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability is measured by a comparison of the carrying amount of an asset to estimated undiscounted future cash flows expected to be generated by the asset. If the carrying amount of an asset exceeds its estimated future cash flows, an impairment charge is recognized by the amount by which the carrying amount of the asset exceeds the fair value of the asset. Through December 31, 2025, no such impairment losses have been recorded by the Company.

License Fees and Royalties

The Company expenses amounts paid to acquire licenses associated with products under development when the ultimate recoverability of the amounts paid is uncertain and the technology has no alternative future use when acquired. Acquisitions of technology licenses are charged to expense or capitalized based upon management's assessment regarding the ultimate recoverability of the amounts paid and the potential for alternative future use. The Company has determined that technological feasibility for its product candidates is reached when the requisite regulatory approvals are obtained to make the product available for sale.

Pursuant to the license agreement with Neuren, the Company has capitalized a total of $138.8 million as intangible assets following the FDA approval and sale of DAYBUE and sale of PRV, as disclosed in Note 9. The intangible assets are amortized on a straight-line basis over the estimated useful life of the licensed patents through early 2036. The Company recorded total amortization expense related to these intangible assets of $10.9 million and $15.0 million for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, estimated future amortization expense related to the Company's intangible assets was $10.9 million for each subsequent year.

Royalties incurred in connection with the Company's license agreement with Neuren, as disclosed in Note 9, are expensed to cost of product sales as revenue from product sales is recognized.

Intangible Assets

Finite-lived intangible assets are recorded at cost, net of accumulated amortization, and, if applicable, impairment charges. Amortization of finite-lived intangible assets is recorded over the assets' estimated useful lives on a straight-line basis or based on the pattern in which economic benefits are consumed, if reliably determinable. We review our finite-lived intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If such intangible assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of intangible the assets exceeds the estimated fair value of the intangible assets. No impairment loss was recorded on intangible assets during the years ended December 31, 2025 or 2024.

Acquisitions

The Company accounts for acquisitions of an asset or group of similar identifiable assets that do not meet the definition of a business as asset acquisition using the cost accumulation method, whereby the cost of the acquisition, including certain transaction costs, is allocated to the assets acquired on the basis of their relative fair values. No goodwill is recognized in an asset acquisition. Intangible assets acquired in an asset acquisition for use in research and development activities which have no alternative future use are expensed as in-process research and development on the acquisition date. Intangible assets acquired for use in research and development activities which have an alternative future use are capitalized as in-process research and development. Future costs to develop these assets are recorded to research and development expense as they are incurred. Contingent milestone payments associated with asset acquisitions are recognized when probable and estimable. These amounts are expensed to research and development if there is no alternative future use associated with the asset, or capitalized as an intangible asset if alternative future use of the asset exists.

Advertising Expense

Advertising costs are expensed when services are performed or goods are delivered. The Company incurred $31.9 million, $21.1 million and $9.4 million in advertising costs during the years ended December 31, 2025, 2024 and 2023, respectively and $0.9 million and $1.3 million of advertising costs were capitalized as prepaid expenses at December 31, 2025 and 2024. No advertising costs were capitalized as prepaid expenses at December 31, 2023.

Revenue Recognition

The Company operates in one business segment. Results of its operations are reported on a consolidated basis for purposes of segment reporting, consistent with internal management reporting. Revenues consist of net product sales to customers, substantially all of which are sales in the U.S.

Revenues by product are as follows (in thousands):

	Years Ended December 31,		
	2025	2024	2023
NUPLAZID	$ 680,086	$ 609,385	$ 549,248
DAYBUE	391,419	348,412	177,189
Product sales, net	$ 1,071,505	$ 957,797	$ 726,437

Product Sales, Net

The Company accounts for contracts with its customers in accordance with *Revenue from Contracts with Customers (Topic 606)*. The Company recognizes revenue when its customer obtains control of promised goods or services which is generally upon delivery. Revenues reflect the consideration which the Company expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that the Company determines are within the scope of Topic 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the Company satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the Company will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of Topic 606, the Company assesses the goods or services promised within each contract, determines those that are performance obligations, and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. Payment terms differ by customer, but typically range from 31 to 35 days from the date of shipment. Revenue for the Company's product sales has not been adjusted for the effects of a financing component as the Company expects, at contract inception, that the period between when the Company transfers control of the product and when the Company receives payment will be one year or less.

The Company's product sales, net consist of U.S. sales of NUPLAZID and DAYBUE. NUPLAZID was approved by the FDA in April 2016 and the Company commenced shipments of NUPLAZID to SPs and SDs in late May 2016. SPs dispense product to a patient based on the fulfillment of a prescription and SDs sell product to government facilities, long-term care pharmacies, or in-patient hospital pharmacies. DAYBUE was approved by the FDA in March 2023 and the

Company commenced shipments of DAYBUE to a single wholesale distributor in April 2023 in the U.S. The Company also sells DAYBUE outside of the U.S. commercially as well as under managed access programs through third party distributors. Product shipping and handling costs are included in cost of product sales.

The Company recognizes revenue from product sales at the net sales price (the "transaction price") which includes estimates of variable consideration for which reserves for sales discounts and allowance are established and reflects each of these as either a reduction to the related account receivable or as an accrued liability, depending on how the amount payable is settled. Overall, these reserves reflect the Company's best estimates of the amount of consideration to which the Company 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 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 estimates, the Company may need to adjust its estimates, which would affect net revenue in the period of adjustment. The following are the Company's significant categories of sales discounts and allowances:

Distribution Fees: Distribution fees include distribution service fees paid to the SPs, SDs and wholesale distributors based on a contractually fixed percentage of the wholesale acquisition cost (WAC), fees for data, and prompt payment discounts. Distribution fees are recorded as an offset to revenue based on contractual terms at the time revenue from the sale is recognized.

Rebates: Allowances for rebates include mandated discounts under the Medicaid Drug Rebate Program and the Medicare Part D prescription drug benefit. Rebates are amounts owed after the final dispensing of the product to a benefit plan participant and are based upon contractual agreements with, or statutory requirements pertaining to, Medicaid and Medicare benefit providers. The allowance for rebates is based on statutory discount rates, estimated payor mix, and expected utilization. The Company's estimates for expected utilization of rebates are based on historical data received from the SPs, SDs and single wholesale distributor since product launch. Rebates are generally invoiced and paid in arrears so that the accrual balance consists of an estimate of the amount expected to be incurred for the current quarter's activity, plus an accrual balance for prior quarters' unpaid rebates still estimated to be incurred. Allowances for rebates also include amounts due under the Inflation Reduction act of 2022 for Medicare Part D unit sales with applicable period AMP increases that outpace inflation over the benchmark period. The applicable period will be twelve months on October 1 of each year, with the initial applicable period beginning on October 1, 2022. The benchmark period AMP price is January 1, 2021 through September 30, 2021 for NUPLAZID and January 1, 2024 through December 31, 2024 for DAYBUE. The Company's estimates are based Medicare Part D sales as a percentage of gross sales and the rate AMP for the current period will be in excess the benchmark period. In December 2025, the Company received its first invoices for Medicare inflation cap rebates from CMS for the applicable periods beginning on October 1, 2022 through September 30, 2024, which were higher than expected. The Company increased its Medicare rebate accruals to reflect actual invoices received and updated expectations. This unfavorable change in estimate of approximately $11.8 million related to the sales from October 1, 2022 to December 31, 2024, which increased its gross-to-net adjustments and reduced its net product sales of NUPLAZID.

Chargebacks: Chargebacks are discounts and fees that relate to contracts with government and other entities purchasing from the SDs at a discounted price. The SDs charge back to the Company the difference between the price initially paid by the SDs and the discounted price paid to the SDs by these entities. The Company also incurs group purchasing organization fees for transactions through certain purchasing organizations. The Company estimates sales with these entities and accrues for anticipated chargebacks and organization fees, based on the applicable contractual terms.

Co-Payment Assistance: The Company offers co-payment assistance to commercially insured patients meeting certain eligibility requirements. Co-payment assistance is accrued for based on actual program participation and estimates of program redemption using data provided by third-party administrators.

Product Returns: Consistent with industry practice, the Company offers the SPs and SDs limited product return rights for damages, shipment errors, and expiring product; provided that the return is within a specified period around the product expiration date as set forth in the applicable individual distribution agreement. The Company does not allow product returns for product that has been dispensed to a patient. As the Company receives inventory reports from the SPs and SDs and has the ability to control the amount of product that is sold to the SPs and SDs, it is able to make a reasonable estimate of future potential product returns based on this on-hand channel inventory data and sell-through data obtained from the SPs and SDs. In arriving at its estimate for product returns, the Company also considers historical product returns, the underlying product demand, and industry data specific to the specialty pharmaceutical distribution industry.

Research and Development Expenses

Research and development expenses are charged to operations as incurred. Research and development expenses include costs associated with services provided by contract organizations for preclinical development, pre-commercialization manufacturing expenses, and clinical trials, salaries and related personnel expenses including stock-based compensation expense, and facilities and equipment expenses. The upfront consideration and transaction costs associated with acquired in-process research and development are also included in the research and development expenses.

The Company accrues for costs incurred as the services are being provided by monitoring the status of the trial or services provided and the invoices received from its external service providers. When the Company makes payments in advance of services being provided, it records those amounts as prepaid expenses on its consolidated balance sheets and expense them as the services are rendered. In the case of clinical trials, a portion of the estimated cost normally relates to the projected cost to treat a patient in the trials, and this cost is recognized based on the number of patients enrolled in the trial. Other indirect costs are generally recognized on a straight-line basis over the estimated period of the study. As actual costs become known, the Company adjusts its accruals accordingly.

Concentration Risk

Financial instruments, which potentially subject the Company to concentrations of credit risk, principally consist of cash, cash equivalents, investment securities, accounts receivable, and restricted cash. The Company invests its excess cash primarily in money market funds, U.S. treasury notes, and high quality, marketable debt instruments of corporations and government sponsored enterprises in accordance with the Company's investment policy. The Company's investment policy defines allowable investments and establishes guidelines relating to credit quality, diversification, and maturities of its investments to preserve principal and maintain liquidity. All investment securities have a credit rating of at least Aa3/AA- or better, or P-1/A-1 or better, as determined by Moody's Investors Service or Standard & Poor's. Further, the Company specifies credit quality standards for its customers that are designed to limit the Company's credit exposure to any single party.

The Company does not currently have any of its own manufacturing facilities, and therefore it depends on an outsourced manufacturing strategy for the production of NUPLAZID and DAYBUE for commercial use and for the production of its product candidates for clinical trials. For the production of NUPLAZID, the Company has contracts in place with two third-party manufacturers of commercial drug product and one third-party manufacturer of drug substance that is approved for the production of NUPLAZID API. For the production of DAYBUE, the Company has contracts in place with two third-party manufacturers of commercial drug product and two third-party manufacturers of drug substance that is approved for the production of DAYBUE API. Although there are potential sources of supply other than the Company's existing suppliers, any new supplier would be required to qualify under applicable regulatory requirements.

The Company has entered into agreements for the distribution of NUPLAZID with a limited number of SPs and SDs, and all of the Company's product sales of NUPLAZID are to these customers. The Company has also entered into agreements for the distribution of DAYBUE with third party distributors, and all of the Company's product sales of DAYBUE and accounts receivable balance at December 31, 2025 are related to these customers. The following table summarizes customers that represent 10% or greater of our consolidated total gross revenues:

	Years Ended December 31,		
	2025	2024	2023
Customer A	34%	34%	23%
Customer B	13%	13%	15%
Customer C	12%	14%	17%
Customer D	12%	12%	14%
Customer E	11%	10%	10%

* Represents less than 10% and/or not a customer in the applicable year

The following table summarizes customers with amounts due that represent 10% or greater of our consolidated accounts receivable balance:

	As of December 31,	
	2025	2024
Customer A	36%	42%
Customer D	14%	12%
Customer B	11%	14%
Customer C	10%	13%
Customer E	*	*

* Represents less than 10% and/or not a customer in the applicable year

Stock-Based Compensation

We measure stock-based compensation expense for equity-classified awards, principally related to stock options, restricted stock units (RSUs), PSUs and stock purchase rights under our employee stock purchase plan (ESPP) based on the estimated fair value of the award on the date of grant.

The fair value of each employee stock option and each employee stock purchase right granted is estimated on the grant date under the fair value method using the Black-Scholes valuation model. The estimated fair value of each stock option and purchase right is then expensed on a straight-line basis over the requisite service period, which is generally the vesting period. The following weighted-average assumptions were used during these periods:

	Years Ended December 31,		
	2025	2024	2023
Stock Options:			
Expected volatility	61%	62%	66%
Risk-free interest rate	4.1%	4.1%	3.9%
Expected dividend yield	0%	0%	0%
Expected life of options in years	5.6	5.5	5.4

	Years Ended December 31,		
	2025	2024	2023
Employee Stock Purchase Plan:			
Expected volatility	37%-58%	46%-63%	40%-67%
Risk-free interest rate	3.6%-4.3%	4.3%-5.3%	4.0%-5.3%
Expected dividend yield	0%	0%	0%
Expected life in years	0.5-2.0	0.5-2.0	0.5-2.0

Expected Volatility. The Company considers its historical volatility and implied volatility when determining the expected volatility.

Risk-Free Interest Rate. The Company determines its risk-free interest rate assumption based on the U.S. Treasury yield for obligations with contractual terms similar to the expected term of the stock option or purchase right being valued.

Expected Dividend Yield. The Company has never paid any dividends and currently has no plans to do so.

Expected Life. In determining the expected life for stock options, the Company considers, among other factors, its historical exercise experience to date as well as the mean time remaining to full vesting of all outstanding options and the mean time remaining to the end of the contractual term of all outstanding options. The estimated life for the Company's employee stock purchase rights is based upon the terms of each offering period.

Forfeitures. The Company recognizes forfeitures as they occur.

The fair value of RSUs is estimated based on the closing market price of the Company's common stock on the date of grant. RSUs generally vest over a four-year period. Certain RSUs also have an accelerated vesting clause based on specified market condition target and continued employment through a minimum vesting period. The fair value of RSUs expected to vest are recognized and amortized on a straight-line basis over the requisite service period, which is generally the vesting period. For those RSUs requiring satisfaction of both market and service conditions, the requisite service period is the longest of the explicit, implicit and derived service periods.

Through 2023, the Company granted PSUs that vest upon the achievement of certain pre-defined company-specific performance-based criteria. Expense related to these PSUs is recognized ratably over the expected performance period once the pre-defined performance-based criteria for vesting becomes probable and can vest up to 200 percent of the target number of shares granted. The fair value of these PSUs is estimated based on the closing market price of the Company's common stock on the date of grant. Beginning in 2024, the structure of the PSU design was revised with a rTSR approach such that awards are earned for the Company's rTSR performance over three-year measurement periods relative to a peer group of companies and the actual numbers of PSUs that will vest at the end of the performance period may be anywhere from zero to 150 percent of the target number of shares granted. The fair value of these PSUs is estimated using a Monte Carlo model because the performance target is based on a market condition. Expense related to these PSUs is recognized ratably over the three-year measurement period.

In connection with the departure of the former CEO, in September 2024 the Company incurred approximately $10.7 million in stock-based compensation expense as a result of accelerated equity award vesting and stock modifications under the former CEO's severance plan.

The table below summarizes the total stock-based compensation expense included in the Company's consolidated statements of operations for the periods presented (in thousands):

	Years Ended December 31,		
	2025	2024	2023
Cost of product sales	$ 858	$ 1,319	$ 1,007
Research and development	16,436	14,100	17,408
Sales, general and administrative	34,841	51,630	48,006
	$ 52,135	$ 67,049	$ 66,421

Segment Reporting

The Company uses "the management approach" in determining reportable operating segments. The management approach considers the internal organization and reporting used by the Company's Chief Operating Decision Maker (CODM) for making operating decisions and assessing performance as the source for determining the Company's reportable segments. The Company determines and presents operating segments based on the information that is internally provided to the CEO who is considered the Company's CODM, in accordance with ASC 280, *Segment Reporting*. The Company has determined that it operates as a single business segment, which is the development and commercialization of innovative medicines. Refer to Note 11 – Segment Reporting for further information related to the segment.

Income Taxes

Current income tax expense or benefit represents the amount of income taxes expected to be payable or refundable for the current year. A deferred income tax asset or liability is computed for the expected future impact of differences between the financial reporting and income tax bases of assets and liabilities and for the expected future tax benefit to be derived from tax credits and loss carryforwards. Deferred income tax expense or benefit represents the net change during the year in the deferred income tax asset or liability. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some portion or all of the deferred tax assets will not be realized.

The Company recognizes the impact of a tax position in the financial statements only if that position is more likely than not to be sustained upon examination by taxing authorities, based on the technical merits of the position. Any interest and penalties related to uncertain tax positions will be reflected in income tax expense.

Earning (Net Loss) Per Share

Basic earnings (net loss) per share is calculated by dividing the net income (loss) by the weighted average number of common shares outstanding for the period, without consideration for common stock equivalents. Diluted net income (loss) per share is computed by dividing the net income (loss) by the weighted average number of common shares and common stock equivalents outstanding for the period determined using the treasury stock method. For purposes of diluted earnings (net loss) per share calculation, equity awards and employee stock purchase plan rights are considered to be common stock equivalents.

	Years Ended December 31,		
	2025	2024	2023
Net income (loss) - basic and diluted	$ 391,000	$ 226,451	$ (61,286)
Weighted average shares outstanding:			
Basic	168,356	165,717	163,819
Effect of potentially dilutive common shares from:			
Equity awards	1,457	576	—
Employee stock purchase plan rights	106	69	—
Diluted	169,919	166,362	163,819
Earnings (net loss) per share:			
Basic	$ 2.32	$ 1.37	$ (0.37)
Diluted	$ 2.30	$ 1.36	$ (0.37)
Potentially dilutive shares excluded from per share amounts as their effect would have been anti-dilutive	17,299	18,233	21,264

3. Investments

The carrying value and amortized cost of the Company's investments, summarized by major security type, consisted of the following (in thousands):

	December 31, 2025			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
U.S. Treasury notes	$ 429,260	$ 1,291	$ —	$ 430,551
Government sponsored enterprise securities	211,239	258	(57)	211,440
	$ 640,499	$ 1,549	$ (57)	$ 641,991

	December 31, 2024			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
U.S. Treasury notes	$ 245,584	$ 319	$ —	$ 245,903
Government sponsored enterprise securities	190,452	157	(108)	190,501
	$ 436,036	$ 476	$ (108)	$ 436,404

The Company has classified all of its available-for-sale investment securities, including those with maturities beyond one year, as current assets on its consolidated balance sheets based on the highly liquid nature of the investment securities and because these investment securities are considered available for use in current operations. The following table summarizes the contract maturity of the available-for-sale securities:

	December 31,	
	2025	2024
One year or less	51%	79%
After one year but within two years	49%	21%
Total	100%	100%

At December 31, 2025 and 2024, the Company had 18 and 17 securities, respectively, in an unrealized loss position. The following table presents gross unrealized losses and fair value for those available-for-sale investments that were in an unrealized loss position as of December 31, 2025 and 2024, aggregated by investment category and length of time that individual securities have been in a continuous loss position (in thousands):

	Less Than 12 Months		12 Months or Greater		Total	
	Estimated Fair Value	Unrealized Losses	Estimated Fair Value	Unrealized Losses	Estimated Fair Value	Unrealized Losses
December 31, 2025						
Government sponsored enterprise securities	$ 91,799	$ (57)	$ —	$ —	$ 91,799	$ (57)
Total	$ 91,799	$ (57)	$ —	$ —	$ 91,799	$ (57)
December 31, 2024						
Government sponsored enterprise securities	$ 84,390	$ (108)	$ —	$ —	$ 84,390	$ (108)
Total	$ 84,390	$ (108)	$ —	$ —	$ 84,390	$ (108)

At each reporting date, the Company performs an evaluation of impairment to determine if any unrealized losses are the result of credit losses. Impairment is assessed at the individual security level. Factors considered in determining whether a loss resulted from a credit loss or other factors include the Company's intent and ability to hold the investment until the recovery of its amortized cost basis, the extent to which the fair value is less than the amortized cost basis, the length of time and extent to which fair value has been less than the cost basis, the financial condition of the issuer, any historical failure of the issuer to make scheduled interest or principal payments, any changes to the rating of the security by a rating agency, any adverse legal or regulatory events affecting the issuer or issuer's industry, any significant deterioration in economic conditions.

As of December 31, 2025, the Company did not have the intention to sell the investments in unrealized loss positions and it is unlikely that the Company will be required to sell the investment before the recovery of its amortized cost basis. The Company has not historically experienced significant losses on its investments. Based on its evaluation, the Company determined its year-to-date credit losses related to its available-for-sale securities were immaterial at December 31, 2025.

4. Fair Value Measurements

The Company's investments include cash equivalents, available-for-sale investment securities consisting of money market funds, U.S. treasury notes, and marketable debt instruments of corporations and government sponsored enterprises in accordance with the Company's investment policy, and equity investments. The Company's investment policy defines allowable investment securities and establishes guidelines relating to credit quality, diversification, and maturities of its investments to preserve principal and maintain liquidity. All investment securities have a credit rating of at least Aa3/AA- or better, or P-1/A-1 or better, as determined by Moody's Investors Service or Standard & Poor's.

The Company's cash equivalents, available-for-sale investment securities, and equity securities are classified within the fair value hierarchy as defined by authoritative guidance. The Company's investment securities and equity securities classified as Level 1 are valued using quoted market prices. The Company obtains the fair value of its Level 2 financial instruments from third-party pricing services. The pricing services utilize industry standard valuation models whereby all significant inputs, including benchmark yields, reported trades, broker/dealer quotes, issuer spreads, bids, offers, or other market-related data, are observable. The Company validates the prices provided by the third-party pricing services by reviewing their pricing methods and matrices and obtaining market values from other pricing sources. After completing the validation procedures, the Company did not adjust or override any fair value measurements provided by these pricing services as of December 31, 2025 and 2024.

The Company has not transferred any investment securities between the classification levels.

The recurring fair value measurements of the Company's cash equivalents, available-for-sale investment securities, and equity securities at December 31, 2025 and 2024 consisted of the following (in thousands):

	December 31, 2025	Fair Value Measurements at Reporting Date Using		
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets				
Money market fund	$ 24,834	$ 24,834	$ —	$ —
U.S. Treasury notes	430,551	430,551	—	—
Government sponsored enterprise securities	211,440	—	211,440	—
Total	$ 666,825	$ 455,385	$ 211,440	$ —

	December 31, 2024	Fair Value Measurements at Reporting Date Using		
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets				
Money market fund	$ 151,555	$ 151,555	$ —	$ —
U.S. Treasury notes	245,903	245,903	—	—
Government sponsored enterprise securities	190,501	—	190,501	—
Total	$ 587,959	$ 397,458	$ 190,501	$ —

5. Balance Sheet Details

Inventory consisted of the following (in thousands):

	December 31,	
	2025	2024
Finished goods	$ 25,952	$ 20,461
Work in process	2,638	1,488
Raw material	82,784	69,741
	$ 111,374	$ 91,690
Reported as:		
Inventory	$ 34,670	$ 21,949
Long-term inventory	76,704	69,741
Total	$ 111,374	$ 91,690

Amount reported as long-term inventory primarily consists of raw materials as of December 31, 2025 and 2024.

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

	December 31,	
	2025	2024
Computers and software	$ 4,306	$ 5,614
Leasehold improvements	4,644	3,746
Furniture and fixtures	4,783	4,549
Construction-in-process	3,262	523
	16,995	14,432
Accumulated depreciation	(9,484)	(10,217)
	$ 7,511	$ 4,215

Depreciation of property and equipment was $0.9 million, $0.9 million, and $1.5 million for the years ended December 31, 2025, 2024, and 2023, respectively. For the years ended December 31, 2025, 2024 and 2023, the Company did not retire any fully depreciated property and equipment.

Accrued liabilities consisted of the following (in thousands):

	December 31,	
	2025	2024
Accrued sales allowances	$ 140,862	$ 148,280
Accrued compensation and benefits	45,579	36,551
Accrued consulting and professional fees	29,843	27,435
Accrued research and development services	19,094	27,181
Accrued royalties	13,314	11,608
Current portion of lease liabilities	11,633	9,958
Accrued taxes	304	12,016
Accrued contingent payments	—	102,262
Other	5,582	3,387
	$ 266,211	$ 378,678

6. Stockholders' Equity

Stock Plans

2024 Equity Incentive Plan

The Company's 2024 Equity Incentive Plan (the 2024 Plan) became effective upon approval of the stockholders in May 2024 and is a successor and continuation of the 2010 Equity Incentive Plan (the 2010 Plan). The 2024 Plan permits the grant of awards to employees, non-employee directors and consultants. In addition, the 2024 Plan permits the grant of stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance awards, and other awards. The 2024 Plan provides that, with limited exceptions, no award will vest until at least 12 months following the date of grant of the award; provided, however, that up to 5% of the aggregate number of shares that may be issued under the 2024 Plan may be subject to awards which do not meet such vesting requirements. The maximum term of any stock option or stock appreciation right awards under 2024 Plan is ten years. All shares that remained eligible for grant under the Company's 2010 Equity Incentive Plan and 2023 Inducement Plan at the time of approval of the 2024 Plan were transferred to the 2024 Plan. At December 31, 2025, there were 13,675,497 shares of common stock available for new grants under the 2024 Plan.

2024 Inducement Plan

The Board adopted the Company's 2024 Inducement Plan (Inducement Plan) in September 2024. The Inducement Plan permits the grant of stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance awards and other stock-related awards. Stock awards granted under the Inducement Plan may only be made to individuals who did not previously serve as employees or non-employee directors of the Company or an affiliate of the Company. In addition, stock awards must be approved by either a majority of the Company's independent directors or the Compensation Committee. The terms of the Inducement Plan are otherwise substantially similar to the 2024 Plan. The

maximum number of shares of Company common stock that may be issued under the Inducement Plan is 2,400,000 shares. At December 31, 2025, there were 234,670 shares available for new grants under the Inducement Plans.

2023 Inducement Plan

The Board adopted the Company's 2023 Inducement Plan (2023 Inducement Plan) on February 1, 2023. The 2023 Inducement Plan permits the grant of stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance stock awards and other stock-related awards. Stock awards granted under the 2023 Inducement Plan may only be made to individuals who did not previously serve as employees or non-employee directors of the Company or an affiliate of the Company. In addition, stock awards must be approved by either a majority of the Company's independent directors or the Compensation Committee. The terms of the 2023 Inducement Plan are otherwise substantially similar to the 2010 Plan. All shares that remained eligible for grant under the 2023 Inducement Plan at the time of approval of the 2024 Plan were transferred to the 2024 Plan.

2010 Equity Incentive Plan

The 2010 Plan, as amended to date, permits the grant of options to employees, directors and consultants. In addition, the 2010 Plan permits the grant of stock bonuses, rights to purchase restricted stock, and other stock awards. The exercise price of options granted under the 2010 Plan cannot be less than 100 percent of the fair market value of the common stock on the date of grant and the maximum term of any option is 10 years. Options granted under the 2010 Plan generally vest over a four-year period. All shares that remained eligible for grant under the Company's 2004 Equity Incentive Plan (the 2004 Plan) at the time of approval of the 2010 Plan were transferred to the 2010 Plan. In June 2015, June 2016, June 2017, June 2018, June 2019 and June 2022, the Company's stockholders approved amendments to its 2010 Plan to, among other things, increase the aggregate number of shares of common stock authorized for issuance under the plan by 5,000,000 shares, 3,000,000 shares, 5,500,000 shares, 6,700,000 shares, 8,300,000 shares and 6,000,000 shares, respectively. All shares that remained eligible for grant under the 2010 Plan at the time of approval of the 2024 Plan were transferred to the 2024 Plan.

Employee Stock Purchase Plan

The Company's 2004 Employee Stock Purchase Plan (the Purchase Plan) became effective upon the closing of the Company's initial public offering in June 2004. In June 2016, June 2019 and June 2020, the Company's stockholders approved an amendment to the Purchase Plan to, among other things, increase the aggregate number of shares of common stock authorized for issuance under the Purchase Plan by 400,000 shares, 600,000 shares and 3,000,000 shares, respectively. At December 31, 2025, a total of 5,525,000 shares of common stock had been reserved for issuance under the Purchase Plan. At December 31, 2025, 1,293,866 shares of common stock remained available for issuance pursuant to the Purchase Plan. Eligible employees who elect to participate in an offering under the Purchase Plan may have up to 15 percent of their earnings withheld, subject to certain limitations, to purchase shares of common stock pursuant to the Purchase Plan. The price of common stock purchased under the Purchase Plan is equal to 85 percent of the lower of the fair market value of the common stock at the commencement date of each offering period or the relevant purchase date.

Stock Option Activity

The equity plans provided for the grant of options to employees, directors and consultants. The exercise price of options granted under the equity plans were at 100 percent of the fair market value of the common stock on the date of grant and the maximum term of any option was 10 years. Options granted under the equity plans generally vested over a four-year period.

The following table summarizes the Company's stock option activity under all equity plans during the year ended December 31, 2025:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2024	17,518,854	$ 26.90		
Granted	4,157,447	$ 18.38		
Exercised	(2,131,414)	$ 20.87		
Cancelled/forfeited	(4,833,434)	$ 31.32		
Outstanding at December 31, 2025	14,711,453	$ 23.91	6.2	$ 79,282
Exercisable at December 31, 2025	8,559,252	$ 27.74	4.4	$ 29,158

The aggregate intrinsic value of options exercisable as of December 31, 2025 is calculated as the difference between the exercise price of the underlying options and the closing market price of the Company's common stock on that date, which was $26.71 per share. The aggregate intrinsic value of options exercised during the years ended December 31, 2025, 2024, and 2023 was approximately $7.2 million, $0.3 million, and $7.9 million, respectively, determined as of the date of exercise. The Company received approximately $44.5 million, $1.6 million and $20.3 million in cash from options exercised during the years ended December 31, 2025, 2024 and 2023, respectively.

The weighted average per share fair value of options granted during the years ended December 31, 2025, 2024, and 2023 was approximately $10.68, $10.42, and $13.25, respectively. As of December 31, 2025, total unrecognized compensation cost related to stock options was approximately $59.2 million and the weighted average period over which this cost is expected to be recognized is approximately 2.8 years.

Restricted Stock Unit Activity

The following table summarizes the Company's RSUs during the year ended December 31, 2025:

	Number of Shares	Weighted Average Grant Date Fair Value	Aggregate Intrinsic Value (in thousands)
Unvested at December 31, 2024	2,713,500	$ 20.65	
Granted	2,211,137	$ 18.17	
Vested	(891,003)	$ 22.54	
Cancelled/forfeited	(564,760)	$ 19.17	
Unvested at December 31, 2025	3,468,874	$ 18.82	$ 92,654

The total fair value of RSUs that vested during the years ended December 31 2025, 2024 and 2023 was $15.8 million, $17.3 million and $12.6 million, respectively. As of December 31, 2025, total unrecognized compensation cost related to RSUs was approximately $48.1 million and the weighted average period over which this cost is expected to be recognized is approximately 2.6 years.

Performance Stock Unit Activity

The following table summarizes the Company's PSUs during the year ended December 31, 2025:

	Number of Shares	Weighted Average Grant Date Fair Value	Aggregate Intrinsic Value (in thousands)
Unvested at December 31, 2024	1,220,790	$ 25.02	
Granted	382,458	$ 21.83	
Vested	(158,471)	$ 22.50	
Cancelled/forfeited	(644,158)	$ 26.25	
Unvested at December 31, 2025[(1)]	800,619	$ 23.00	$ 21,385

(1) The unvested balance consisted of 158,876 PSUs that vest upon achievement of certain pre-defined company-specific performance-based targets and 641,743 that vest based on the Company's rTSR performance over a three-year measurement period.

The total fair value of PSUs that vested during the years ended December 31 2025, 2024 and 2023 was $3.1 million and $10.2 million, and $13.3 million, respectively. As of December 31, 2025, total unrecognized compensation cost related to PSUs was approximately $5.9 million and the weighted average remaining contractual term was 2.0 years.

Contingent Cash Awards

In November 2021, the Company established a plan whereby substantially all full-time employees excluding executive management are eligible to receive a series of cash bonuses over certain periods based on continued employment and the Company's stock price reaching a pre-specified target. The maximum potential payout of the cash awards at the grant date was $15.1 million. The Company has determined that the cash awards were classified as liabilities pursuant to ASC Topic 718, *Compensation – Stock Compensation*. The Company estimates the fair value of the awards at each reporting period using the Monte Carlo simulation, which is recognized as compensation cost over the derived service period. Total fair value of the awards at the grant date was $4.4 million. The awards were forfeited in November 2024 as the Company's stock price did not reach the pre-specified target and the Company recorded a reversal of $4.5 million of compensation expense related to the awards during the year ended December 31, 2024. During the year ended December 31, 2023, the awards had a total fair value of $5.2 million and the Company recorded a total of $3.6 million of compensation cost related to the awards.

7. 401(k) Plan

Effective January 1997, the Company established a deferred compensation plan (the 401(k) Plan) pursuant to Section 401(k) of the Internal Revenue Code of 1986, as amended (the Code), whereby substantially all employees are eligible to contribute up to 60 percent of their pretax earnings, not to exceed amounts allowed under the Code. The Company makes discretionary contributions to the 401(k) Plan equal to 100 percent of each employee's pretax contributions up to 5 percent of his or her eligible compensation, subject to limitations under the Code. The Company's total contributions to the 401(k) Plan were $7.9 million, $6.9 million, and $6.1 million for the years ended December 31, 2025, 2024, and 2023, respectively.

8. Income Taxes

Domestic and foreign pre-tax income (loss) is as follows (in thousands):

	Years Ended December 31,		
	2025	2024	2023
Domestic	$ 72,159	$ 95,845	$ (100,215)
Foreign	66,745	162,230	49,179
	$ 138,904	$ 258,075	$ (51,036)

The income tax provision consists of the following (in thousands):

	Years Ended December 31,		
	2025	2024	2023
Current provision:			
Federal	$ (4,804)	$ 19,542	$ 5,440
State	2,819	12,064	4,805
Foreign	213	18	5
Total current provision	(1,772)	31,624	10,250
Deferred provision:			
Federal	$ (212,448)	$ —	$ —
State	(26,663)	—	—
Foreign	(11,213)	—	—
Total deferred provision	(250,324)	—	—
Total income tax provision	$ (252,096)	$ 31,624	$ 10,250

At December 31, 2025, the Company had federal, state, and foreign net operating losses (NOL) carryforwards of approximately $111.4 million, $453.0 million, and $271.0 million, respectively. Utilization of the domestic NOL and research and development (R&D) credit carryforwards may be subject to a substantial annual limitation due to ownership change limitations that have occurred or that could occur in the future, as required by Section 382 of the Code, as well as similar state and foreign provisions. These ownership changes may limit the amount of NOL and R&D credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively. In general, an “ownership change” as defined by Section 382 of the Code results from a transaction or series of transactions over a three-year period resulting in an ownership change of more than 50 percentage points of the outstanding stock of a company by certain stockholders or public groups.

The Company previously completed a study to assess whether an ownership change, as defined by Section 382 of the Code, had occurred from the Company’s formation through December 31, 2013. Based upon this study, the Company determined that several ownership changes had occurred. Accordingly, the Company reduced its deferred tax assets related to the federal NOL carryforwards and the federal R&D credit carryforwards that are anticipated to expire unused as a result of these ownership changes. These tax attributes were excluded from deferred tax assets with a corresponding reduction of the valuation allowance with no net effect on income tax expense or the effective tax rate. The Company completed a study through December 31, 2024 and concluded no additional ownership changes occurred. Future ownership changes may further limit the Company’s ability to utilize its remaining tax attributes.

The Company has federal and state NOL carryforwards of $2.4 million and $453.0 million that will begin to expire in 2037 and 2026, respectively, unless utilized. The remaining federal and state NOL carryforwards of $109.0 million and $1.6 million, respectively, will carry forward indefinitely. At December 31, 2025, the Company had federal and state charitable contribution carryforwards of $141.0 million which will begin to expire in 2026. At December 31, 2025, the Company had $64.0 million of federal R&D credit carryforwards, of which $1.0 million will expire in 2026 unless utilized, and the remaining federal R&D credit carryforwards will begin to expire beginning in 2027. At December 31, 2025, the Company had state R&D credit carryforwards of approximately $1.9 million that will begin to expire in 2026 and $22.8 million that have no expiration date. At December 31, 2025, the Company had Switzerland NOL carryforwards of $253.9 million, of which, $108.0 million will expire in 2026 unless utilized. At December 31, 2025, the Company had other foreign NOL carryforwards of $17.1 million which do not expire. The Company continues to record the deferred tax assets related to these attributes, subject to valuation allowance, until expiration occurs.

The components of the deferred tax assets are as follows (in thousands):

	December 31,	
	2025	2024
Deferred tax assets		
NOL carryforwards	$ 77,118	$ 117,052
R&D credit carryforwards	52,481	27,543
Capitalized R&D	92,957	110,848
Stock-based compensation	37,994	51,438
Charitable contributions	33,765	40,008
Lease liabilities	12,334	12,753
Intangibles	47,320	50,431
Accrued rebates	—	35,186
Other	21,675	21,130
Total deferred tax assets	375,644	466,389
Valuation allowance	(114,603)	(454,966)
Deferred tax liabilities		
Right-of-use assets	(11,162)	(11,423)
Total deferred tax liabilities	(11,162)	(11,423)
Total net deferred tax assets	$ 249,879	$ —

The Company recognized a valuation allowance of $114.6 million and $455.0 million as of December 31, 2025 and 2024, respectively, against the net deferred tax assets as realization of such assets is uncertain.

Realization of deferred tax assets is dependent upon future earnings, if any, the timing and amount of which are uncertain. As of each reporting date, management considers new evidence, both positive and negative, that could affect its view of the future realization of its deferred tax assets. As of December 31, 2024, management determined none of their deferred tax assets were realizable. As of December 31, 2025, in part because in the current year the Company achieved three years of cumulative pretax income, management determined that there is sufficient positive evidence to conclude that it is more likely than not that deferred taxes of $249.9 million are realizable. Accordingly, the valuation allowance was reduced by $340.4 million.

The amount of the deferred tax asset considered realizable could be further adjusted if estimates of the future taxable income during the carryforward period are increased, or if objective negative evidence in the form of cumulative losses is no longer present and additional weight is given to subjective evidence such as the Company’s projections for future growth.

An accounting policy may be selected to either (i) treat taxes due on future U.S. inclusions in taxable income related to global intangible low-taxed income (GILTI) as a current-period expense when incurred or (ii) factor such amounts into a company’s measurement of its deferred taxes. The Company has elected to account for GILTI as a period cost.

The Company adopted ASU 2023-09, Income Taxes (Topic 740): *Improvements to Income Tax Disclosures* on a prospective basis. As a result, the rate reconciliation for 2025 is presented in accordance with the new disclosure requirements, while the reconciliation for 2024 and 2023 continues to be presented under disclosure requirements in effect for those periods.

A reconciliation of the provision for income taxes to the amount computed by applying the statutory federal income tax rate to the net loss is summarized as follows (in thousands):

	Year Ended December 31, 2025	
	Amount	Percent
U.S. federal statutory tax rate	$ 29,308	21.10%
State and local income taxes, net of federal income tax effect [1]	(24,819)	-17.87%
Foreign tax effects		
Switzerland		
Foreign rate differential	(9,579)	-6.90%
Change in valuation allowance	(16,416)	-11.82%
Other	196	0.14%
Other foreign jurisdictions		
Other	749	0.55%
Effects of cross-border tax laws		
GILTI	1,904	1.37%
Federal R&D tax credits	(10,600)	-7.63%
Change in valuation allowance	(247,298)	-178.03%
Non-deductible items		
Stock compensation	17,185	12.37%
IP R&D write-off	1,892	1.36%
BPD fees	1,862	1.34%
Other	1,916	1.38%
Changes in unrecognized tax benefits	1,450	1.04%
Other adjustments		
Other	154	0.11%
Income tax expense (benefit)	$ (252,096)	-181.48%

[1] During the year ended December 31, 2025, state taxes in Tennessee and Kentucky comprised greater than 50% of the tax effect in this category.

Below is a rate reconciliation of income taxes to the amount computed by applying the statutory federal income tax rate to the pretax income (loss) is summarized as follows (in thousands):

	Years Ended December 31,	
	2024	2023
Amounts computed at statutory federal rate	$ 54,196	$ (10,718)
Stock-based compensation and other permanent differences	9,986	7,865
Branded pharmaceutical drug fee	2,122	1,848
Write-off of IP R&D	1,260	—
Other permanent differences	1,008	593
R&D credits	(18,406)	(5,827)
Change in valuation allowance	(27,013)	1,100
State taxes	3,050	(977)
Contingencies	5,960	(2,071)
Foreign rate differential	(13,715)	(5,076)
Deferred adjustments for limits on executive compensation	2,375	2,112
Deferred rate adjustment	(528)	(438)
Expiration of attributes	3,264	17,225
GILTI	8,215	7,665
Other	(150)	(3,051)
Income tax expense	$ 31,624	$ 10,250

The tax years 2003 – 2025 remain open to examination by the major taxing jurisdictions to which the Company is subject.

The Company recognizes a tax benefit from an uncertain tax position when it is more likely than not that the position will be sustained upon examination. The Company recorded an uncertain tax position reserve of $3.2 million, $1.3 million and $18.0 million for the years ended December 31, 2025, 2024, and 2023, respectively. Due to the partial valuation allowance recorded against the Company's deferred tax assets, approximately $39.4 million and $8.7 million of the total unrecognized tax benefits as of December 31, 2025 and 2024, respectively, would reduce the annual effective tax rate if recognized. The Company's practice is to recognize interest and/or penalties related to uncertain income tax positions in income tax expense. The Company had immaterial interest and/or penalties accrued on the Company's consolidated balance sheets at December 31, 2025 or 2024, respectively. Further, the Company recognized an insignificant amount of interest and/or penalties in the statement of operations for the years ended December 31, 2025, 2024 and 2023, respectively, related to uncertain tax positions.

The following table provides a reconciliation of changes in unrecognized tax benefits (in thousands):

	Years Ended December 31,		
	2025	2024	2023
Balance at beginning of period	$ 38,375	$ 37,112	$ 19,064
Additions related to current period tax positions	3,102	6,337	5,304
Additions related to prior period tax positions	2,149	—	12,956
Reductions related to prior period tax positions	(2,048)	(5,074)	(212)
Balance at end of period	$ 41,578	$ 38,375	$ 37,112

The Company asserts that any foreign earnings will be indefinitely reinvested, and accordingly, the Company has not recorded a liability for taxes associated with these undistributed earnings. If the Company determines that all or a portion of such foreign earnings are no longer indefinitely reinvested, the Company may be subject to additional foreign withholding taxes and U.S. state income taxes.

	Years Ended December 31, 2025 Income Taxes Paid (Net of Refunds)
US federal	$ 12,700
US state and local	
Kentucky	2,100
Tennessee	7,472
Other	1,767
Foreign	—
Total income taxes paid (net of refunds)	$ 24,039

9. Commitments and Contingencies

License and Merger Agreements

The Company has entered into various collaboration, licensing and merger agreements which provide the Company with rights to certain know-how, technology and patent rights. The agreements generally include upfront license fees, development and commercial milestone payments upon achievement of certain clinical and commercial development and annual net sales milestones, as well as royalties calculated as a percentage of product revenues, with rates that vary by agreement. The Company incurred $12.0 million, $34.5 million and $102.5 million in upfront and license payments in the years ended December 31, 2025, 2024 and 2023, respectively. These upfront and license payments were included in the research and development expenses in the consolidated statements of operations as there was no alternative future use associated with the payments. As of December 31, 2025, the Company may be required to make milestone payments up to $3.5 billion in the aggregate for candidates in its pipeline.

In May 2018, the Company signed an Exclusivity Deed (the Deed) with Neuren that provided for exclusive negotiations for a period of three months from the date of the Deed. Under the terms of the Deed, the Company invested $3.1 million to subscribe for 1,330,000 shares of Neuren and paid $0.9 million for the exclusive right to negotiate a deal with Neuren, which was recorded in selling, general and administrative expenses in the consolidated statements of operations in the second quarter of 2018. In 2023, the Company sold the 1,330,000 shares of Neuren for total proceeds of $12.3 million. Net gain on the strategic investments recognized in other income in the consolidated statements of operations for the year ended December 31, 2023 was $5.1 million. No gains were recorded for the years ended December 31, 2025 and 2024.

In August 2018, the Company entered into a license agreement with Neuren and obtained exclusive North American rights to develop and commercialize trofinetide for Rett syndrome and other indications. Under the terms of the agreement, the Company paid Neuren an upfront license fee of $10.0 million and it may be required to pay up to an additional $455.0 million in milestone payments based on the achievement of certain development and annual net sales milestones. In addition, the Company will be required to pay Neuren tiered, escalating, double-digit percentage royalties based on net sales. The license agreement was accounted for as an asset acquisition and the upfront cash payment of $10.0 million was expensed to research and development in the third quarter of 2018 as there is no alternative use for the asset. In connection with the FDA approval of DAYBUE, the Company paid a milestone payment of $40.0 million to Neuren following the first commercial sale of DAYBUE pursuant to the license agreement. The Company capitalized the $40.0 million milestone payment as an intangible asset as it was deemed probable of occurring as of March 31, 2023. In addition, the Company was granted a Rare Pediatric Disease PRV following the FDA approval of DAYBUE. Pursuant to the license agreement, the Company is required to pay Neuren one third of the value of the PRV at the time of sale or use of the PRV. The Company capitalized the $29.6 million for the estimated PRV value owed to Neuren as an intangible asset in 2023. During the year ended December 31, 2024, the Company sold the PRV to a third party for aggregate net proceeds of $146.5 million. Upon sale of the PRV, the Company capitalized an additional $19.2 million for the one third PRV value owed to Neuren as an intangible asset.

In July 2023, the Company expanded its licensing agreement for trofinetide with Neuren to acquire rights to the drug outside of North America as well as global rights in Rett syndrome and Fragile X syndrome to Neuren's development candidate NNZ-2591. Under the terms of the expanded agreement, Neuren received an upfront payment of $100.0 million and is eligible to receive up to an additional $426.3 million in milestone payments based on the achievement of certain commercial and sales milestones for trofinetide outside of North America and up to $831.3 million in milestone payments based on the achievement of certain development and sales milestones for NNZ-2591. In addition, the Company will be required to pay Neuren tiered royalties from the mid-teens to low-twenties percent of trofinetide net sales outside of North America. Percentage royalties related to NNZ-2591 net sales are identical to the trofinetide in each of North America and outside North America. The expanded license agreement was accounted for as an asset acquisition and the upfront cash payment of $100.0 million was expensed to research and development in the third quarter of 2023 as there is no alternative use for the asset.

In January 2022, the Company entered into a license and collaboration agreement with Stoke Therapeutics, Inc. (Stoke) to discover, develop and commercialize novel RNA-based medicines for the potential treatment of severe and rare genetic neurodevelopmental diseases of the CNS. The collaboration included SYNGAP1 syndrome, Rett syndrome (MECP2), and an undisclosed neurodevelopmental target. For the SYNGAP1 program, the two companies will jointly share global research, development and commercialization responsibilities and share 50/50 in all worldwide costs and future profits. In addition, Stoke is eligible to receive potential development, regulatory, first commercial sales and sales milestones. The MECP2 program and the undisclosed neurodevelopmental program were ended by the Company. Under the terms of the agreement, the Company paid Stoke a $60.0 million upfront payment which was accounted for as an asset acquisition and was expensed to research and development in the first quarter of 2022 as there is no alternative use for the asset. The Company may be required to pay up to an additional $245.0 million in milestones as well as royalties on future sales.

In November 2024, the Company entered into a license agreement with Saniona, for the development and commercialization of ACP-711, a highly selective GABAA-α3 positive allosteric modulator. The first indication the Company plans to pursue is development of ACP-711 for essential tremor, a neurological condition that includes shaking or trembling movements in one or more parts of the body. The Company will lead further clinical development, regulatory submissions, and global commercialization efforts for ACP-711 while also providing financial support for Saniona's ongoing Phase 1 study and preparations for Phase 2. Under the terms of the license agreement, the Company paid Saniona an upfront fee of $28.0 million and it may be required to pay up to $582.0 million in milestone payments based on the achievement of certain development and annual net sales milestones. In addition, the Company will be required to pay Saniona tiered royalties of mid-single digits to low double digits on net sales of commercial products that may result from development of ACP-711. The license agreement was accounted for as an asset acquisition and the upfront cash payment of $28.0 million

was expensed to research and development in the fourth quarter of 2024 as there is no alternative use for the asset. The potential milestone payments to Saniona consist of up to $147.0 million subject to achievement of development and commercial milestones related to potential first and second indications, and up to $435.0 million subject to achievement of thresholds of annual net sales of ACP-711 worldwide.

Corporate Credit Card Program

In connection with the Company's credit card programs, the Company established letters of credit for a total of $3.0 million, which have automatic annual extensions and are fully secured by restricted cash.

Fleet Program

In connection with the Company's fleet program, the Company established a letter of credit for $0.4 million, which has automatic annual extensions and is fully secured by restricted cash.

Legal Proceedings

Patent Infringement

On July 24, 2020, the Company filed complaints against (i) Aurobindo Pharma Limited and its affiliate Aurobindo Pharma USA, Inc. and (ii) Teva Pharmaceuticals USA, Inc. and its affiliate Teva Pharmaceutical Industries Ltd., and on July 30, 2020, the Company filed complaints against (i) Hetero Labs Limited and its affiliates Hetero Labs Limited Unit-V and Hetero USA Inc., (ii) MSN Laboratories Private Ltd. and its affiliate MSN Pharmaceuticals, Inc., and (iii) Zydus Pharmaceuticals (USA) Inc. and its affiliate Cadila Healthcare Limited. These complaints, which were filed in the United States District Court for the District of Delaware, allege infringement of certain of the Company's Orange Book-listed patents covering NUPLAZID (Pimavanserin I Cases).

The Company entered into an agreement effective April 22, 2021 with Hetero settling all claims and counterclaims in the litigation. The agreement allows Hetero to launch its generic pimavanserin product on February 27, 2038, subject to certain triggers for earlier launch. The Hetero case was dismissed by joint agreement on May 3, 2021.

On September 30, 2022, the Company filed a stipulation and proposed order to stay the claims currently asserted against Teva and for Teva to be bound by the result of the litigation rendered against the remaining defendants Aurobindo and MSN, which was ordered by the Court on October 4, 2022.

On October 21, 2022, the Company filed additional complaints against Aurobindo, MSN and Zydus in the United States District Court for the District of Delaware alleging infringement of an additional Orange Book-listed patent covering NUPLAZID (Pimavanserin II Cases).

The Company entered into an agreement, effective March 31, 2023, with Zydus settling all claims and counterclaims in the Pimavanserin I Cases and Pimavanserin II Cases. The agreement allows Zydus to launch its generic pimavanserin 10 mg tablet products on September 23, 2036 and 34 mg capsule products on February 27, 2038, subject to certain triggers for earlier launch. The Zydus case was dismissed by joint agreement on April 5, 2023.

As a result of the above, only MSN remained as an active defendant in the Pimavanserin I Cases. On January 11, 2024, following summary judgment motions, the District Court entered final judgment in the Company's favor that MSN's submission of ANDA No. 214925 was an act of infringement in the Pimavanserin I Case and the '740 patent was not invalid. On January 18, 2024, MSN filed a Notice of Appeal to the United States Court of Appeals for the Federal Circuit from the final judgment entered on January 11, 2024. On June 9, 2025, the Federal Circuit issued a decision affirming the final judgement of the District Court in the Company's favor.

In connection with the Pimavanserin II cases, MSN and Aurobindo are the remaining defendants. A bench trial was conducted from December 3, 2024 to December 6, 2024 in the matter. Post-trial briefing was completed on February 12, 2025. On June 9, 2025, the District Court issued a final judgement the Company's favor that Aurobindo's ANDA infringes the asserted NUPLAZID patent and that the defendants failed to demonstrate such patent is invalid. On June 16, 2025, MSN and Aurobindo filed a Notice of Appeal to the United States Court of Appeals for the Federal Circuit from the final judgment entered on June 9, 2025. Briefing was completed on December 19, 2025. An oral argument has not been scheduled as yet.

On February 14, 2025, the Company filed a complaint against Zydus Lifesciences Limited, Zydus Worldwide DMCC, and Zydus Pharmaceuticals (USA) Inc. (collectively "Zydus") in the United States District Court for the District of Delaware, alleging infringement of certain of the Company's Orange Book-listed patents covering NUPLAZID (Pimavanserin) by Zydus' proposed 34 mg pimavanserin tablet product. The case is scheduled for trial commencing November 2, 2026.

Securities Class Action

On April 19, 2021, a purported stockholder of the Company filed a putative securities class action complaint (captioned *City of Birmingham Relief Retirement Systems* v. Acadia Pharmaceuticals, Inc., Case No. 21-cv-0762) in the U.S. District Court for the Southern District of California against the Company and certain of the Company's then-current executive officers. On September 29, 2021, the Court issued an order designating lead plaintiff and lead counsel. On December 10, 2021, lead plaintiff filed an amended complaint. The amended complaint generally alleges that defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, by failing to disclose that the materials submitted in support of its sNDA seeking approval of pimavanserin for the treatment of hallucinations and delusions associated with dementia-related psychosis contained statistical and design deficiencies and that the FDA was unlikely to approve the sNDA in its current form. The amended complaint seeks unspecified monetary damages and other relief. On March 11, 2024, the Court granted plaintiffs' motion for class certification and appointment of class representatives and class counsel. The parties concluded discovery on September 24, 2025. The parties submitted pretrial motions on November 12, 2025 and briefing for these motions will be complete on February 25, 2026. The Court has scheduled a pretrial motions hearing for April 10, 2026. Remaining pretrial deadlines will be determined pending the Court's rulings on the parties' pretrial motions.

Opt-Out Litigation

On March 7, 2024, a purported stockholder of the Company filed a complaint (captioned Alger Dynamic Opportunities Fund v. Acadia Pharmaceuticals, Inc., Case No. 24-cv-00451) in the U.S. District Court for the Southern District of California against the Company and one executive officer. The complaint is based on the same underlying allegations as the Securities Class Action described above, and alleged claims under federal and state securities laws, and for common law fraud and negligent misrepresentations. On May 24, 2024, Defendants moved to dismiss the complaint. On October 31, 2024, the Court granted in part and denied in part Defendants' motion to dismiss. The Court dismissed with leave to amend the purported stockholder's state and common law claims, as well as the claim brought under Section 18(a) of the Securities Exchange Act of 1934, as amended. Defendants filed their answer to the Sections 10(b) and 20(a) claims on December 16, 2024. On January 13, 2025, the Court stayed this suit pending the outcome of the Securities Class Action.

Derivative Suit

On December 15, 2023, a purported stockholder of the Company filed a derivative action (captioned *Kanner et al v. Biggar et al.*, Case No. 23-cv-2293) in the U.S. District Court for the Southern District of California against certain of the Company's current directors. The Company is named as a nominal defendant. The complaint is based on the same alleged misconduct as the Securities Class Action, and asserts state law claims, on behalf of the Company, against the individual defendants for breach of fiduciary duty, unjust enrichment, abuse of control, waste of corporate assets, and insider trading. The complaint also asserts federal claims under sections 10(b), 21D, and 14(a) of the Securities Exchange Act of 1934, as amended. On December 27, 2023, the action was reassigned to District Judge William Q. Hayes and Magistrate Judge Michael S. Berg due to its relation to the Securities Class Action. On January 30, 2024, the parties jointly requested a stay of the action. The Court granted that request and the action was stayed on February 20, 2024, pending the outcome of our Demand Review Committee's investigation into the underlying claims. The stay was briefly lifted on September 5, 2025 but reinstated on October 17, 2025 and remains in place. On January 15, 2026, the parties informed the Court that they had reached a settlement in principle regarding the derivative claims. Pursuant to the proposed settlement, which is still subject to Court approval, defendants agreed to certain governance reforms and agreed to an award of $1.5 million in attorneys' fees to be paid by the Company's insurance carrier.

Given the unpredictability inherent in litigation, the Company cannot predict the outcome of these matters. The Company is unable to estimate possible losses or ranges of losses that may result from these matters, and therefore it has not accrued any amounts in connection with these matters other than attorneys' fees incurred to date.

10. Leases

The Company leases facilities, vehicles and certain equipment under noncancelable operating leases with remaining lease terms of 0.1 year to 5.4 years, some of which include options to extend the lease for up to two five-year terms. These optional periods were not considered in the determination of the right-of-use asset or the lease liability as the Company did not consider it reasonably certain that it would exercise such options.

The operating lease costs were as follows (in thousands):

	Years Ended December 31,		
	2025	2024	2023
Operating lease cost	$ 14,980	$ 11,836	$ 10,343
Operating sublease income	(2,371)	(1,824)	(93)
Net operating lease costs	$ 12,609	$ 10,012	$ 10,250

Supplemental cash flow information related to the Company's leases were as follows (in thousands):

	Years Ended December 31,	
	2025	2024
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$ 12,114	$ 10,327
Right-of-use assets obtained in exchange for operating lease obligations:	9,450	2,218

The balance sheet classification of the Company's lease liabilities was as follows (in thousands):

	December 31, 2025	December 31, 2024
Operating lease liabilities		
Current portion included in accrued liabilities	$ 11,633	$ 9,958
Operating lease liabilities	40,554	42,037
Total operating lease liabilities	$ 52,187	$ 51,995

Maturities of lease liabilities were as follows (in thousands):

	Operating Leases
Years ending December 31,	
2026	$ 11,966
2027	11,938
2028	11,466
2029	10,612
2030	8,902
Thereafter	3,656
Total lease payments	58,540
Less:	
Imputed interest	(6,353)
Total operating lease liabilities	$ 52,187

Operating lease liabilities are based on the net present value of the remaining lease payments over the remaining lease term. In determining the present value of lease payments, the Company uses its incremental borrowing rate based on the information available at the lease commencement date. As of December 31, 2025 and 2024, the weighted average remaining lease term was 5.2 years and 6.1 years, respectively, and the weighted average discount rate used to determine the operating lease liability was 4.8% and 4.5%, respectively.

In the fourth quarter of 2018, the Company entered into an agreement to lease the 4th and 5th floors of corporate office space in San Diego, California with total minimum lease payments of $50.4 million over an initial term of 10 years and 9 months. In February 2020, the Company entered into the first amendment to the lease agreement to lease the 2nd floor of corporate office space in San Diego, California with total minimum lease payments of $25.3 million over an initial term of approximately 10 years and 7 months. In March 2020, the Company entered into the second amendment to the lease agreement which increased the total minimum lease payments of the original corporate office space to $51.4 million. In the third quarter of 2020, the lease for the 4th and 5th floors of corporate office space commenced and the Company capitalized a right of use asset and related lease liability of $40.3 million. In the first quarter of 2021, the lease for the 2nd floor of corporate office space commenced and the Company capitalized a right of use asset and related lease liability of $19.2 million. In connection with this lease and the amendment, the Company established a letter of credit for $3.1 million, which has automatic annual extensions and is fully secured by restricted cash.

In May 2023, the Company entered into an agreement to sublease its 2nd floor of corporate office space in San Diego to a sublessee with a total minimum sublease income of $18.4 million over a term of approximately 7 years and 6 months. The Company delivered the full possession of its 2nd floor of corporate office space to the sublessee in August 2023. Pursuant to the sublease agreement, the Company received the first sublease payment in December 2023.

In May 2025, the Company entered into an agreement to lease the 2nd and a portion of the 3rd floors of corporate office space in Princeton, New Jersey (the New Princeton Lease) with total minimum lease payments of $24.5 million over an initial term of 12 years and 2 months. As of December 31, 2025, the New Princeton Lease had not yet commenced. This operating lease is expected to commence in the second quarter of 2026, but may commence earlier if the lessor makes the space available for use earlier than anticipated. In connection with this New Princeton Lease agreement, the Company established a letter of credit for $0.6 million, which has automatic annual extensions and is fully secured by restricted cash. The current Princeton office lease will terminate five days after the commencement of the New Princeton Lease.

11. Segment Reporting

In accordance with FASB ASC Topic 280, *Segment Reporting*, management has determined that the Company operates in one business segment which is the development and commercialization of innovative medicines. Substantially all revenues for the years ended December 31, 2025, 2024, and 2023 were generated from customers in North America.

The Company's CODM is the CEO who uses the consolidated statement of operations to make decisions about allocating resources and assessing performance for the entire Company. Managing and allocating resources on a consolidated basis enables the CODM to assess the overall level of resources available and how to best deploy these resources across functions and research and development programs that are in line with the Company's long-term company-wide strategic goals.

The key areas of focus by CODM for allocation of resources are revenues from each product, as well as operating expenses (cost of goods sold, license fees and royalties, research and development expense, selling, general and administrative expense, and other income or loss). While the CODM analyzes these categories, the area of focus is period over period fluxes and budget-to-actual variances to determine the right allocation of resources is attributed to the segment in order to ensure profitability is maximized.

The following table illustrates reported segment revenue, segment profit and significant segment expenses (in thousands):

	Year Ended December 31,		
	2025	2024	2023
NUPLAZID net revenue	$ 680,086	$ 609,385	$ 549,248
DAYBUE net revenue	391,419	348,412	177,189
Total revenues	1,071,505	957,797	726,437
Less:			
Cost of goods sold	35,840	30,068	19,826
License fees and royalties	53,158	51,773	21,812
Research and development expense			
External research and development	220,071	194,539	170,036
Internal costs[(1)]	96,731	74,210	79,083
Upfront and milestone payments	12,000	34,500	102,500
Total research and development expense	328,802	303,249	351,619
Selling, general and administrative	548,894	488,428	406,559
Gain on sale of non-financial asset	—	(146,515)	—
Interest income, net	(31,722)	(25,458)	(17,234)
Other income	(2,371)	(1,823)	(5,109)
Income tax expense	(252,096)	31,624	10,250
Consolidated net income	$ 391,000	$ 226,451	$ (61,286)

(1) Includes personnel expenses and costs allocated to multiple research and development programs, including benefits, information technology, facilities and inventory.

SCHEDULE II – Valuation and Qualifying Accounts
(in thousands)

	Balance at Beginning of Period	Additions: Provision Related to Current Period Sales	Deductions: Actual Distribution Fees, Discounts and Chargebacks Related to Current Period Sales	Deductions: Actual Distribution Fees, Discounts and Chargebacks Related to Prior Period Sales	Balance at End of Period
Allowance for distribution fees, discounts and chargebacks:					
For the year ended December 31, 2023	$ 10,923	$ 97,797	$ (85,641)	$ (10,923)	$ 12,156
For the year ended December 31, 2024	$ 12,156	$ 122,083	$ (110,200)	$ (12,156)	$ 11,883
For the year ended December 31, 2025	$ 11,883	$ 145,584	$ (129,127)	$ (11,883)	$ 16,457

Exhibit 10.25

REGISTRATION RIGHTS AGREEMENT

This Registration Rights Agreement (this "Agreement") is made as of February 24, 2026 by and between Acadia Pharmaceuticals Inc., a Delaware corporation (the "Company"), and the persons listed on the attached Schedule A who are signatories to this Agreement (each, an "Investor", and collectively, the "Investors"). Unless otherwise defined herein, capitalized terms used in this Agreement have the respective meanings ascribed to them in Section 1.

RECITALS

WHEREAS, the Company and the Investors wish to provide for certain arrangements with respect to the registration of the Registrable Securities (as defined below) by the Company under the Securities Act (as defined below).

NOW, THEREFORE, in consideration of the mutual promises and covenants set forth herein, and other consideration, the receipt and adequacy of which are hereby acknowledged, the parties hereto agree as follows:

Section 1.
Definitions

1.1. Certain Definitions. In addition to the terms defined elsewhere in this Agreement, as used in this Agreement, the following terms have the respective meanings set forth below:

(a) "Block Trade" shall mean an offering of Registrable Securities which requires both the Investors and the Company to enter into a sale agreement and is limited in scope of selling efforts as compared to an Underwritten Offering.

(b) "Board" shall mean the Board of Directors of the Company.

(c) "Commission" shall mean the Securities and Exchange Commission or any other federal agency at the time administering the Securities Act.

(d) "Common Stock" shall mean the common stock of the Company, par value $0.0001 per share.

(e) "Exchange Act" shall mean the Securities Exchange Act of 1934, as amended, or any similar successor federal statute and the rules and regulations thereunder, all as the same shall be in effect from time to time.

(f) "Governmental Entity" shall mean any federal, state, local or foreign government, or any department, agency, or instrumentality of any government; any public international organization, any transnational governmental organization; any court of competent jurisdiction, arbitral, administrative agency, commission, or other governmental regulatory authority or quasi-governmental authority, any political party; and any national securities exchange or national quotation system.

(g) "Other Securities" shall mean securities of the Company, other than Registrable Securities (as defined below).

(h) "Person" shall mean any individual, partnership, corporation, company, association, trust, joint venture, limited liability company, unincorporated organization, entity or division, or any government, governmental department or agency or political subdivision thereof.

(i) "Registrable Securities" shall mean all securities of the Company (whether debt, equity, or otherwise) and any Common Stock issued or issuable upon the exercise or conversion of any such securities of the Company, in each case that is now owned or hereafter acquired by the any of the Investors; provided, however, that, notwithstanding the foregoing, debt securities shall only constitute "Registrable Securities" to the extent acquired by the Investors: (i) directly from the Company, (ii) directly from an initial purchaser in a Rule 144A offering of the Company's debt securities or directly from an underwriter in a public offering of the Company's debt securities pursuant to an effective registration statement under the Securities Act, or (iii) in the secondary market for debt securities that were originally issued in a public offering of the Company's debt securities pursuant to an effective registration statement under the Securities Act. Registrable Securities shall cease to be Registrable Securities upon the earliest to occur of the following events: (i) such Registrable Securities have been sold pursuant to an effective Registration Statement; (ii) such Registrable Securities have been sold by the Investors pursuant to Rule 144 (or other similar rule), (iii) at any time after any of the Investors become an affiliate of the Company, such Registrable Securities may be resold by the Investor holding such Registrable Securities without limitations as to volume or manner of sale pursuant to Rule 144; or (iv) ten (10) years after the date of this Agreement. For purposes of this definition, in order to determine whether an Investor is an "affiliate" (as such term is defined and used in Rule 144, and including for determining whether volume or manner of sale limitations of Rule 144 apply) the parties will calculate beneficial ownership in accordance with Rule 13d-3 under the Exchange Act.

(j) The terms "register," "registered" and "registration" shall refer to a registration effected by preparing and filing a Registration Statement in compliance with the Securities Act, and such Registration Statement becoming effective under the Securities Act.

(k) "Registration Expenses" shall mean all expenses incurred by the Company in effecting any registration pursuant to this Agreement, including, without limitation, all registration, qualification, and filing fees, printing expenses, escrow fees, fees and disbursements of counsel for the Company, up to (1) $50,000 of reasonable out-of-pocket legal expenses of one outside counsel for Investors (if different from the Company's counsel and if such counsel is reasonably approved by the Company) in connection with the preparation and filing of the Resale Registration Shelf (as defined below), and (2) up to $50,000 of reasonable out-of-pocket legal expenses of one outside counsel for the Investors (if different from the Company's counsel and if such counsel is reasonably approved by the Company) per Underwritten Offering, blue sky fees and expenses, and expenses of any regular or special audits incident to or required by any such registration, but shall not include Selling Expenses.

(l) "Registration Statement" means any registration statement of the Company filed with, or to be filed with, the Commission under the Securities Act, including the related prospectus,

amendments and supplements to such registration statement, including pre- and post-effective amendments, and all exhibits and all material incorporated by reference in such registration statement as may be necessary to comply with applicable securities laws other than a registration statement (and related prospectus) filed on Form S-4 or Form S-8 or any successor forms thereto.

(m) "Rule 144" shall mean Rule 144 as promulgated by the Commission under the Securities Act, as such rule may be amended from time to time, or any similar successor rule that may be promulgated by the Commission.

(n) "Securities Act" shall mean the Securities Act of 1933, as amended, or any similar successor federal statute and the rules and regulations thereunder, all as the same shall be in effect from time to time.

(o) "Selling Expenses" shall mean all underwriting discounts and selling commissions applicable to the sale of Registrable Securities, the fees and expenses of any legal counsel (except as provided in the definition of "Registration Expenses") and any other advisors any of the Investors engage and all similar fees and commissions relating to the Investors' disposition of the Registrable Securities.

(p) "Underwritten Offering" shall mean a public offering of Registrable Securities pursuant to an effective registration statement under the Securities Act (other than pursuant to a registration statement on Form S-4 or S-8 or any similar or successor form) which requires the Investors and the Company to enter into an underwriting agreement.

Section 2.
Resale Registration Rights

2.1. Resale Registration Rights.

(a) Following demand by any Investor the Company shall file with the Commission a Registration Statement on Form S-3 (except if the Company is not then eligible to register for resale the Registrable Securities on Form S-3, in which case such registration shall be on another appropriate form in accordance with the Securities Act) covering the resale of the Registrable Securities by the Investors (the "Resale Registration Shelf"), and the Company shall file such Resale Registration Shelf as promptly as reasonably practicable following such demand, and in any event within sixty (60) days of such demand. Such Resale Registration Shelf shall include a "final" prospectus, including the information required by Item 507 of Regulation S-K of the Securities Act, as provided by the Investors in accordance with Section 2.7. Notwithstanding the foregoing, before filing the Resale Registration Shelf, the Company shall furnish to the Investors a copy of the Resale Registration Shelf and afford the Investors an opportunity to review and comment on the Resale Registration Shelf. The Company's obligation pursuant to this Section 2.1(a) is conditioned upon the Investors providing the information contemplated in Section 2.7.

(b) The Company shall use its reasonable best efforts to cause the Resale Registration Shelf and related prospectuses to become effective as promptly as practicable after filing. The Company

shall use its reasonable best efforts to cause such Registration Statement to remain effective under the Securities Act until the earlier of the date (i) all Registrable Securities covered by the Resale Registration Shelf have been sold or may be sold freely without limitations or restrictions as to volume or manner of sale pursuant to Rule 144 or (ii) all Registrable Securities covered by the Resale Registration Shelf otherwise cease to be Registrable Securities pursuant to the definition of Registrable Securities. The Company shall promptly, and within two (2) business days after the Company confirms the effectiveness of the Resale Registration Shelf with the Commission, notify the Investors of the effectiveness of the Resale Registration Shelf.

(c) Notwithstanding anything contained herein to the contrary, the Company shall not be obligated to effect, or to take any action to effect, a registration pursuant to Section 2.1(a):

(i) if the Company has and maintains an effective Registration Statement on Form S-3ASR that provides for the resale of an unlimited number of securities by selling stockholders (a "Company Registration Shelf");

(ii) during the period forty-five (45) days prior to the Company's good faith estimate of the date of filing of a Company Registration Shelf; or

(iii) if the Company has caused a Registration Statement to become effective pursuant to this Section 2.1 during the prior twelve (12) month period.

(d) If the Company has a Company Registration Shelf in place at any time in which the Investors make a demand pursuant to Section 2.1(a), the Company shall file with the Commission, as promptly as practicable, and in any event within fifteen (15) business days after such demand, a "final" prospectus supplement to its Company Registration Shelf covering the resale of the Registrable Securities by the Investors (the "Prospectus"); provided, however, that the Company shall not be obligated to file more than one Prospectus pursuant to this Section 2.1(d) in any six month period to add additional Registrable Securities to the Company Registration Shelf that were acquired by the Investors other than directly from the Company or in an underwritten public offering by the Company. The Prospectus shall include the information required under Item 507 of Regulation S-K of the Securities Act, which information shall be provided by the Investors in accordance with Section 2.7. Notwithstanding the foregoing, before filing the Prospectus, the Company shall furnish to the Investors a copy of the Prospectus and afford a single outside counsel (in addition to any inside counsel) of the Investors an opportunity to review and comment on the Prospectus.

(e) Deferral and Suspension. At any time after being obligated pursuant to this Agreement to file a Resale Registration Shelf or Prospectus, or after any such Resale Registration Shelf has become effective or such Prospectus has been filed with the Commission, the Company may defer the filing of or suspend the use of any such Resale Registration Shelf or Prospectus, upon giving written notice of such action to the Investors with a certificate signed by any of the Chief Executive Officer, Chief Financial Officer or Chief Legal Officer of the Company stating that in the good faith judgment of the Board, the filing or use of any such Resale Registration Shelf or Prospectus covering the Registrable Securities would be seriously detrimental to the Company or its stockholders at such time and that the Board concludes, as a result, that it is in the best interests of

the Company and its stockholders to defer the filing or suspend the use of such Resale Registration Shelf or Prospectus at such time. The Company shall have the right to defer the filing of or suspend the use of such Resale Registration Shelf or Prospectus for a period of not more than one hundred twenty (120) days from the date the Company notifies the Investors of such deferral or suspension; provided that the Company shall not exercise the right contained in this Section 2.1(e) more than once in any twelve month period. In the case of the suspension of use of any effective Resale Registration Shelf or Prospectus, the Investors, immediately upon receipt of notice thereof from the Company, shall discontinue any offers or sales of Registrable Securities pursuant to such Resale Registration Shelf or Prospectus until advised in writing by the Company that the use of such Resale Registration Shelf or Prospectus may be resumed. In the case of a deferred Prospectus or Resale Registration Shelf filing, the Company shall provide prompt written notice to the Investors of (i) the Company's decision to file or seek effectiveness of the Prospectus or Resale Registration Shelf, as the case may be, following such deferral and (ii) in the case of a Resale Registration Shelf, the effectiveness of such Resale Registration Shelf. In the case of either a suspension of use of, or deferred filing of, any Resale Registration Shelf or Prospectus, the Company shall not, during the pendency of such suspension or deferral, be required to take any action hereunder (including any action pursuant to Section 2.2 hereof) with respect to the registration or sale of any Registrable Securities pursuant to any such Resale Registration Shelf, Company Registration Shelf or Prospectus.

(f) Other Securities. Subject to Section 2.2(e) below, any Resale Registration Shelf or Prospectus may include Other Securities, and may include securities of the Company being sold for the account of the Company; *provided* such Other Securities are excluded first from such Registration Statement in order to comply with any applicable laws or request from any Governmental Entity, Nasdaq or any applicable listing agency. No Other Securities may be included in an Underwritten Offering pursuant to Section 2.2 without the consent of the Investors.

2.2. Sales and Underwritten Offerings of the Registrable Securities.

(a) Notwithstanding any provision contained herein to the contrary, the Investors, collectively, shall and subject to the limitations set forth in this Section 2.2, be permitted (i) one Underwritten Offering per calendar year, but no more than three Underwritten Offerings in total, and (ii) no more than two Underwritten Offerings or Block Trades in any twelve month period, to effect the sale or distribution of Registrable Securities.

(b) If the Investors intend to effect an Underwritten Offering or Block Trade pursuant to a Resale Registration Shelf or Company Registration Shelf to sell or otherwise distribute Registrable Securities, they shall so advise the Company and provide as much notice to the Company as reasonably practicable (and, in either case, not less than fifteen (15) business days prior to the Investors' request that the Company file a prospectus supplement to a Resale Registration Shelf or Company Registration Shelf).

(c) In connection with any offering initiated by the Investors pursuant to this Section 2.2 involving an underwriting of shares of Registrable Securities, the Investors shall be entitled to select the underwriter or underwriters for such offering, subject to the consent of the Company, such consent not to be unreasonably withheld, conditioned or delayed.

(d) In connection with any offering initiated by the Investors pursuant to this Section 2.2 involving an Underwritten Offering of Registrable Securities, the Company shall not be required to include any of the Registrable Securities in such underwriting unless the Investors (i) enter into an underwriting agreement in customary form with the underwriter or underwriters, (ii) accept customary terms in such underwriting agreement with regard to representations and warranties relating to ownership of the Registrable Securities and authority and power to enter into such underwriting agreement and (iii) complete and execute all questionnaires, powers of attorney, custody agreements, indemnities and other documents as may be requested by such underwriter or underwriters. Further, the Company shall not be required to include any of the Registrable Securities in an Underwritten Offering or Block Trade if (Y) the underwriting/sale agreement proposed by the underwriter or underwriters contains representations, warranties or conditions that are not reasonable in light of the Company's then-current business (for the avoidance of doubt, the limitation in this clause (Y) is not related to the Company's then-current disclosure, which may need to be updated prior to such offering) or (Z) the underwriter, underwriters or the Investors require the Company to participate in any marketing, roadshow or comparable activity that may be required to complete the orderly sale of shares by the underwriter or underwriters.

(e) If the total amount of securities to be sold in any offering initiated by the Investors pursuant to this Section 2.2 involving an underwriting of shares of Registrable Securities exceeds the amount that the underwriters determine in their sole discretion is compatible with the success of the offering, then the Company shall be required to include in the offering only that number of such securities, including Registrable Securities (subject in each case to the cutback provisions set forth in this Section 2.2(e)), that the underwriters and the Company determine in their sole discretion shall not jeopardize the success of the offering. If the Underwritten Offering has been requested pursuant to Section 2.2(a) hereof, the number of shares that are entitled to be included in the registration and underwriting shall be allocated in the following manner: (a) first, shares of Company equity securities that the Company desires to include in such registration shall be excluded and (b) second, Registrable Securities requested to be included in such registration by the Investors shall be excluded. For the avoidance of doubt, no other person besides the Investors shall be entitled to participate in any Block Trade initiated by the Investors pursuant to this Section 2.2. To facilitate the allocation of shares in accordance with the above provisions, the Company or the underwriters may round down the number of shares allocated to any of the Investors to the nearest 100 shares.

2.3. Fees and Expenses. All Registration Expenses incurred in connection with registrations pursuant to this Agreement shall be borne by the Company. All Selling Expenses relating to securities registered on behalf of the Investors shall be borne by the Investors.

2.4. Registration Procedures. In the case of each registration of Registrable Securities effected by the Company pursuant to Section 2.1 hereof, the Company shall keep the Investors advised as to the initiation of each such registration and as to the status thereof. The Company shall use its reasonable best efforts, within the limits set forth in this Section 2.4, to:

(a) prepare and file with the Commission such amendments and supplements to such Registration Statement and the prospectuses used in connection with such Registration Statement as may be necessary to keep such Registration Statement effective and current and comply with

the provisions of the Securities Act with respect to the disposition of all securities covered by such Registration Statement;

(b) furnish to the Investors such numbers of copies of a prospectus, including preliminary prospectuses, in conformity with the requirements of the Securities Act, and such other documents as the Investors may reasonably request in order to facilitate the disposition of Registrable Securities;

(c) use its reasonable best efforts to register and qualify the Registrable Securities covered by such Registration Statement under such other securities or blue sky laws of such jurisdictions in the United States as shall be reasonably requested by the Investors, provided that the Company shall not be required in connection therewith or as a condition thereto to qualify to do business or to file a general consent to service of process in any such states or jurisdictions;

(d) in the event of any Underwritten Offering or Block Trade, and subject to Section 2.2(d), enter into and perform its obligations under an underwriting agreement or Block Trade sale agreement, in usual and customary form (including any "lock-ups" on behalf of the Company and its directors and officers), with the managing underwriter of such offering and take such other usual and customary action as the Investors may reasonably request in order to facilitate the disposition of such Registrable Securities;

(e) notify the Investors at any time when a prospectus relating to a Registration Statement covering any Registrable Securities is required to be delivered under the Securities Act of the happening of any event as a result of which the prospectus included in such Registration Statement, as then in effect, includes an untrue statement of a material fact or omits to state a material fact required to be stated therein or necessary to make the statements therein not misleading in the light of the circumstances then existing. The Company shall use its reasonable best efforts to amend or supplement such prospectus in order to cause such prospectus not to include any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading in the light of the circumstances then existing;

(f) provide a transfer agent and registrar for all Registrable Securities registered pursuant to such Registration Statement and, if required, a CUSIP number for all such Registrable Securities, in each case not later than the effective date of such registration;

(g) if requested by an Investor, use reasonable best efforts to cause the Company's transfer agent to remove any restrictive legend from any Registrable Securities as to which such Investor has agreed to sell only pursuant to a Registration Statement covering any Registrable Securities or Rule 144, (i) as soon as practicable following such request for debt securities or (ii) within two business days following such request for equity securities; provided, however, that the Company may request reasonable representations and covenants regarding the manner of sale when such securities are ultimately sold in connection with such instruction to the Company's transfer agent;

(h) cause to be furnished, at the request of the Investors, on the date that Registrable Securities are delivered to underwriters for sale in connection with any Underwritten Offering or Block Trade, (i) an opinion, dated such date, of the counsel representing the Company for the purposes of such registration, in form and substance as is customarily given to underwriters in an

underwritten public offering or sales agents in a Block Trade, as applicable, addressed to the underwriters or sales agents, as applicable, and (ii) a letter or letters from the independent certified public accountants of the Company, in form and substance as is customarily given by independent certified public accountants to underwriters in an underwritten public offering or sales agents in a Block Trade, as applicable, addressed to the underwriters or sales agents, as applicable; and

(i) cause all such Registrable Securities included in a Registration Statement pursuant to this Agreement to be listed on each securities exchange or other securities trading markets on which Common Stock is then listed.

2.5. The Investors' Obligations.

(a) Discontinuance of Distribution. The Investors agree that, upon receipt of any notice from the Company of the occurrence of any event of the kind described in Section 2.4(e) hereof, the Investors shall immediately discontinue disposition of Registrable Securities pursuant to any Registration Statement covering such Registrable Securities until the Investors' receipt of the copies of the supplemented or amended prospectus contemplated by Section 2.4(e) hereof or receipt of notice that no supplement or amendment is required and that the Investors' disposition of the Registrable Securities may be resumed. The Company may provide appropriate stop orders to enforce the provisions of this Section 2.5(a).

(b) Compliance with Prospectus Delivery Requirements. The Investors covenant and agree that they shall comply with the prospectus delivery requirements of the Securities Act as applicable to them or an exemption therefrom in connection with sales of Registrable Securities pursuant to any Registration Statement filed by the Company pursuant to this Agreement.

(c) Notification of Sale of Registrable Securities. The Investors covenant and agree that they shall notify the Company following the sale of Registrable Securities to a third party as promptly as reasonably practicable, and in any event within thirty (30) days, following the sale of such Registrable Securities.

2.6. Indemnification.

(a) To the extent permitted by law, the Company shall indemnify the Investors, and, as applicable, their officers, directors, and constituent partners, legal counsel for each Investor and each Person controlling the Investors, with respect to which registration, related qualification, or related compliance of Registrable Securities has been effected pursuant to this Agreement, and each underwriter, if any, and each Person who controls any underwriter within the meaning of the Securities Act against all claims, losses, damages, or liabilities (or actions in respect thereof) to the extent such claims, losses, damages, or liabilities arise out of or are based upon (i) any untrue statement (or alleged untrue statement) of a material fact contained in any prospectus or other document (including any related Registration Statement) incident to any such registration, qualification, or compliance, or (ii) any omission (or alleged omission) to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading, or (iii) any violation or alleged violation by the Company of the Securities Act, the Exchange Act, any state securities law, or any rule or regulation promulgated under the Securities Act, the Exchange Act or any state securities law applicable to the Company and relating to action or

inaction required of the Company in connection with any such registration, qualification, or compliance; and the Company shall pay as incurred to the Investors, each such underwriter, and each Person who controls the Investors or underwriter, any reasonable out-of-pocket legal expenses and any other expenses reasonably incurred in connection with investigating or defending any such claim, loss, damage, liability, or action; provided, however, that the indemnity contained in this Section 2.6(a) shall not apply to amounts paid in settlement of any such claim, loss, damage, liability, or action if settlement is effected without the consent of the Company (which consent shall not unreasonably be withheld); and provided, further, that the Company shall not be liable in any such case to the extent that any such claim, loss, damage, liability, or expense arises out of or is based upon any violation by such Investor of the obligations set forth in Section 2.5 hereof or any untrue statement or omission contained in such prospectus or other document based upon written information furnished to the Company by the Investors, such underwriter, or such controlling Person and stated to be for use therein or any bad faith, willful misconduct or gross negligence of the Investor.

(b) To the extent permitted by law, each Investor (severally and not jointly) shall, if Registrable Securities held by such Investor are included for sale in the registration and related qualification and compliance effected pursuant to this Agreement, indemnify the Company, each of its directors, each officer of the Company who signs the applicable Registration Statement, each legal counsel and each underwriter of the Company's securities covered by such a Registration Statement, each Person who controls the Company or such underwriter within the meaning of the Securities Act against all claims, losses, damages, and liabilities (or actions in respect thereof) arising out of or based upon (i) any untrue statement (or alleged untrue statement) of a material fact contained in any such Registration Statement, or related document, or (ii) any omission (or alleged omission) to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading, or (iii) any violation or alleged violation by such Investor of Section 2.5 hereof, the Securities Act, the Exchange Act, any state securities law, or any rule or regulation promulgated under the Securities Act, the Exchange Act or any state securities law applicable to such Investor and relating to action or inaction required of such Investor in connection with any such registration and related qualification and compliance, and shall pay as incurred to such persons, any reasonable out-of-pocket legal expenses and any other expenses reasonably incurred in connection with investigating or defending any such claim, loss, damage, liability, or action, in each case only to the extent that such untrue statement (or alleged untrue statement) or omission (or alleged omission) is made in (and such violation pertains to) such Registration Statement or related document in reliance upon and in conformity with written information furnished to the Company by such Investor and stated to be specifically for use therein; provided, however, that the indemnity contained in this Section 2.6(b) shall not apply to amounts paid in settlement of any such claim, loss, damage, liability, or action if settlement is effected without the consent of such Investor (which consent shall not unreasonably be withheld); provided, further, that the Investor shall not be liable in any such case to the extent that any such claim, loss, damage, liability or expense arises out of or is based upon any bad faith, willful misconduct or gross negligence of the Company; and provided, further, that such Investor's liability under this Section 2.6(b) (when combined with any amounts such Investor is liable for under Section 2.6(d)) shall not exceed such Investor's net proceeds from the offering of securities made in connection with such registration.

(c) Promptly after receipt by an indemnified party under this Section 2.6 of notice of the commencement of any action, such indemnified party shall, if a claim in respect thereof is to be made against an indemnifying party under this Section 2.6, notify the indemnifying party in writing of the commencement thereof and generally summarize such action. The indemnifying party shall have the right to participate in and to assume the defense of such claim at its own expense; provided, however, that the indemnifying party shall be entitled to select counsel for the defense of such claim with the approval of any parties entitled to indemnification, which approval shall not be unreasonably withheld; provided further, however, that if either party reasonably determines that there may be a conflict between the position of the Company and the Investors in conducting the defense of such action, suit, or proceeding by reason of recognized claims for indemnity under this Section 2.6, then counsel for such party shall be entitled to conduct the defense to the extent reasonably determined by such counsel to be necessary to protect the interest of such party. The failure to notify an indemnifying party promptly of the commencement of any such action, if prejudicial to the ability of the indemnifying party to defend such action, shall relieve such indemnifying party, to the extent so prejudiced, of any liability to the indemnified party under this Section 2.6, but the omission so to notify the indemnifying party shall not relieve such party of any liability that such party may have to any indemnified party otherwise than under this Section 2.6.

(d) If the indemnification provided for in this Section 2.6 is held by a court of competent jurisdiction to be unavailable to an indemnified party with respect to any loss, liability, claim, damage, or expense referred to therein, then the indemnifying party, in lieu of indemnifying such indemnified party hereunder, shall contribute to the amount paid or payable by such indemnified party as a result of such loss, liability, claim, damage, or expense in such proportion as is appropriate to reflect the relative fault of the indemnifying party on the one hand and of the indemnified party on the other in connection with the statements or omissions that resulted in such loss, liability, claim, damage, or expense as well as any other relevant equitable considerations. The relative fault of the indemnifying party and of the indemnified party shall be determined by reference to, among other things, whether the untrue or alleged untrue statement of a material fact or the omission to state a material fact relates to information supplied by the indemnifying party or by the indemnified party and the parties' relative intent, knowledge, access to information, and opportunity to correct or prevent such statement or omission. In no event, however, shall (i) any amount due for contribution hereunder be in excess of the amount that would otherwise be due under Section 2.6(a) or Section 2.6(b), as applicable, based on the limitations of such provisions and (ii) a Person found by a court of competent jurisdiction to be liable for fraudulent misrepresentation (within the meaning of the Securities Act), bad faith or willful misconduct be entitled to contribution from a Person who was not also found by a court of competent jurisdiction to be liable for such fraudulent misrepresentation (within the meaning of the Securities Act), bad faith or willful misconduct.

(e) Notwithstanding the foregoing, to the extent that the provisions on indemnification and contribution contained in the underwriting agreement entered into in connection with an Underwritten Offering, or the Block Trade sale agreement, are in conflict with the foregoing provisions, the provisions in the underwriting agreement or Block Trade sale agreement shall control; provided, however, that the failure of the underwriting agreement or Block Trade sale agreement to provide for or address a matter provided for or addressed by the foregoing provisions

shall not be a conflict between the underwriting agreement or the Block Trade sale agreement and the foregoing provisions.

(f) The obligations of the Company and the Investors under this Section 2.6 shall survive the completion of any offering of Registrable Securities in a Registration Statement under this Agreement or otherwise.

2.7. Information. The Investors shall furnish to the Company such information regarding the Investors and the distribution proposed by the Investors as the Company may reasonably request and as shall be reasonably required in connection with any registration referred to in this Agreement. The Investors agree to, as promptly as practicable (and in any event prior to any sales made pursuant to a prospectus), furnish to the Company all information required to be disclosed in order to make the information previously furnished to the Company by the Investors not misleading or to correct an untrue statement. The Investors agree to keep confidential the receipt of any notice received pursuant to Section 2.4(e) and the contents thereof, except as required pursuant to applicable law. Notwithstanding anything to the contrary herein, the Company shall be under no obligation to name the Investors in any Registration Statement or include such Investors' Registrable Securities if the Investors have not provided the information required by this Section 2.7 with respect to the Investors as a selling securityholder in such Registration Statement or any related prospectus.

2.8. Rule 144 Requirements. With a view to making available to the Investors the benefits of Rule 144 and any other rule or regulation of the Commission that may at any time permit the Investors to sell Registrable Securities to the public without registration, the Company agrees to use its reasonable best efforts to:

(a) make and keep public information available, as those terms are understood and defined in Rule 144 at all times after the date hereof;

(b) file with the Commission in a timely manner all reports and other documents required of the Company under the Securities Act and the Exchange Act;

(c) prior to the filing of the Registration Statement or any amendment thereto (whether pre-effective or post-effective), and prior to the filing of any prospectus or prospectus supplement related thereto, to provide the Investors with copies of all of the pages thereof (if any) that reference the Investors; and

(d) furnish to any Investor, so long as the Investor owns any Registrable Securities, forthwith upon request (i) a written statement by the Company that it has complied with the reporting requirements of Rule 144, (ii) a copy of the most recent annual or quarterly report of the Company and such other reports and documents so filed by the Company, and (iii) such other information as may be reasonably requested by an Investor in availing itself of any rule or regulation of the Commission which permits an Investor to sell any such securities without registration.

2.9. Limitations on Subsequent Registration Rights. From and after the date of this Agreement, the Company shall not, without prior written consent of the Investors, enter into any agreement with any holder or prospective holder of any securities of the Company which would provide to

such holder rights with respect to the registration of such securities under the Securities Act or the Exchange Act that would conflict with or adversely affect any of the rights provided to the Investors in this Section 2 (such rights, the "Investor Registration Rights"); it being understood and agreed that any subsequent agreement of the Company with any holder or prospective holder of any securities of the Company of the same class (or convertible into or exchangeable for securities of the same class) as the Registrable Securities granting such Person rights with respect to registration of any securities of the Company under the Securities Act or the Exchange Act (such rights, "Third-Person Registration Rights"), including, without limitation, rights substantially equivalent to the Investor Registration Rights, shall not be deemed to conflict with or adversely affect any of the Investor Registration Rights if the Third-Person Registration Rights provide that, in the event the total number of securities (including Registrable Securities) requested to be included in a firm-commitment underwritten offering pursuant to a registration statement (a "Firm-Commitment Offering") pursuant to Third-Person Registration Rights and/or Investor Registration Rights exceeds the number of securities to be sold that the applicable underwriters in their reasonable discretion determine is compatible with the success of the Firm-Commitment Offering, the securities (including the Registrable Securities) that are included in such Firm-Commitment Offering shall be allocated among all the selling holders thereof (including, if applicable, the Investors) in proportion (as nearly as practicable) to the number of securities of the type owned by each selling holder (including, if applicable, the Investors) or in such other proportions as shall mutually be agreed to by all such selling holders.

Section 3.
Miscellaneous

3.1. Amendment. No amendment, alteration or modification of any of the provisions of this Agreement shall be binding unless made in writing and signed by each of the Company and the Investors.

3.2. Injunctive Relief. It is hereby agreed and acknowledged that it shall be impossible to measure in money the damages that would be suffered if the parties fail to comply with any of the obligations herein imposed on them and that in the event of any such failure, an aggrieved Person shall be irreparably damaged and shall not have an adequate remedy at law. Any such Person shall, therefore, be entitled (in addition to any other remedy to which it may be entitled in law or in equity) to injunctive relief, including, without limitation, specific performance, to enforce such obligations, and if any action should be brought in equity to enforce any of the provisions of this Agreement, none of the parties hereto shall raise the defense that there is an adequate remedy at law.

3.3. Notices. All notices required or permitted under this Agreement must be in writing and sent to the address or facsimile number identified below. Notices must be given: (a) by personal delivery, with receipt acknowledged; (b) by electronic mail followed by hard copy delivered by the methods under clause (c) or (d); (c) by prepaid certified or registered mail, return receipt requested; or (d) by prepaid reputable overnight delivery service. Notices shall be effective upon receipt. Either party may change its notice address by providing the other party written notice of such change. Notices shall be delivered as follows:

If to the Investors:

Baker Brothers Investments
860 Washington St., 3rd Floor
New York, NY 10014
Attention: Scott Lessing, President
Email:

If to the Company:

Acadia Pharmaceuticals Inc.
12830 El Camino Real, Suite 400
San Diego, CA, 92130
Attention: Chief Legal Officer
E-mail:

with a copy to:

Cooley LLP
Attention: Carlos Ramirez
E-mail:

3.4. Governing Law; Jurisdiction; Venue; Jury Trial.

(a) This Agreement shall be governed by, and construed in accordance with, the law of the State of New York without giving effect to any choice or conflict of law provision or rule (whether of the State of New York or any other jurisdiction) that would cause the application of the laws of any jurisdiction other than the State of New York.

(b) Each of the Company and the Investors irrevocably and unconditionally submits, for itself and its property, to the nonexclusive jurisdiction of the courts of the State of New York sitting in the Borough of Manhattan, New York and of the United States District Court of the Southern District of New York, and any appellate court from any thereof, in any action or proceeding arising out of or relating to this Agreement and the transactions contemplated herein, or for recognition or enforcement of any judgment, and each of the Company and the Investors irrevocably and unconditionally agrees that all claims in respect of any such action or proceeding may be heard and determined in such New York state court or, to the fullest extent permitted by applicable law, in such federal court. Each of the Company and the Investors hereto agrees that a final judgment in any such action or proceeding shall be conclusive and may be enforced in other jurisdictions by suit on the judgment or in any other manner provided by law.

(c) Each of the Company and the Investors irrevocably and unconditionally waives, to the fullest extent permitted by applicable law, any objection that it may now or hereafter have to the laying of venue of any action or proceeding arising out of or relating to this Agreement and the transactions contemplated herein in any court referred to in Section 3.4(b) hereof. Each of the Company and the Investors hereby irrevocably waives, to the fullest extent permitted by applicable

law, the defense of an inconvenient forum to the maintenance of such action or proceeding in any such court.

(d) EACH OF THE COMPANY AND THE INVESTORS HEREBY IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY RIGHT IT MAY HAVE TO A TRIAL BY JURY IN ANY LEGAL PROCEEDING DIRECTLY OR INDIRECTLY ARISING OUT OF OR RELATING TO THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY (WHETHER BASED ON CONTRACT, TORT OR ANY OTHER THEORY). EACH OF THE COMPANY AND THE INVESTORS (A) CERTIFIES THAT NO REPRESENTATIVE, AGENT OR ATTORNEY OF ANY OTHER PERSON HAS REPRESENTED, EXPRESSLY OR OTHERWISE, THAT SUCH OTHER PERSON WOULD NOT, IN THE EVENT OF LITIGATION, SEEK TO ENFORCE THE FOREGOING WAIVER AND (B) ACKNOWLEDGES THAT EACH OF THE COMPANY AND THE INVESTORS HAS BEEN INDUCED TO ENTER INTO THIS AGREEMENT BY, AMONG OTHER THINGS, THE MUTUAL WAIVERS AND CERTIFICATIONS IN THIS SECTION.

3.5. Successors, Assigns and Transferees. Any and all rights, duties and obligations hereunder shall not be assigned, transferred, delegated or sublicensed by any party hereto without the prior written consent of the other party; provided, however, that the Investors shall be entitled to transfer Registrable Securities to one or more of their affiliates and, solely in connection therewith, may assign their rights hereunder in respect of such transferred Registrable Securities, in each case, so long as such Investor is not relieved of any liability or obligations hereunder, without the prior consent of the Company; and provided further, that the Company shall be entitled to assign, transfer, delegate or sublicense its rights or obligations under this Agreement without the consent of the Investors in the event of a Permitted Acquisition (as defined below). Any transfer or assignment made other than as provided in the first sentence of this Section 3.5 shall be null and void. Subject to the foregoing and except as otherwise provided herein, the provisions of this Agreement shall inure to the benefit of, and be binding upon, the successors, permitted assigns, heirs, executors and administrators of the parties hereto. The Company shall not consummate any recapitalization, merger, consolidation, reorganization or other similar transaction whereby stockholders of the Company receive (either directly, through an exchange, via dividend from the Company or otherwise) equity (the "Other Equity") in any other entity (the "Other Entity") with respect to Registrable Securities hereunder, unless such Other Entity shall have assumed the assigned obligations of this Agreement or provided reasonable assurances to the Investors that, by virtue of such transaction, the Other Entity will be deemed to have assumed the obligations of the Company hereunder, the term "Company" shall be deemed to refer to such Other Entity and the term "Registrable Securities" shall be deemed to include the Other Equity. In the event of such recapitalization, merger, consolidation, reorganization or other similar transaction, if the Other Equity is otherwise freely tradable by the Investors after giving effect to such transaction, such transaction will be deemed a "Permitted Acquisition."

3.6. Entire Agreement. This Agreement, together with any exhibits hereto, constitute the entire agreement between the parties relating to the subject matter hereof and all previous agreements or arrangements between the parties, written or oral, relating to the subject matter hereof are superseded.

3.7. Waiver. No failure on the part of either party hereto to exercise any power, right, privilege or remedy under this Agreement, and no delay on the part of either party hereto in exercising any power, right, privilege or remedy under this Agreement, shall operate as a waiver thereof; and no single or partial exercise of any such power, right, privilege or remedy shall preclude any other or further exercise thereof or of any other power, right, privilege or remedy.

3.8. Severability. If any part of this Agreement is declared invalid or unenforceable by any court of competent jurisdiction, such declaration shall not affect the remainder of the Agreement and the invalidated provision shall be revised in a manner that shall render such provision valid while preserving the parties' original intent to the maximum extent possible.

3.9. Titles and Subtitles. The titles and subtitles used in this Agreement are used for convenience only and are not to be considered in construing or interpreting this Agreement. All references in this Agreement to sections, paragraphs and exhibits shall, unless otherwise provided, refer to sections and paragraphs hereof and exhibits attached hereto.

3.10. Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be enforceable against the parties that execute such counterparts (including by facsimile or other electronic means), and all of which together shall constitute one instrument.

3.11. Term and Termination. The Investors' rights to demand the registration of the Registrable Securities under this Agreement, as well as the Company's obligations under Section 2.1 hereof, shall terminate automatically once all Registrable Securities cease to be Registrable Securities pursuant to the terms of this Agreement.

[*Remainder of Page Intentionally Left Blank; Signature Page Follows*]

IN WITNESS WHEREOF, the parties hereto have executed this Registration Rights Agreement effective as of the day, month and year first above written.

COMPANY:

ACADIA PHARMACEUTICALS INC.

By: /s/ Catherine Owen Adams
Name: Catherine Owen Adams
Title: Chief Executive Officer

[Signature Page to Registration Rights Agreement]

IN WITNESS WHEREOF, the parties hereto have executed this Registration Rights Agreement effective as of the day, month and year first above written.

INVESTORS:

667, L.P.

By: BAKER BROS. ADVISORS LP, management company and investment adviser to 667, L.P., pursuant to authority granted to it by Baker Biotech Capital, L.P., general partner to 667, L.P., and not as the general partner

By: /s/ Scott L. Lessing
Scott L. Lessing
President

BAKER BROTHERS LIFE SCIENCES, L.P.

By: BAKER BROS. ADVISORS LP, management company and investment adviser to BAKER BROTHERS LIFE SCIENCES, L.P., pursuant to authority granted to it by Baker Brothers Life Sciences Capital, L.P., general partner to BAKER BROTHERS LIFE SCIENCES, L.P., and not as the general partner

By: /s/ Scott L. Lessing
Scott L. Lessing
President

Schedule A

The Investors

667, L.P.
BAKER BROTHERS LIFE SCIENCES, L.P.

To the above Investors:
Baker Brothers Investments
860 Washington Street
New York, NY 10014
Attn: Scott Lessing
Email:

Exhibit 10.52

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

COMMERCIAL SUPPLY AGREEMENT

This Commercial Supply Agreement is made as of this 22nd day of February, 2018 (the "**Effective Date**"), by and between ACADIA Pharmaceuticals Inc., a Delaware corporation, with a place of business at 3611 Valley Centre Drive, Suite 300, San Diego, California 92130 **(**"**Client**"), and Catalent Pharma Solutions, LLC, a Delaware limited liability company, having a place of business at 14 Schoolhouse Road, Somerset, New Jersey 08873, USA **(**"**Catalent**").

RECITALS

A. Client develops, markets and sells pharmaceutical products;

B. Catalent is a leading provider of advanced technologies, and development, manufacturing and packaging services, for pharmaceutical, biotechnology and consumer healthcare companies;

C. Client desires to have Catalent provide the services set forth in this Agreement (as defined below) in connection with Client's Product (as defined below), and Catalent desires to provide such services, all pursuant to the terms and conditions in this Agreement.

THEREFORE, in consideration of the circumstances described above and the mutual covenants, terms and conditions set forth below, the parties agree as follows:

ARTICLE 1
DEFINITIONS

The following terms have the following meanings in this Agreement:

1.1 "**Acknowledgement**" has the meaning set forth in Section 4.3(B).

1.2 "**Affiliate(s)**" means, with respect to Client or any third party, any corporation, firm, partnership or other entity that controls, is controlled by or is under common control with such entity; and with respect to Catalent, Catalent, Inc. and any corporation, firm, partnership or other entity controlled by it. For the purposes of this definition, "**control**" means the ownership of at least 50% of the voting share capital of an entity or any other comparable equity or ownership interest.

1.3 "**Agreement**" means this document, including all its Attachments and other appendices (all of which are incorporated by reference) and any amendment to any of the foregoing made in accordance with Section 18.1.

1.4 "**API**" means the generic compound Pimavanserin as further described in the Specifications.

1.5 "**Applicable Laws**" means, with respect to Client all laws, ordinances, rules and regulations, currently in effect or enacted or promulgated during the Term, and as amended from time to time, of each jurisdiction in the Territory in which API or Product is produced, marketed, distributed, used or sold; and with respect to Catalent, all laws, ordinances, rules and regulations, currently in effect or enacted or promulgated during the Term, and as amended from time to time, (a) of the jurisdiction in which Catalent Processes Product and (b) with respect to the Processing of Product only under this Agreement (e.g. not with respect to employment or other general business matters), in the Territory, in each case including cGMP.

1.6 "**Batch**" means a defined quantity of Product that has been or is being Processed in accordance with the Specifications.

1.7 "**Catalent**" has the meaning set forth in the introductory paragraph, or any successor or permitted assign.

1.8 "**Catalent Cause**" has the meaning set forth in Section 5.2.

1.9 "**Catalent Indemnitees**" has the meaning set forth in Section 13.2.

1.10 "**Catalent IP**" has the meaning set forth in Article 11.

1.11 "**Catalent Inventions**" has the meaning set forth in Article 11.

1.12 "**cGMP**" means current Good Manufacturing Practices promulgated by the Regulatory Authorities in the jurisdictions included in Applicable Laws (as applicable to Client and Catalent respectively). In the United States, this includes 21 C.F.R. Parts 210 and 211, as amended; and in the European Union, this includes 2003/94/EEC Directive (as supplemented by Volume 4 of EudraLex published by the European Commission), as amended, if and as implemented in the relevant constituent country.

1.13 "**Client**" has the meaning set forth in the introductory paragraph, or any successor or permitted assign.

1.14 "**Client Indemnitees**" has the meaning set forth in Section 13.1.

1.15 "**Client Inventions**" has the meaning set forth in Article 11.

1.16 "**Client IP**" has the meaning set forth in Article 11.

1.17 "**Client-supplied Materials**" means any materials to be supplied by or on behalf of Client to Catalent for Processing, as described in Attachment B, which is limited to API and reference standards unless agreed in writing by the parties.

1.18 "**Commencement Date**" means the first date upon which a Regulatory Authority in the Territory approves Catalent as a manufacturer of Product.

1.19 "**Confidential Information**" has the meaning set forth in Section 10.1.

1.20 "**Contract Year**" means the consecutive twelve (12)-month period beginning on the Commencement Date or any anniversary of the Commencement Date during the Term, as applicable.

1.21 "**Defective Product**" has the meaning set forth in Section 5.2.

1.22 "**Discloser**" has the meaning set forth in Section 10.1.

1.23 "**Effective Date**" has the meaning set forth in the introductory paragraph.

1.24 "**EMA**" means the European Medicines Agency, and any successor agency in the European Union.

1.25 "**European Union**" means the European Union and its member states as of the Effective Date, which are: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxemburg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and the United Kingdom, and each of their constituent parts, territories and possessions and their successors to the extent such successors occupy the same territory, regardless of whether any of such countries ceases to be a member state after the Effective Date.

1.26 "**Exception Notice**" has the meaning set forth in Section 5.2.

1.27 "**Facility**" means Catalent's facility located in Somerset, New Jersey or such other facility as agreed by the parties in writing.

1.28 "**FDA**" means the United States Food and Drug Administration, and any successor agency in the United States.

1.29 "**Firm Commitment**" has the meaning set forth in Section 4.2.

1.30 "**Intellectual Property**" means all patents, patent applications, know-how, trade secrets, copyrights, trademarks, designs, concepts, technical information, manuals, standard operating procedures, instructions, specifications, processes, data, inventions and other forms of intellectual property (whether or not patented or patentable).

1.31 "**Invention**" has the meaning set forth in Article 11.

1.32 "**Latent Defect**" means a defect in a Product that (a) was not discoverable upon reasonable inspection during the Review Period, and (b) Client provides Catalent written notice of within no more than [***] after delivery of such Product.

1.33 "**Losses**" has the meaning set forth in Section 13.1.

1.34 "**Minimum Commitment**" has the meaning set forth in Section 4.1.

1.35 "**PPI**" has the meaning set forth in Section 7.2.

1.36 "**Process**" or "**Processing**" means the compounding, filling, encapsulating, producing and bulk packaging (but not secondary packaging) of Client-supplied Materials and Raw Materials into Product by Catalent, in accordance with the Specifications and under the terms of this Agreement.

1.37 "**Processing Date**" means the day on which the first step of physical Processing is scheduled to occur, as identified in an Acknowledgement.

1.38 "**Product**" means the bulk pharmaceutical product comprising the 34 mg capsule containing the API, as more specifically described in the Specifications.

1.39 "**Product Maintenance Services**" has the meaning set forth in Section 2.3.

1.40 "**Purchase Order**" has the meaning set forth in Section 4.3(A).

1.41 "**Quality Agreement**" has the meaning set forth in Section 9.6.

1.42 "**Raw Materials**" means all raw materials, supplies, components and packaging necessary to Process and ship Product in accordance with the Specifications, but excluding Client-supplied Materials.

1.43 "**Recall**" has the meaning set forth in Section 9.5.

1.44 "**Recipient**" has the meaning set forth in Section 10.1.

1.45 "**Regulatory Approval**" means each approval, permit, product and/or establishment license, registration or authorization, including each approval pursuant to U.S. Investigational New Drug Applications, New Drug Applications and Abbreviated New Drug Applications (or equivalent non-U.S. filings, such as European marketing authorization applications), as applicable, of a Regulatory Authority that is necessary or advisable in connection with the development, manufacture, testing, use, storage, exportation, importation, transport, promotion, marketing, distribution or sale of API or Product in the Territory.

1.46 "**Regulatory Authority**" means an international, federal, state or local governmental or regulatory body, agency, department, bureau, court or other entity in the Territory that is responsible for (A) the regulation (including pricing) of any aspect of pharmaceutical or medicinal products intended for human use or (B) health, safety or environmental matters generally. In the United States, this includes the FDA; and in the European Union, this includes the EMA.

1.47 "**Representatives**" of an entity means such entity's duly authorized officers, directors, employees, agents, accountants, attorneys or other professional advisors.

1.48 "**Retained Liability**" has the meaning set forth in Section 14.1(A).

1.49 "**Review Period**" has the meaning set forth in Section 5.2.

1.50 "**Rolling Forecast**" has the meaning set forth in Section 4.2.

1.51 "**Safety Stock**" has the meaning set forth in Section 3.2(A).

1.52 "**Specifications**" means the procedures, requirements, standards, quality control testing and other data and the scope of services as set forth in Attachment B, as modified from time to time in accordance with Article 8.

1.53 "**Term**" has the meaning set forth in Section 16.1.

1.54 "**Territory**" means [***].

1.55 "**Unit**" means one capsule of Product.

1.56 "**United States**" means the United States of America and its territories and possessions.

1.57 "**Unit Pricing**" has the meaning set forth in Section 7.1(B).

1.58 "**Validation Services**" has the meaning set forth in Section 2.1.

1.59 "**Vendor**" has the meaning set forth in Section 3.2(B).

ARTICLE 2
VALIDATION, PROCESSING & RELATED SERVICES

2.1 Validation Services. Catalent shall perform the Product qualification, validation and stability services described in Attachment A (the "**Validation Services**") in accordance with the Specifications, Applicable Laws and the terms and conditions of this Agreement.

2.2 Supply and Purchase of Product. Catalent shall Process Product in accordance with the Specifications, Applicable Laws and the terms and conditions of this Agreement.

2.3 Product Maintenance Services. Catalent shall provide and Client will receive those product maintenance services specified in Attachment D (the "**Product Maintenance Services**") in accordance with the Specifications, Applicable Laws and the terms and conditions of this Agreement.

2.4 Other Related Services. Catalent shall provide Product-related services, other than Validation Services, Processing or Product Maintenance Services, as agreed in writing by the parties from time to time. Such writing shall include the scope and fees for any such service and be appended to this Agreement. The terms and conditions of this Agreement shall govern and apply to such services unless otherwise agreed in writing by the parties.

2.5 Affiliates. Catalent shall have the right to cause any of its Affiliates to perform any of its obligations hereunder, and Client shall accept such performance as if it were performance by Catalent; provided that Catalent shall notify Client in advance of performance of Catalent's obligations by any of its Affiliates and shall remain directly responsible to Client for the performance of such obligations to the same extent it would if it had performed such obligations itself, and in no event shall such performance occur at a facility other than the Facility unless agreed in advance in writing by Client.

ARTICLE 3
MATERIALS

3.1 Client-supplied Materials.

A. Client shall supply to Catalent for Processing, at Client's cost, Client-supplied Materials in quantities sufficient to meet Client's requirements for Product. Client shall deliver such items and associated certificates of analysis to the Facility no later than [***] days (but not earlier than [***] days) before the scheduled delivery date. Client shall be responsible at its expense for securing any necessary DEA, export, import or other governmental clearance, permit or certification required in respect of such supply of Client-supplied Materials. Catalent shall use Client-supplied Materials solely for Processing. Prior to delivery of any Client-supplied Materials, Client shall provide to Catalent a copy of all associated material safety data sheets, safe handling instructions and health and environmental information and any governmental certification or authorization that may be required under Applicable Laws relating to the API and Product, and thereafter shall provide promptly any update thereto.

B. Catalent shall inspect all Client-supplied Materials received to verify their identity. Unless otherwise expressly required by the Specifications, Catalent shall have no obligation to test Client-supplied Materials it receives to confirm that they meet the associated specifications, certificate of analysis or otherwise; but in the event that Catalent detects a nonconformity with the Specifications, Catalent shall give Client prompt notice of such nonconformity. Catalent shall not be liable for any defect in Client-supplied Materials, or in Product as a result of defective Client-supplied Materials, unless Catalent did not perform the foregoing obligations in accordance with the Specifications. Catalent shall follow Client's reasonable written instructions in respect of return or disposal of defective Client-supplied Materials, at Client's cost.

C. Client shall retain title to Client-supplied Materials at all times and shall bear the risk of loss of any such Client-supplied Materials; provided that Catalent shall be responsible for losses resulting from its gross negligence or willful misconduct subject to the limitations on liability for Client-supplied Materials as set forth in Article 14.

3.2 Raw Materials.

A. Catalent shall be responsible for procuring, inspecting and releasing adequate Raw Materials as necessary to meet the Firm Commitment, unless otherwise agreed by the parties in writing, and, without limiting the foregoing, shall order and hold sufficient capsules and such other Raw Materials as may be agreed by the parties (collectively, the "**Safety Stock**"). Catalent shall not be liable for any delay in delivery of Product if (i) Catalent is unable to obtain, in a timely manner, a particular Raw Material necessary for Processing and (ii) Catalent placed orders for such Raw Materials promptly following receipt of Client's Firm Commitment. In the event that any Raw Material becomes subject to purchase lead time beyond the Firm Commitment time frame, the parties will negotiate in good faith an appropriate amendment to this Agreement, including Section 4.2. Client shall bear the risk of loss of such Safety Stock in accordance with Section 3.2(C) as long as Catalent has ordered such Safety Stock in accordance with the Rolling Forecast.

B. If Client requires a specific supplier, manufacturer or vendor **(**"**Vendor**") to be used for Raw Material, then (i) such Vendor will be identified in the Specifications and (ii) the Raw Materials from such Vendor shall be deemed Client-supplied Materials for purposes of the other Sections of this Agreement. If the cost of the Raw Material from any such Vendor is greater than

Catalent's costs for the same raw material of equal quality from other vendors, Catalent shall add the difference between Catalent's cost of the Raw Material and the Vendor's cost of the Raw Material to the Unit Pricing, unless Client directly pays the Vendor the cost thereof. Client will be responsible for all costs associated with qualification of any such Vendor that has not been previously qualified by Catalent.

C. In the event of (i) a Specification change for any reason, (ii) obsolescence of any Raw Material or (iii) termination or expiration of this Agreement, Client shall bear the cost of any Raw Materials (including packaging) unusable for Processing or Product and unused by Catalent for another customer, so long as Catalent purchased such Raw Materials in quantities consistent with Client's most recent Firm Commitment and the vendor's minimum purchase obligations, and at Client's election, Catalent shall promptly ship such unused Raw Materials to Client at Client's cost.

3.3 Artwork and Labeling. Client shall provide or approve, prior to the procurement of applicable Raw Material, all artwork, advertising and labeling information necessary for Processing, if any. Such artwork, advertising and labeling information is and shall remain the exclusive property of Client, and Client shall be solely responsible for the content thereof. Such artwork, advertising and labeling information or any reproduction thereof may not be used by Catalent in any manner other than performing its obligations hereunder without Client's written consent.

3.4 API Yield.

A. Catalent will give Client a quarterly inventory report of the API held by Catalent within [***] business days of the end of the most recent [***]-month period in a Contract Year which contains the following information for such period: (a) quantity of API conforming to specifications that is received at the Facility ("Quantity Received"), (b) quantity of API dispensed in Processing Product at the Facility calculated by adding the Quantity Received to the inventory of API that complies with the specifications and is held by Catalent at the beginning of the applicable period, less the inventory of API that complies with the specifications and is held by Catalent at the end of the period ("Quantity Dispensed"), and (c) the total amount of API contained in the Product manufactured with the Quantity Dispensed delivered by Catalent and not rejected, recalled or returned due to Catalent Cause as defined below ("Quantity Converted").

B. Within [***] days after the end of each Contract Year, Catalent will prepare an annual reconciliation of API that sets out the "Actual Annual Yield" or "AAY" for the Product at the Facility during the Contract Year. AAY is the percentage of the Quantity Dispensed that was converted to Product and is calculated as follows: Quantity Converted in Contract Year/Quantity Dispensed during Contract Year * 100. The parties agree that the target AAY will be determined as follows:

i. Initial Target Yield - will be the actual yield of the initial pre-validation and validation batches of Product that is Processed for Client and calculated as follows: Quantity Converted in the initial pre-validation and validation batches /Quantity Dispensed in the initial pre-validation and validation batches * 100 (the "Initial Target Yield"). The Initial Target Yield will be

in effect until there is enough campaign experience to calculate an Adjusted Target Yield as defined below.

ii. Adjusted Target Yield - will be the actual average yield of the initial [***] commercial batches of Product that is Processed for Client and calculated as follows: average Quantity Converted in the first [***] post validation batches /average Quantity Dispensed in the first [***] post validation [***] batches* 100 (the "Adjusted Target Yield").

iii. Without limiting Client's other rights or remedies, if AAY falls more than [***] percent ([***]%) below the Initial or Adjusted Target Yield in a Contract Year in which Client Processes as least [***] batches of Product for Client, then within [***] days after the end of the applicable Contract Year, Catalent will credit to Client's account the amount of the shortfall, calculated as follows: [(Initial or Adjusted Target Yield – [***]%) – AAY] * API cost * Quantity Dispensed.

C. Catalent's liability for API calculated in accordance with this Section 3.4 will be subject to the limits on Catalent's liability set forth in Section 14.2.

ARTICLE 4
MINIMUM COMMITMENT, PURCHASE ORDERS & FORECASTS

4.1 Minimum Commitment. During each Contract Year, Client shall spend the minimum amount of [***] million U.S. dollars (US$[***]) on the purchase of Product pursuant to this Agreement (the "**Minimum Commitment**")**.** For purposes of the Minimum Commitment, the amount spent in a Contract Year shall be based on the amount owed under Purchase Orders placed for Product with a requested delivery date in the applicable Contract Year, as long as such requested delivery dates are made pursuant to Sections 4.2 and 4.3 below. The cost of the validation Batches and any Batches that are Processed in preparation for Product launch prior to the Commencement Date shall be included for purposes of the Minimum Commitment in the first Contract Year. If Client does not spend at least the Minimum Commitment on the purchase of Product during any Contract Year, then within [***] days after the end of such Contract Year, Client shall pay Catalent the difference between (A) the Minimum Commitment and (B) the sum of the amount paid with respect to all purchases of Product from Catalent during such Contract Year. In addition, Client agrees that Catalent shall be the supplier in the Territory for no less than [***] percent ([***]%) of Client's total commercial requirements of Product (expressly excluding any supplies for clinical or other non-commercial purposes) in the Territory for each Contract Year during the Term. Notwithstanding the foregoing, in the event of a Supply Failure as defined below, the Minimum Commitment shall be adjusted pursuant to Section 5.6 below. For clarity and without limiting Client's other rights or remedies, in the event Catalent breaches its obligations with respect to delivery of Product under this Agreement, and Client obtains Product from an alternate source, the Minimum Commitment for such Contract Year shall be adjusted downward accordingly consistent with the amount Client would have had to pay Catalent for such Product, and the amount of such Product from such alternate source shall be excluded from the calculation of the percentage of Client's total commercial requirements of Product purchased from Catalent as described above.

4.2 Forecast. On or before the [***] day of each calendar month, beginning at least [***] months prior to the anticipated Commencement Date, Client shall furnish to Catalent a written [***] month rolling forecast of the quantities of Product that Client intends to order from Catalent during such [***] month period (the "**Rolling Forecast**"). The first [***] months of each Rolling Forecast shall constitute a binding order for the quantities of Product specified in such Rolling Forecast (the "**Firm Commitment**") and the following [***] months of the Rolling Forecast shall be non-binding, good-faith estimates. Client shall purchase and Catalent shall supply to Client all quantities of Product set forth in the Firm Commitment in accordance with this Agreement.

4.3 Purchase Orders.

A. From time to time as provided in this Section 4.3(A), Client shall submit to Catalent a binding, non-cancelable purchase order for Product specifying the number of Batches to be Processed, the Batch size (to the extent the Specifications permit Batches of different sizes) and the requested delivery date for each Batch (each, a "**Purchase Order**"). Concurrently with the submission of each Rolling Forecast, Client shall submit a Purchase Order for the Firm Commitment. Purchase Orders for quantities of Product in excess of the Firm Commitment shall be submitted by Client at least [***] days in advance of the delivery date requested in the Purchase Order.

B. Promptly (and in any event within [***] days) following receipt of a Purchase Order, Catalent shall issue a written acknowledgement (each, an "**Acknowledgement**") that it accepts or rejects such Purchase Order. Each acceptance Acknowledgement shall either confirm the delivery date set forth in the Purchase Order or set forth a reasonable alternative delivery date, as agreed in advance with Client. Catalent may reject any Purchase Order in excess of the Firm Commitment or otherwise not given in accordance with this Agreement.

C. Notwithstanding Section 4.3(B), Catalent shall accept Purchase Orders for quantities specified in the Firm Commitment, and shall use [***] to supply Client with quantities of Product set forth in a Purchase Order which are up to [***] percent ([***]%) (rounded up to the nearest whole Batch) in excess of the quantities specified in the Firm Commitment subject to Catalent's other supply commitments and manufacturing, packaging and equipment capacity.

D. In the event of a conflict between the terms of any Purchase Order or Acknowledgement and this Agreement, the terms of this Agreement shall control.

4.4 Catalent's Cancellation of Purchase Orders. Notwithstanding anything in Section 4.3 and Section 4.5 to the contrary, Catalent reserves the right to cancel all, or any part of, a Purchase Order upon written notice to Client, and Catalent shall have no further obligation or liability with respect to such Purchase Order to the extent Client refuses or fails to supply conforming Client-supplied Materials in accordance with Section 3.1 that is necessary in order for Catalent to manufacture a complete Batch of Product for such Purchase Order. Any cancellation of Purchase Orders in accordance with this Section 4.4 shall not constitute a breach of this Agreement by Catalent nor shall it absolve Client of its obligation in respect of the Minimum Commitment.

4.5 Client's Modification or Cancellation of Purchase Orders.

A. Client may modify the delivery date or quantity of Product in a Purchase Order only by submitting a written change order to Catalent at least [***] days in advance of

the earliest delivery date (which period shall be reduced to [***] days for delivery dates/quantities scheduled for delivery in the first [***] months after the Commencement Date) covered by such change order, or on such other timeline or other quantity as may be mutually agreed by the Parties. Such change order shall be effective and binding against Catalent only upon the written approval of Catalent, and, notwithstanding any such written approval, Client shall remain responsible for the Firm Commitment.

B. Notwithstanding any amount due to Catalent under Section 4.1, if Client fails to place Purchase Orders sufficient to satisfy the Firm Commitment, Client shall pay to Catalent in accordance with Article 7 the Unit Pricing for all Units that would have been Processed if Client had placed Purchase Orders sufficient to satisfy the Firm Commitment. Any amounts paid by Client pursuant to this Section 4.5(B) shall be counted toward the Minimum Commitment for the applicable Contract Year.

C. Neither changes to nor postponement of any Batch of Product, nor the payment of the fees described in this Section 4.5, will reduce or in any way affect the Minimum Commitment obligations set forth in Section 4.1.

4.6 Unplanned Delay of Processing. Catalent shall provide Client with as much advance notice as practicable prior to the scheduled date of Processing if Catalent determines that any Processing will be delayed for any reason.

4.7 Observation of Processing. In addition to Client's audit right pursuant to Section 9.4, Client may send up to [***] Representatives to the Facility to observe Processing for a maximum of [***] days per Contract Year (unless otherwise agreed by Catalent in writing), upon at least [***] days' prior notice, at reasonable times during regular business hours. Such Representatives shall abide by all Catalent safety rules and other applicable employee policies and procedures, and Client shall be responsible for such compliance. Client shall indemnify and hold harmless Catalent for any action, omission or other activity of its Representatives while on Catalent's premises. Client's Representatives who are not employees of Client shall be required to sign Catalent's standard visitor confidentiality agreement prior to being allowed access to the Facility.

ARTICLE 5
TESTING; RELEASE

5.1 Batch Records and Data; Release. Unless otherwise agreed to by the parties in writing, after Catalent completes Processing of a Batch, Catalent shall provide Client with copies of Batch records prepared in accordance with the Specifications; *provided,* that if testing reveals an out-of-Specification result, Catalent shall provide such Batch records promptly following resolution of the out-of-Specification result. After Catalent completes Processing of a Batch, Catalent shall also provide Client or its designee with Catalent's certificate of analysis for such Batch. Issuance of a certificate of conformance/analysis by Catalent constitutes release of the Batch by Catalent to Client. Client shall be responsible for final release of Product (including testing, at its cost) to the market.

5.2 Testing; Rejection. No later than [***] days after Client's or its designee's receipt of the Batch and the certificate of conformance/analysis **(**"**Review Period**"), Client shall notify Catalent whether the Batch conforms to the Specifications and meets cGMP (for purposes of this Article 5, "conformity/conform(s) to Specifications"). Upon receipt of notice from Client that a Batch conforms to the Specifications, or upon failure of Client to provide any written notice to Catalent by the end of the Review Period subject to Section **Error! Reference source not found.,** the Batch shall be deemed accepted by Client and Client shall have no right to reject such Batch, except in the case of a Latent Defect that causes a Batch to fail to conform to the Specifications. If Client timely notifies Catalent in writing by the end of the Review Period or the later period set forth in the definition of Latent Defect with respect to any Latent Defect (an "**Exception Notice**") that a Batch does not conform to the Specifications **(**"**Defective Product**"), and provides a sample of the alleged Defective Product, then Catalent shall promptly conduct an appropriate investigation in its discretion to determine whether Catalent agrees with Client that Product is Defective Product and to determine the cause of any nonconformity. Catalent shall provide written notice to Client as promptly as reasonably possible, but in any event within [***] days after completing its internal investigation, and in any event no later than [***] days after date of the Exception Notice, whether Catalent agrees that Product is Defective Product. If Catalent agrees that Product is Defective Product and determines that the cause of nonconformity is attributable to Catalent's negligence or willful misconduct (a "**Catalent Cause**"), or if Catalent fails to timely provide written notice to Client that (a) it disagrees with Client's position that Product is Defective Product or (b) it disagrees with Client's position that the cause of nonconformity is a Catalent Cause, then Section 5.4 shall apply. Catalent will work in good faith with Client to identify the cause of nonconformity in the case that Client provides notice of Defective Product after the Review Period (or after the period in the definition of Latent Defect with respect to any Latent Defect).

5.3 Discrepant Results. If the parties disagree as to whether Product is Defective Product and/or whether the cause of the nonconformity is a Catalent Cause, and such disagreement is not resolved within [***] days of the Exception Notice date, the parties shall cause a mutually acceptable independent third party to review records, test data and to perform comparative tests and/or analyses on samples of the alleged Defective Product and its components, including Client-supplied Materials. The independent party's results as to whether or not Product is Defective Product and the cause of any nonconformity shall be final and binding. For avoidance of doubt, where the cause of nonconformity cannot be determined or assigned, it shall be deemed not Catalent Cause. Unless otherwise agreed by the parties in writing, the costs associated with such testing and review shall be borne by Catalent, except that if the cause of Defective Product is not attributable to Catalent Cause then Client shall bear the costs associated with such testing and review.

5.4 Remedy for Defective Product. Catalent shall, at the option of Client, either (A) replace such Defective Product, at Catalent's cost (including, only in the case of a Catalent Cause, the cost of Client-supplied Materials used in such Product, subject to the limits of liability with regard to Client-supplied Materials in Article 14) with Product that conforms to the Specifications, or (B) if such replacement cannot be accomplished within [***] days from the later of (i) the date of Client's request or (ii) the date that Client-supplied Materials are made available to Process such replacement Product (if there are not sufficient amounts already available to Catalent), credit any payment made by Client for such rejected Batch (including, only in the case of a Catalent Cause, the cost of Client-supplied Materials used in such rejected Batch, subject to the limits of liability

with regard to Client-supplied Materials in Article 14). For the avoidance of doubt, Client shall be liable to pay for either the rejected Batch(es) or the replacement Batch(es), but not both; provided that if the Defective Product was not caused by a Catalent Cause then Client shall pay for both. THE OBLIGATION OF CATALENT TO REPLACE DEFECTIVE PRODUCT IN ACCORDANCE WITH THE SPECIFICATIONS OR CREDIT PAYMENTS MADE BY CLIENT FOR DEFECTIVE PRODUCT AND COSTS OF CLIENT-SUPPLIED MATERIALS AS PROVIDED IN THIS SECTION 5.4, SHALL BE CLIENT'S SOLE AND EXCLUSIVE REMEDY UNDER THIS AGREEMENT FOR CATALENT CAUSED DEFECTIVE PRODUCT AND IS IN LIEU OF ANY OTHER WARRANTY, EXPRESS OR IMPLIED.

5.5 Supply of Material for Defective Product. In the event Catalent replaces Defective Product pursuant to Section 5.4, Client shall supply, at Client's cost (except in the case of a Catalent Cause, subject to the limits of liability with regard to Client-supplied Materials in Article 14), Catalent with sufficient quantities of Client-supplied Materials in order for Catalent to complete such replacement.

5.6 Repeated Supply Failures. Without limiting Client's other rights or remedies in this Agreement, if Catalent is unable to deliver the quantities of Product ordered in a Purchase Order within [***] days of the scheduled delivery date, and/or delivers Product that does not conform to the Specifications due to Catalent Cause (each a "**Supply Failure**"), on [***] or more separate occasions within a [***]-month period, the percentage of Client's commercial requirements that it is obligated to purchase from Catalent for the Territory pursuant to Section 4.1 above shall be reduced from [***] percent ([***]%) to [***] percent ([***]%) and the Minimum Commitment shall be reduced from $[***] to $[***] (pro-rated for any partial Contract Year). In such case, such reduced percentage and Minimum Commitment shall apply until Catalent has no Supply Failures for a [***]-month period in which case the percentage and Minimum Commitment, respectively, shall revert to the amounts set forth in Section 4.1. Notwithstanding the foregoing, if Catalent has [***] or more Supply Failures within a [***]-month period, the parties will meet and agree on and implement a delivery improvement action plan within [***] business days. If, after the delivery improvement plan is in place, [***] additional Supply Failures occur within a [***]-month period, these Supply Failures may be considered a material breach of this Agreement by Client under Section 16.2(B) and Catalent will not be allowed any further opportunity to remedy the material breach. Notwithstanding the foregoing, a Supply Failure for purposes of this Section 5.6 will not include any delay in shipment of Product caused by events outside of Catalent's reasonable control, such as a force majeure event, a delay in delivery of API or other Client-supplied Materials, or receipt of non-conforming API or Client-supplied Materials.

ARTICLE 6
DELIVERY

6.1 Delivery. Catalent shall deliver [***] promptly following Catalent's release of Product and in accordance with Acknowledgments made in accordance with Section 4.3. Catalent shall segregate and store all Product until tender of delivery. To the extent not already held by Client, title to Product shall transfer to Client upon Catalent's tender of delivery. If Catalent provides storage services, title to such items shall pass to Client upon transfer to storage. Client shall be responsible for coordinating the use of a qualified carrier to ship Product. In the event Catalent arranges shipping or performs similar loading and/or logistics services for Client at Client's request, such services are performed by Catalent as a convenience to Client only and do not alter

the terms and limitations set forth in this Section 6.1. Catalent shall not be responsible for Product in transit, including any cost of insurance or transport fee for Product, or any risk associated with transit or customs delays, storage and handling.

6.2 Storage Fees. If Client fails to take delivery of any Product on any scheduled delivery date, Catalent shall store such Product and have the right to invoice Client monthly following such scheduled delivery for reasonable administration and storage fees.

ARTICLE 7
PAYMENTS

7.1 Fees. In consideration for Catalent performing services hereunder:

A. Client shall pay to Catalent the fees for Validation Services (including cost of validation Batches) set forth on Attachment A. Catalent shall submit an invoice to Client for such fees upon the completion of the relevant phase of the Validation Services.

B. Client shall pay Catalent the unit pricing for Product set forth on Attachment C (the "**Unit Pricing**"). Client shall pay the Unit Pricing that is in effect on the date of delivery pursuant to Section 6.1. Catalent shall submit an invoice to Client for such fees upon tender of delivery of Product as provided in Section 6.1.

C. Client shall pay Catalent the annual fees for Product Maintenance Services set forth on Attachment C. Catalent shall submit an invoice to Client for such fees upon the Commencement Date and thereafter, upon the [***] day of each Contract Year.

D. Other Fees. Client shall pay Catalent for all other fees and expenses of Catalent owing in accordance with the terms of this Agreement, including pursuant to Sections 2.4, 4.1, 6.2 and 16.3, as applicable. Catalent shall submit an invoice to Client for such fees as and when appropriate.

7.2 Unit Pricing Increase. The Unit Pricing shall be adjusted on an annual basis, effective on 1st of each calendar year after the Effective Date beginning on January 1, 2019 for Product in Purchase Orders placed on or after January 1st, upon [***] days prior written notice from Catalent to Client, to reflect increases in labor, utilities and overhead in an amount equal to the change in the Producer Price Index **(**"**PPI**"**),** "Pharmaceutical Preparation Manufacturing" (Series ID: PCU325412325412), not seasonally adjusted, as published by the U.S. Department of Labor, Bureau of Labor Statistics, over the most recent [***] month period preceding such adjustment date for which the PPI is available. In addition, price increases for Raw Materials (including those Raw Materials referenced in Section 3.2(B)) shall be passed through to Client at the time of such price increase through an adjustment to the Unit Pricing.

7.3 Intentionally Omitted.

7.4 Payment Terms. Payment of all undisputed portions of Catalent invoices shall be due [***] days after the date of receipt of invoice. Client shall make payment in U.S. dollars, and otherwise as directed in the applicable invoice. If any undisputed payment is not received by Catalent by its due date, then Catalent may, in addition to other remedies available at equity or in law, charge

interest on the outstanding sum from the due date (both before and after any judgment) at [***] percent ([***]%) per month until paid in full (or, if less, the maximum amount permitted by Applicable Laws).

7.5 Taxes. All taxes, duties and other amounts (excluding taxes based on net income and franchise taxes) assessed in respect of Client-supplied Materials, services or Product prior to or upon provision or sale pursuant to this Agreement, as the case may be, whether assessed on Catalent or Client, are the responsibility of Client, and either Client shall reimburse Catalent for all such taxes, duties or other amounts paid by Catalent or such sums will be added to invoices directed at Client. If any deduction or withholding in respect of tax or otherwise is required by law to be made from any of the sums payable hereunder, Client shall be obliged to pay to Catalent such greater sum as will leave Catalent, after deduction or withholding as is required to be made, with the same amount as it would have been entitled to receive in the absence of any such requirement to make a deduction or withholding.

7.6 Client and Third-Party Expenses. Except as may be expressly covered by Product Maintenance Service fees, Client shall be responsible for [***] percent ([***]%) of its own and all third-party expenses associated with development, Regulatory Approval and commercialization of Product, including regulatory filings and post-approval marketing studies.

7.7 Development Batches. Each Batch produced under this Agreement, including those necessary to support the validation portion of Client's submissions for Regulatory Approvals, will be considered to be a "development batch" unless and until Processing has been validated. Client shall be responsible for the cost of each such Batch, even if such Batch fails to meet the Specifications, unless Catalent was grossly negligent or failed to comply with Applicable Laws in the Processing of the out-of-Specification Batch. Catalent and Client shall cooperate in good faith to resolve any problem causing the out-of-Specification Batch. For clarity, when a validation Batch is ultimately used for commercial purposes, such Batch shall no longer be considered a development batch.

ARTICLE 8
CHANGES TO SPECIFICATIONS

All Specifications, and any change to the Specifications agreed by the parties from time to time, shall be in writing, dated and signed by the parties. No change in the Specifications shall be implemented by Catalent, whether requested by Client or requested or required by any Regulatory Authority, until the parties have agreed in writing to such change, the implementation date of such change, and any increase or decrease in costs, expenses or fees associated with such change (including any change to Unit Pricing) and any Regulatory Approvals required by Applicable Laws have been obtained. Catalent shall respond promptly to any request made by Client for a change in the Specifications, and both parties shall use [***] to agree to the terms of such change in a timely manner. As soon as practicable after a request is made for any change in Specifications, Catalent shall notify Client of the costs associated with such change and shall provide such supporting documentation as Client may reasonably require. Client shall pay all costs associated with agreed changes to the Specifications. If there is a conflict between the terms of this Agreement and the terms of the Specifications, this Agreement shall control. Catalent reserves the right to postpone effecting changes to the Specifications until such time as the parties agree to and execute the required written amendment.

ARTICLE 9
RECORDS; REGULATORY MATTERS

9.1 Recordkeeping. Catalent shall maintain materially complete and accurate Batch, laboratory data and other technical records relating to Processing in accordance with Catalent standard operating procedures. Such information shall be maintained for a period of at least [***] years from the relevant finished Product expiration date or longer if required under Applicable Laws or the Quality Agreement.

9.2 Regulatory Compliance. Catalent shall obtain and maintain all permits and licenses with respect to general Facility operations required by any Regulatory Authority in the jurisdiction in which Catalent Processes Product. Client shall obtain and maintain all other Regulatory Approvals required of Client by Applicable Law with respect to Product or the services provided pursuant to this Agreement, including those necessary for Catalent to commence Processing. Client shall not identify Catalent in any ANDA/NDA application or other such initial regulatory filing or submission without Catalent's prior written consent. Such consent shall not be unreasonably withheld and shall be memorialized in a writing signed by authorized Representatives of both parties. Upon written request, Client shall provide Catalent with a copy of each Regulatory Approval required to distribute, market or sell Product in the Territory. If Client is unable to provide such information, other than for Product ordered prior to Regulatory Approval in anticipation of launch, Catalent shall have no obligation to deliver Product to Client, notwithstanding anything to the contrary in this Agreement. During the Term, Catalent will assist Client with all regulatory matters relating to Processing, at Client's request and expense. The parties shall cooperate to allow each party to satisfy their respective obligations under Applicable Laws relating to Processing under this Agreement.

9.3 Government/Regulatory Inspections and Requests. Catalent shall promptly advise Client if any Regulatory Authority (or agent acting on its behalf) notifies Catalent that the Regulatory Authority intends to or does visit the Facility where at least one purpose relates to Processing. Upon request, Catalent shall provide Client with a copy of any report provided to Catalent by such Regulatory Authority following such visit, which report may be redacted as appropriate to protect any confidential information of Catalent that is unrelated to Processing or any confidential information of Catalent's other customers; and Client shall provide Catalent with any material correspondence with such Regulatory Authority, including FDA refusal to file, rejection or warning letters. Client acknowledges that it may not direct the manner in which Catalent fulfills its obligations to permit inspection by and to communicate with Regulatory Authorities. Client shall reimburse Catalent for all reasonable and documented costs incurred by Catalent associated with inspections by Regulatory Authorities in connection with Product to the extent such inspection does not directly relate to the gross negligence of Catalent, and pay the applicable fees specified in Attachment D. In connection with such inspection, Catalent shall respond promptly to the inspectors and shall use [***] to notify Client of such inspection and disclose Confidential Information of Client only to the extent necessary.

9.4 Client Facility Audits. During the Term, Client's Representatives shall be granted access upon at least [***] days' prior notice, at reasonable times during regular business hours, to (A) the portion of the Facility where Catalent performs Processing, (B) relevant personnel involved in Processing and (C) Processing records described in Section 9.1, in each case solely for the purpose of verifying that Catalent is Processing in accordance with cGMPs, the Specifications and the

Product master Batch records. Client may not conduct an audit under this Section 9.4 more than once during any [***] month period; *except* that additional inspections may be conducted in the event there is a material quality or compliance issue concerning Product or Processing. Audits and inspections shall be designed to minimize disruption of operations at the Facility. The obligations of Client and its Representatives in Section 4.7 shall apply to all audits undertaken by Client and its Representatives pursuant to this Section 9.4.

9.5 Recall. If a Regulatory Authority orders or requires the recall of Product supplied pursuant to this Agreement or if either Catalent or Client believes a recall, field alert, Product withdrawal or field correction **(**"**Recall**") may be necessary with respect to Product supplied under this Agreement, the party receiving the notice from the Regulatory Authority or that holds such belief shall promptly (within [***] business days) notify the other party in writing. Catalent shall not initiate a Recall without the express prior written approval of Client, unless required by Applicable Laws. With respect to any Recall, Catalent shall provide all necessary cooperation and assistance to Client. Client shall provide Catalent with an advance copy of any proposed submission to a Regulatory Authority in respect of any Recall, such copy being provided no less than [***] prior to submission to a Regulatory Authority. Client shall consider in good faith any comments from Catalent relating to such submission. The cost of any Recall shall be borne by Client, and Client shall reimburse Catalent for expenses incurred in connection with any Recall, in each case unless such Recall is caused solely by Catalent's breach of its manufacturing obligations under this Agreement or Catalent's violation of Applicable Laws or its negligence or willful misconduct, in which case Catalent shall bear the reasonable, actual and documented administrative costs *(e.g.,* printed materials, postage, cost of shipment of return product) incurred by Client for such Recall and, if applicable, the cost of replacing Product returned to Catalent pursuant to such Recall, both to the extent and as provided in Article 5.

9.6 Quality Agreement. Within [***] after the Effective Date, and in any event prior to the first Processing of Product under this Agreement, the parties shall negotiate in good faith and enter into a quality agreement (the "**Quality Agreement**"). The Quality Agreement shall in no way determine liability or financial responsibility of the parties for the responsibilities set forth in that agreement. In the event of a conflict between any provision of this Agreement and the Quality Agreement with respect to quality-related activities, including compliance with cGMP, the provisions of the Quality Agreement shall govern. In the event of a conflict between any provision of this Agreement and the Quality Agreement with respect to any commercial matter, including allocation of risk, liability and financial responsibility, the provisions of this Agreement shall govern.

9.7 Adverse Events. Catalent shall promptly report to Client all adverse drug events and customer complaints with regard to Product of which Catalent or its Affiliates or its or their employees becomes aware within [***] of becoming aware of such events or complaints.

9.8 Regulatory Authority Fees. Catalent reserves the right to assess Client for any Regulatory Authority fees that may be established by any Regulatory Authority, which fees result directly from Catalent's formulation, development, manufacturing, processing, filling, packaging, storing or testing of Product or Client-supplied Materials.

ARTICLE 10
CONFIDENTIALITY AND NON-USE

10.1 Definition. As used in this Agreement, the term "**Confidential Information**" means all confidential information of the disclosing person of whatever type, including all information furnished by or on behalf of Catalent or Client (as the case may be, "**Discloser**"), its Affiliates or any of its or their respective Representatives, to the other party (as the case may be, "**Recipient**"), its Affiliates or any of its or their respective Representatives, whether furnished before, on or after the Effective Date and furnished in any form, including written, verbal, visual, electronic or in any other media or manner and information acquired by observation or otherwise during any site visit at the other party's facility. Confidential Information includes all proprietary technologies, know-how, trade secrets, discoveries, inventions and any other Intellectual Property (whether or not patented), analyses, compilations, business or technical information and other materials prepared by either party, their respective Affiliates, or any of its or their respective Representatives, containing or based in whole or in part on any Confidential Information furnished by Discloser, its Affiliates or any of its or their respective Representatives. Confidential Information also includes the existence and terms of this Agreement, and each party shall be considered the Discloser and the Recipient with respect thereto.

10.2 Exclusions. Notwithstanding anything in Section 10.1 to the contrary, Confidential Information does not include information that (A) is or becomes generally available to the public or within the industry to which such information relates other than as a result of a breach of this Agreement, (B) is already known by Recipient or its Affiliate at the time of disclosure as evidenced by Recipient's written records, (C) becomes available to Recipient or its Affiliate on a non-confidential basis from a source that is entitled to disclose it on a non-confidential basis or

(D) was or is independently developed by or for Recipient or its Affiliate without reference to Discloser's Confidential Information as evidenced by Recipient's written records.

10.3 Mutual Obligation. Recipient (A) will keep confidential all Confidential Information, employing such protections as it would use for its own Confidential Information of a similar type but in no case less than reasonable protections under the circumstances, (B) will not use Discloser's Confidential Information except in connection with the performance of its obligations under this Agreement and (C) will not disclose to any third party, without Discloser's prior written consent, Discloser's Confidential Information, except that Recipient may disclose Discloser's Confidential Information to any of its Affiliates and its or their respective Representatives that (A) need to know such Confidential Information for the purpose of performing obligations or exercising rights under this Agreement, (B) are advised of the contents of this Article and (C) are bound to Recipient by obligations of confidentiality at least as restrictive as the terms of this Article. Each party shall be responsible for any breach of this Article by its Affiliates or any of its or their respective Representatives.

10.4 Permitted Disclosure. Recipient may disclose Discloser's Confidential Information to the extent required by Applicable Laws or pursuant to a valid order of a court or other governmental authority; *provided,* that prior to making any such legally required disclosure, Recipient shall give Discloser as much prior notice of the requirement for and contents of such disclosure as is practicable under the circumstances and shall provide reasonable assistance, at Discloser's request and cost, in obtaining a protective order or confidential treatment preventing or limiting the disclosure or requiring that Confidential Information so disclosed be used only for the purposes required by Applicable Laws or the applicable order. Any such disclosure, however, shall not relieve Recipient of its obligations under this Agreement. The parties will consult with each other

on the provisions of this Agreement to be redacted in any public filings made by a party as required by Applicable Laws; provided that each party shall have the right, after good faith review and discussion of the other Party's recommendations regarding such redactions, to make any such filing as it reasonably determines necessary under Applicable Laws. In addition, following such disclosure, either party shall be free to disclose, without the other party's prior written consent, the existence of this Agreement, the identity of the other party and those terms of the Agreement which have already been publicly disclosed in accordance herewith.

10.5 No Implied License. Recipient will obtain no right of any kind or license under any of Discloser's Confidential Information, including any patent application or patent, by reason of this Agreement. Discloser's Confidential Information will remain Discloser's sole property, subject to Article 11.

10.6 Equitable Relief. Given the nature of the Confidential Information and the competitive damage that a party would suffer upon unauthorized disclosure, use or transfer of its Confidential Information, the parties agree that monetary damages would not be a sufficient remedy for any breach of this Article 10. In addition to all other remedies, a party shall be entitled to specific performance and injunctive and other equitable relief as a remedy for any breach or threatened breach of this Article 10.

10.7 Return of Confidential Information. Upon expiration or termination of this Agreement, Recipient will (and will cause its Affiliates and its and their respective Representatives to) cease its use and, upon written request, within [***] days either return or destroy (and certify as to such destruction) all of Discloser's Confidential Information, including any copy of such information, except for a single copy, which may be retained under a continuing obligation of confidentiality for the sole purpose of ensuring compliance with its obligations under this Agreement.

10.8 Survival. The obligations of this Article will terminate [***] years from the expiration or termination of this Agreement, except with respect to trade secrets, for which the obligations of this Article will continue for so long as such information remains a trade secret under law.

ARTICLE 11
INTELLECTUAL PROPERTY

As used in this Agreement, "**Client IP**" means all Intellectual Property and related embodiments owned by or licensed to Client as of the Effective Date or developed by Client other than in connection with this Agreement; "**Catalent IP**" means all Intellectual Property and related embodiments owned by or licensed to Catalent as of the Effective Date or developed by Catalent other than in connection with this Agreement; "**Invention**" means any Intellectual Property developed by either party or jointly by the parties in connection with this Agreement; "**Client Inventions**" means any Invention, other than a Catalent Invention, that relates to the Client IP or to API or other Client-supplied Materials or the capsule shells used in Processing the Product; and "**Catalent Inventions**" means any Invention, other than a Client Invention, that relates exclusively to Catalent IP or relates to developing, formulating, manufacturing, filling, processing, packaging, analyzing or testing pharmaceutical products generally, but not specifically to Product. All Client IP and Client Inventions shall be owned solely by Client and no right therein is granted to Catalent under this Agreement, except that Catalent shall have a non-exclusive, royalty-free license to Client IP and Client Inventions that is necessary for use in Processing Product solely to the extent

necessary for Catalent to perform its obligations under this Agreement. Catalent hereby assigns to Client all right, title and interest it or any of its Affiliates may have in or to any Client Inventions. All Catalent IP and Catalent Inventions shall be owned solely by Catalent and no right therein is granted to Client under this Agreement. Client hereby assigns to Catalent all right, title and interest it or any of its Affiliates may have in or to any Catalent Inventions. The parties shall cooperate to achieve the allocation of rights to Inventions set forth in this Article 11, and each party shall be solely responsible for costs associated with the protection of its Intellectual Property. Each party will cause its employees or contractors who perform activities pursuant to this Agreement to enter into agreements that protect Confidential Information and enable compliance with the foregoing provisions regarding ownership of Inventions.

ARTICLE 12
REPRESENTATIONS AND WARRANTIES

12.1 Catalent. Catalent represents, warrants and undertakes to Client that:

A. At the time of delivery by Catalent as provided in Section 6.1, Product shall have been Processed in accordance with Applicable Laws and Product shall conform with the Specifications and shall not be adulterated, misbranded or mislabeled within the meaning of Applicable Laws; *provided,* that Catalent shall not be liable for defects attributable to Client-supplied Materials (including artwork, advertising and labeling).

B. Neither Catalent nor its Affiliates will in the performance of its obligations under this Agreement use the services of any person debarred or suspended under 21 U.S.C. §335(a) or (b)., excluded from a federal healthcare program, debarred from federal contracting or convicted or plead nolo contendere to any felony or to any violation of laws relating to fraud, and Catalent will comply in all material respects with Applicable Laws relating to Catalent's performance under this Agreement. In the event that during the Term Catalent becomes aware of any non-compliance with this Section 12.1(B), Catalent shall notify Client immediately. In either such event, Client will have the right to terminate this Agreement upon written notice to Catalent if such non-compliance is not cured within [***] days.

C. Catalent has all necessary authority to use the Catalent IP as contemplated by this Agreement.

D. To its knowledge, there is (i) no patent owned by a third party related to the Catalent IP used to Process Product that would be infringed or misused by performance under this Agreement, and (ii) no trade secret or other proprietary right of a third party related to the Catalent IP used to Process Product that would be infringed or misused by performance under this Agreement.

E. No transaction or dealing under this Agreement shall be conducted with or for an individual or entity that is designated as the target of any sanction, restriction or embargo administered by the United Nations, European Union, United Kingdom, or United States.

F. Catalent has full power and authority to enter into this Agreement, and this Agreement has been duly authorized by it and this Agreement is binding upon it.

12.2 Client. Client represents, warrants and undertakes to Catalent that:

A. All Client-supplied Materials shall have been produced in accordance with Applicable Laws, shall comply with all applicable specifications, including the Specifications shall not be adulterated, misbranded or mislabeled within the meaning of Applicable Laws, and shall have been provided in accordance with the terms and conditions of this Agreement.

B. The content of all artwork provided by or on behalf of Client to Catalent shall comply with all Applicable Laws.

C. All Product delivered to Client by Catalent shall be held, used and disposed of by or on behalf of Client in accordance with Applicable Laws, and Client will otherwise comply with Applicable Laws relating to Client's performance under this Agreement.

D. Client will not release any Batch of Product if the required certificates of conformance indicate that Product does not comply with the Specifications or if Client does not hold all necessary Regulatory Approvals to market and sell the Product.

E. Client has all necessary authority to use and to permit Catalent to use pursuant to and in accordance with this Agreement all Client IP related to Product or Client-supplied Materials (including artwork) or the Processing of either of them, including all applicable copyrights, trademarks, trade secrets, patents, inventions and developments.

F. To its knowledge, there is (i) no patent owned by a third party related to the Client IP used to Process Product that would be infringed or misused by performance under and in accordance with this Agreement and (ii) no trade secret or other proprietary right of a third party related to the Client IP used to Process Product that would be infringed or misused by performance under and in accordance with this Agreement.

G. To its knowledge, the services to be performed by Catalent under this Agreement if performed in strict accordance with the Specifications will not violate or infringe upon any trademark, tradename, copyright, patent, trade secret, or other Intellectual Property or other right held by any person or entity. Client has all authorizations and permits required to deliver (or have delivered) API to the Facility.

H. No transaction or dealing under this Agreement shall be conducted with or for an individual or entity that is designated as the target of any sanction, restriction or embargo administered by the United Nations, European Union, United Kingdom, or United States.

I. Client has full power and authority to enter into this Agreement, and this Agreement has been duly authorized by it and this Agreement is binding upon it.

12.3 Limitations. THE REPRESENTATIONS AND WARRANTIES SET FORTH IN THIS ARTICLE ARE THE SOLE AND EXCLUSIVE REPRESENTATIONS AND WARRANTIES MADE BY EACH PARTY TO THE OTHER PARTY, AND NEITHER PARTY MAKES ANY OTHER REPRESENTATION, WARRANTY OR GUARANTEE OF ANY KIND WHATSOEVER, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY, NON-INFRINGEMENT OR FITNESS FOR A PARTICULAR PURPOSE.

ARTICLE 13
INDEMNIFICATION

13.1 Indemnification by Catalent. Catalent shall indemnify, defend and hold harmless Client, its Affiliates, and their respective directors, officers, employees and agents (collectively, "**Client Indemnitees**"), from and against any and all losses, liabilities, damages, costs and expenses (including reasonable attorneys' fees and expenses and reasonable investigative costs) in connection with any claim, demand, suit, demand or action by any third party **(**"**Losses**") arising out of, relating to or resulting from (A) any breach of representations, warranties or obligations of Catalent set forth in this Agreement, (B) any actual or alleged infringement or violation of any third party Intellectual Property to the extent resulting exclusively from practice or use of Catalent IP or Catalent Inventions, or (C) any negligence or willful misconduct by Catalent or any of its Affiliates, in each case, except to the extent of any Losses that arise out of, relate to or result from any negligence or willful misconduct by any Client Indemnitee or breach of representations, warranties or obligations of Client set forth in this Agreement.

13.2 Indemnification by Client. Client shall indemnify, defend and hold harmless Catalent, its Affiliates, and their respective directors, officers, employees and agents (collectively, "**Catalent Indemnitees**"), from and against any and all Losses arising out of, relating to or resulting from (A) any breach of representations, warranties or obligations of Client set forth in this Agreement, (B) any manufacture (other than by Catalent), packaging, sale, promotion, distribution or use of or exposure to Product or Client-supplied Materials, including product liability or strict liability, (C) Client's exercise of control over the Processing, to the extent that Client's instructions or directions violate Applicable Laws, (D) the conduct of any clinical trial utilizing Product or API, (E) any actual or alleged infringement or violation of any third party Intellectual Property to the extent resulting exclusively from the practice or use of Client IP, Client Inventions or Client-supplied Materials, or (F) any negligence or willful misconduct by Client or any of its Affiliates, in each case, except to the extent of any Losses that arise out of, relate to or result from any negligence or willful misconduct by any Catalent Indemnitee or breach of representations, warranties or obligations of Catalent set forth in this Agreement.

13.3 Indemnification Procedures. All indemnification obligations in this Agreement are conditioned upon the indemnified party (A) promptly notifying the indemnifying party of any claim or liability of which the indemnified party becomes aware (including a copy of any related complaint, summons, notice or other instrument); *provided, however,* that failure to provide such notice within a reasonable period shall not relieve the indemnifying party of its obligations under this Article 13 except to the extent, if any, the indemnifying party is prejudiced by such failure, (B) allowing the indemnifying party to conduct and control the defense of any such claim or liability and any related settlement negotiations (at the indemnifying party's expense), *provided,* that the indemnifying party shall promptly provide and continuously maintain such defense, (C) cooperating with the indemnifying party in the defense of any such claim or liability and any related settlement negotiations (at the indemnifying party's expense) and (D) not compromising or settling any claim or liability without prior written consent of the indemnifying party.

ARTICLE 14
LIMITATIONS OF LIABILITY

14.1 EXCEPT FOR CATALENT'S FRAUD, WILLFUL MISCONDUCT, GROSS NEGLIGENCE AND ANY LIABILITY THAT BY APPLICABLE LAW CANNOT BE EXCLUDED OR LIMITED **(**"**RETAINED LIABILITY**")**,** CATALENT'S TOTAL LIABILITY PER CLAIM UNDER THIS AGREEMENT SHALL IN NO EVENT EXCEED THE GREATER

OF (A) [***] DOLLARS ($[***]) OR (B) [***] UP TO A MAXIMUM OF [***] DOLLARS ($[***]) OVER THE TERM OF THIS AGREEMENT.

14.2 EXCEPT IN THE CASE OF RETAINED LIABILITY, CATALENT'S LIABILITY UNDER THIS AGREEMENT FOR ANY AND ALL CLAIMS FOR LOST, DAMAGED OR DESTROYED CLIENT-SUPPLIED MATERIALS, WHETHER OR NOT SUCH CLIENT-SUPPLIED MATERIALS ARE INCORPORATED INTO PRODUCT, SHALL NOT EXCEED THE LESSER OF [***] PERCENT ([***]%) OF THE COST OF THE CLIENT-SUPPLIED MATERIALS OR [***] U.S. DOLLARS (US$[***]) PER BATCH.

14.3 EXCEPT IN THE CASE OF DAMAGES FOR BREACH OF ARTICLE 10 (SUBJECT TO THE LIABILITY CAP DESCRIBED IN SECTION 14.1), NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR INDIRECT, INCIDENTAL, SPECIAL, PUNITIVE OR CONSEQUENTIAL DAMAGES OR LOSS OF REVENUES, PROFITS OR DATA ARISING OUT OF PERFORMANCE UNDER THIS AGREEMENT, WHETHER IN CONTRACT OR IN TORT, EVEN IF SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

ARTICLE 15
INSURANCE

Each party shall, at its own cost and expense, obtain and maintain in full force and effect during the Term the following: (A) Commercial General Liability and/or Foreign Liability Insurance with a per occurrence limit of $[***] ([***] million United States Dollars) or equivalent and an annual aggregate limit of $[***] ([***] million United States Dollars) or equivalent; (B) Products and Completed Operations Liability Insurance with a per occurrence limit of not less than $[***] ([***] million United States Dollars) or equivalent covering each party's own operations arising out of or in connection with this Agreement, providing coverage for bodily injury and property damage claims; (C) Workers' Compensation as required by any Applicable Law; and (D) Auto Liability insurance in a minimum amount of $[***] ([***] million United States Dollars) or equivalent combined single limit for all vehicles used in connection with the performance of this Agreement. Customer shall, at its own cost and expense, obtain and maintain in full force and effect during the Term, All Risk Property Insurance, including transit coverage, an amount equal to the full replacement value of its property while in, or in transit to, or from, a Catalent facility. Customer shall obtain a waiver of subrogation clause from its property insurance carrier in favor of Catalent. Customer shall not seek reimbursement from Catalent corporate affiliates, and their respective officers, directors, employees, agents, successors and assigns for any property claim or portion thereof that is not fully recovered from Customer's Property Insurance policy. Each party shall be named as an additional insured within the other party's General Liability and / or Foreign Liability insurance and Products Completed Operations Liability policies; provided, that such additional insured status will apply solely to the extent of the insured party's indemnity obligations under this agreement. The policy(ies) under this Agreement will provide, by endorsement or otherwise, that Customer's insurance will be primary insurance and that any other insurance maintained by or otherwise afforded to Catalent, its corporate affiliates, and their respective officers, directors, employees, agents, successors, and assigns will be excess only and non-contributing except where prohibited by law. If any of the required policies of insurance are written on a claims made basis, such policies shall be maintained throughout the Term and for a period of at least [***] years thereafter. Each insurance policy that is required under this Agreement shall be obtained from an insurance carrier with an A.M. Best or equivalent rating of at least A- VII or an S&P rating of A. Each party may self-insure all or any portion of the required insurance as long as, together with its Affiliates, its US GAAP net worth is greater than $[***] million United States Dollars or equivalent or its annual EBITDA (earnings before interest, taxes, depreciation and amortization) is greater than $[***] million United States Dollars or equivalent. Waivers of subrogation and additional insured status obligations will operate the same whether insurance is carried through third parties or self-insured. Upon the other party's written request from time to time, each party shall promptly furnish to the other party a certificate of insurance or other evidence of the required insurance. Customer certificates of insurance, which will include the Catalent affiliate contracting party of this Agreement as the certificate holder, will be sent to the following contact:

Catalent Pharma Solutions LLC
Attn:

ARTICLE 16
TERM AND TERMINATION

16.1 Term. This Agreement shall commence on the Effective Date and shall continue until the end of the fifth (5th) Contract Year, unless earlier terminated in accordance with Section 16.2 (such term, including any extension in accordance with this Section 16.1, the "**Term**"). Unless this Agreement is terminated in accordance with Section 16.2, the Term shall automatically extend for successive two (2)-year periods unless and until one party gives the other party at least eighteen (18) months' prior written notice of its desire to terminate as of the end of the then-current Term.

16.2 Termination. This Agreement may be terminated immediately without further action:

A. by either party if the other party files a petition in bankruptcy, or enters into an agreement with its creditors, or applies for or consents to the appointment of a receiver, administrative receiver, trustee or administrator, or makes an assignment for the benefit of creditors, or suffers or permits the entry of any order adjudicating it to be bankrupt or insolvent and such order is not discharged within [***] days, or takes any equivalent or similar action in consequence of debt in any jurisdiction.

B. by either party if the other party materially breaches this Agreement and such breach is not cured within [***] days after the giving of written notice requiring the breach to be remedied; *provided,* that in the case of a failure of Client to make payments in accordance with the terms of this Agreement, Catalent may terminate this Agreement if such payment breach is not cured within [***] days of receipt of notice of non-payment from Catalent.

C. by Client (i) upon [***] days' prior written notice to Catalent in the event a Regulatory Authority takes an enforcement or other regulatory action against the Facility which affects Catalent's ability to Process the Product, or (ii) upon [***] days' prior written notice if any Regulatory Authority takes any action or raises any objection that prevents Client from manufacturing, importing, exporting, purchasing or selling Product, or (iii) if Client otherwise does not obtain Regulatory Approval of Product in the United States or (iv) upon [***] days' prior written notice if Client determines not to launch Product or to discontinue commercialization of Product, in the United States due to safety or efficacy reasons.

16.3 Effect of Expiration or Termination. Expiration or termination of this Agreement shall be without prejudice to any right or obligation that accrued to the benefit of either party prior to such expiration or termination. In the event of an expiration or termination of this Agreement:

A. Catalent shall promptly return to Client, at Client's expense and direction, any remaining inventory of Product or Client-supplied Materials; *provided,* that all outstanding invoices have been paid in full;

B. Client shall pay Catalent all invoiced amounts outstanding hereunder unless disputed in good faith, plus, upon receipt of invoice therefor, for any (i) Product that has been shipped pursuant to Purchase Orders but not yet invoiced, (ii) Product Processed pursuant to Purchase Orders that has been completed but not yet shipped, and (iii) in the event that this

Agreement is terminated for any reason other than by Client pursuant to Section 16.2(A) or (B), all Product being Processed pursuant to Purchase Orders (or, alternatively, Client may instruct

Catalent to complete such work in process, and the resulting completed Product shall be governed by clause (ii)); and

C. in the event that this Agreement is terminated for any reason other than by Client pursuant to Section 16.2(A) or (B), Client shall pay Catalent for all costs and expenses incurred, and all noncancellable commitments made, in connection with Catalent's performance of this Agreement, so long as such costs, expenses or commitments were made by Catalent consistent with Client's most recent Firm Commitment and the vendor's minimum purchase obligations.

16.4 Survival. Expiration or termination of this Agreement shall not relieve the parties of any obligation or right accruing prior to such expiration or termination. The rights and obligations of the parties shall continue under Articles 11 (Intellectual Property), 13 (Indemnification), 14 (Limitations of Liability), 17 (Notice), 18 (Miscellaneous); under Articles 10 (Confidentiality and Non-Use) and 15 (Insurance), in each case to the extent expressly stated therein; and under Sections 7.4 (Payment Terms), 7.6 (Taxes), 7.7 (Client and Third Party Expenses), 9.1 (Recordkeeping), 9.5 (Recall), 12.3 (Limitations), 16.3 (Effect of Termination) and 16.4 (Survival), in each case in accordance with their respective terms if applicable, notwithstanding expiration or termination of this Agreement.

ARTICLE 17
NOTICE

All notices and other communications under this Agreement shall be in writing and shall be deemed given: (A) when delivered personally or by hand; (B) when delivered by electronic mail (e-mail); (C) when received or refused, if sent by registered or certified mail (return receipt requested), postage prepaid; or (D) when delivered, if sent by express courier service; in each case to the parties at the following addresses (or at such other address for a party as shall be specified by like notice; *provided,* that notices of a change of address shall be effective only upon receipt thereof):

To Client: ACADIA Pharmaceuticals Inc.

Attn:
E-Mail:
Facsimile:

With a copy to: ACADIA Pharmaceuticals Inc.

Attn:
E-Mail:

Facsimile:

To Catalent Catalent Pharma Solutions,

LLC

Attn:
E-Mail:
Facsimile:

With a copy to: Catalent Pharma Solutions, LLC

Attn:
E-Mail:
Facsimile:

ARTICLE 18
MISCELLANEOUS

18.1 Entire Agreement; Amendments. This Agreement, together with the Quality Agreement, constitutes the entire understanding between the parties, and supersedes any contract, agreement or understanding (oral or written) of the parties, with respect to its subject matter. For the avoidance of doubt, this Agreement does not supersede any existing generally applicable confidentiality agreement between the parties as it relates to periods prior to the Effective Date or to business dealings not covered by this Agreement. No term of this Agreement may be amended except upon written agreement of both parties, unless otherwise expressly provided in this Agreement.

18.2 Captions; Certain Conventions. The captions in this Agreement are for convenience only and are not to be interpreted or construed as a substantive part of this Agreement. Unless otherwise expressly provided in this Agreement or the context of this Agreement otherwise requires, (A) words of any gender include each other gender, (B) words such as "herein", "hereof", and "hereunder" refer to this Agreement as a whole and not merely to the particular provision in which such words appear, (C) words using the singular include the plural, and vice versa, (D) the words "include(s)" and "including" shall be deemed to be followed by the phrase "but not limited to", "without limitation" or words of similar import, (E) the word "or" shall be deemed to include the word "and" *(e.g.,* "and/or"), and (F) references to "Article," "Section," "subsection," "clause" or other subdivision, or to an Attachment or other appendix, without reference to a document are to the specified provision or Attachment of this Agreement. This Agreement shall be construed as if it were drafted jointly by the parties.

18.3 Further Assurances. The parties shall execute, acknowledge and deliver such further instruments and take all such other incidental acts as may be reasonably necessary or appropriate to carry out the purpose and intent of this Agreement.

18.4 No Waiver. Failure by either party to insist upon strict compliance with any term of this Agreement in any one or more instances will not be deemed a waiver of its rights to insist upon such strict compliance with respect to any subsequent failure.

18.5 Severability. If any term of this Agreement is declared invalid or unenforceable by a court or other body of competent jurisdiction, the remaining terms of this Agreement will continue in full force and effect.

18.6 Independent Contractors. The relationship of the parties is that of independent contractors, and neither party will incur any debt or make any commitment for the other party except to the extent expressly provided in this Agreement. Nothing in this Agreement is intended to create or will be construed as creating between the parties the relationship of joint venturers, co-partners, employer/employee or principal and agent. Neither party shall have any responsibility for the hiring, termination or compensation of the other party's employees or contractors or for any employee benefits of any such employee or contractor.

18.7 Successors and Assigns. This Agreement will be binding upon and inure to the benefit of the parties, their successors and permitted assigns. Neither party may assign this Agreement, in whole or in part, without the prior written consent of the other party, except that either party may, without the other party's consent (but subject to prior written notice), assign this Agreement in its entirety to an Affiliate or to a successor to substantially all of the business or assets of the assigning party or the assigning party's business unit responsible for performance under this Agreement, and any assignment in violation of this Section 18.7 shall be void *ab initio.*

18.8 No Third Party Beneficiaries. This Agreement shall not confer any right or remedy upon any individual or entity other than the parties and their respective successors and permitted assigns, except that the Client Indemnitees and the Catalent Indemnitees may invoke the benefits of the indemnification provisions of this Agreement.

18.9 Governing Law. This Agreement shall be governed by and construed under the laws of the State of New York, USA, excluding its conflicts of law provisions. The United Nations Convention on Contracts for the International Sale of Goods shall not apply to this Agreement.

18.10 Alternative Dispute Resolution. Any dispute arising between the parties in connection with this Agreement shall first be presented to the respective senior executives of the parties for their consideration and resolution. If such parties' executives cannot resolve such dispute within [***] days, then such dispute may be submitted by either party to arbitration by the [***] (**"**[***]") by one (1) arbitrator selected by the parties. If no agreement on an arbitrator can be reached within [***] days after the [***] offers names of potential arbitrators, then the [***] will choose one arbitrator having reasonable experience in commercial transactions of the type described in this Agreement. The arbitration shall take place in the English language in New York City, New York, in accordance with the [***] administered arbitration rules then in effect, and judgment upon any award rendered in such arbitration will be binding and may be entered in any court having jurisdiction of the matter. The arbitration shall commence within [***] days of the date on which an arbitrator is selected. The arbitrator's decision shall set forth a reasoned basis for any award of damages or finding of liability. The arbitrator shall not have power to award damages in excess of actual compensatory damages and shall not multiply actual damages or award punitive damages. The arbitrator shall award to the prevailing party, if any, its costs and attorneys' fees and expenses reasonably incurred in connection with the arbitration, in accordance with Section 18.11.

18.11 Prevailing Party. In any dispute resolution proceeding between the parties in connection with this Agreement, the prevailing party will be entitled to recover its reasonable attorney's fees

and costs in such proceeding, including any subsequent or related enforcement proceeding, from the other party.

18.12 Publicity. Neither party will make any press release or other public disclosure regarding this Agreement or the transactions contemplated hereby without the other party's express prior written consent, except as required under Applicable Laws, by any governmental agency or by the rules of any stock exchange on which the securities of the disclosing party are listed, in which case the party required to make the press release or public disclosure shall obtain the prior approval of the other party, which shall not be unreasonably withheld or delayed, as to the form, nature and extent of the press release or public disclosure prior to issuing the press release or making the public disclosure.

18.13 Right to Dispose and Settle. If Catalent requests in writing from Client direction with respect to disposal of any inventories of Product, Client-supplied Materials, equipment, samples or other items belonging to Client and is unable to obtain a response from Client within a reasonable period after making [***] to do so (provided that Client has not responded to Catalent for at least [***] months from Catalent's initial request), Catalent shall be entitled in its sole discretion to (A) dispose of all such items and (B) set-off any and all amounts due to Catalent or any of its Affiliates from Client against any credits Client may hold with Catalent or any of its Affiliates.

18.14 Force Majeure. Except as to payments required under this Agreement, neither party shall be liable in damages for, nor shall this Agreement be terminable or cancelable by reason of, any delay or default in such party's performance hereunder if such default or delay is caused by events beyond such party's reasonable control, including acts of God, law or regulation or other action or failure to act of any government or agency thereof, war or insurrection, civil commotion, any act of terrorism, destruction of production facilities or materials by earthquake, fire, flood or weather, labor disturbances, epidemic or failure of suppliers, vendors, public utilities or common carriers; *provided,* that the party seeking relief under this Section 18.14 shall promptly notify the other party of such cause(s) beyond such party's reasonable control. The party that may invoke this Section 18.14 shall use [***] to reinstate its ongoing obligations to the other party as soon as practicable. If the cause(s) shall continue unabated for [***] days, then both parties shall meet to discuss and negotiate in good faith what modifications to this Agreement should result from such cause(s).

18.15 Counterparts. This Agreement may be executed in one or more counterparts, each of which will be deemed an original but all of which together will constitute one and the same instrument. Any photocopy, facsimile or electronic reproduction of the executed Agreement shall constitute an original.

[Signature page follows]

IN WITNESS WHEREOF, the parties have caused their respective duly authorized Representatives to execute this Agreement effective as of the Effective Date.

CATALENT PHARMA SOLUTIONS, LLC	**ACADIA PHARMACEUTICALS INC.**
By: /s/ Thomas A. Yezza	By: /s/ Bob Mischler
Name: Thomas A. Yezza	Name: Bob Mischler
Title: Vice President & General Manager	Title: SVP Strategy & Technology Operations

ATTACHMENT A

VALIDATION SERVICES

[***]

ATTACHMENT B

SPECIFICATIONS

[***]

ATTACHMENT C

UNIT PRICING AND FEES

[***]

ATTACHMENT D

PRODUCT MAINTENANCE SERVICES & OTHER RELATED SERVICES

[***]

AMENDMENT #1
to
COMMERCIAL SUPPLYAGREEMENT BETWEEN
ACADIA PHARMACEUTICALS INC. AND CATALENT PHARMA SOLUTIONS, LLC

This **AMENDMENT #1 ("Amendment")** is made and entered into as of August 21, 2019 effective as of May 1st, 2019 **("Amendment Effective Date"),** by and between ACADIA Pharmaceuticals Inc. **("Client"),** a Delaware corporation, with a place of business at 3611 Valley Centre Drive, Suite 300, San Diego, California 92130, and Catalent Pharma Solutions, LLC, a Delaware limited liability company with a place of business at 14 Schoolhouse Road, Somerset, New Jersey 08873, USA **("Catalent").**

A. Client and Catalent have entered into that certain Commercial Supply Agreement effective as of February 22, 2018 (the "Agreement").

B. Pursuant to Section 18.1 of the Agreement, Client and Catalent now desire to amend the Agreement.

NOW, THEREFORE, in consideration of the mutual covenants, promises, rights and obligations contained herein, the Parties agree as follows:

1. The Agreement is hereby amended as of the Amendment Effective Date as follows:

   a. Section 1.27 of the Agreement shall be amended to read as follows:

   "Facility" means Catalent's facility located in Somerset, New Jersey; Winchester, Kentucky; or such other facility as agreed by the parties in writing.

   b. The Additional Fees table in Attachment C shall be amended to read as follows:

ADDITIONAL FEES		
Type of Fee	**Amount**	**Payable**
Product Maintenance Fee	US$[***]	As set forth in Article 7
Quality Assurance Support	US$[***]/hour	As set forth in Article 7

2.Other Terms. Except as expressly amended herein, all other terms and conditions of the Agreement will remain in full force and effect. Any capitalized term used herein and not otherwise defined will have the same meaning as set forth in the Agreement.In the event of any conflict between this Amendment and the Agreement, the terms of this Amendment will control.

3.This Amendment may be executed in two or more counterparts, each of which shall be deemed an original document, and all of which, together with this writing, shall be deemed one instrument. An electronic signature is the legally binding equivalent of a hand-written signature and shall have the same force and effect as an original signature. Signatures delivered by electronic means, and signed counterpart PDFs delivered by email shall have the same force and effect as original signatures.

IN WITNESS WHEREOF, the Parties have caused this Amendment to be duly executed as of the date above to be effective as of the Amendment Effective Date.

ACADIA PHARMACEUTICALS INC.

By: /s/ Jane Ryskamp
Name: Jane Ryskamp
Title: VP, Manufacturing

CATALENT PHARMA SOLUTIONS, LLC

By: /s/ Michael Valazza
Name: Michael Valazza
Title: VP, Business Development

EXECUTION VERSION

AMENDMENT NUMBER 2
to
COMMERCIAL SUPPLY AGREEMENT BETWEEN
ACADIA PHARMACEUTICALS INC. AND CATALENT PHARMA SOLUTIONS, LLC

THIS AMENDMENT #2 TO COMMERCIAL SUPPLY AGREEMENT **("Second Amendment")** between ACADIA Pharmaceuticals Inc. **("Client"),** a Delaware corporation, with a place of business at 3611 Valley Centre Drive, Suite 300, San Diego, California 92130, and Catalent Pharma Solutions, LLC, a Delaware limited liability company with a place of business at 14 Schoolhouse Road, Somerset, New Jersey, 08873 **("Catalent")** is effective as of May 29th, 2020 **("Second Amendment Effective Date").**

WHEREAS, Client and Catalent entered into a Commercial Supply Agreement effective as of February 22, 2018 (as previously amended, **"Agreement");**

WHEREAS, Client and Catalent now wish to amend the Agreement.

NOW, THEREFORE, in consideration of the mutual covenants, promises, rights and obligations contained herein, the Parties agree as follows:

1. The following Definitions are added to Article 1 of the Agreement:

   1.60**"Bulk Product"** means the bulk pharmaceutical product containing the API, as more specifically described in the Specifications.
   1.61**"Package"** or **"Packaging"** or **"Packaged"** means the primary and/or secondary packaging of Bulk Product in accordance with the Specifications.
   1.62 **"Packaged Product"** means the Bulk Product that has been Packaged.

2. Section 1.17 of the Agreement is hereby deleted in its entirety and replaced with the following:

   "Client-supplied Materials" means any materials to be supplied by or on behalf of Client to Catalent for Processing, as described in Attachment B, which is limited to API and reference standards, as well as Bulk Product, unless agreed in writing by the parties.

3. Section 1.36 of the Agreement is hereby deleted in its entirety and replaced with the following:

   "Process" or **"Processing"** means the compounding, filling, encapsulating, producing, bulk packaging and/or Packaging of Client-supplied Materials and Raw Materials into Product by Catalent, in accordance with the Specifications and under the terms of this Agreement.

4. Section 1.38 of the Agreement is hereby deleted in its entirety and replaced with the following:

"Product" means the Bulk Product and Packaged Product.

5. Section 1.55 of the Agreement is hereby deleted in its entirety.

6. Section 3.2 (C) of the Agreement is hereby deleted in its entirety and replaced with the following:

C. In the event of (i) Specification or printed component copy changes for any reason, (ii) obsolescence of any Raw Material or (iii) termination or expiration of this Agreement, Client shall bear the cost of any Raw Materials (including packaging components) unusable for Processing or Product and unusable by Catalent for another customer, so long as Catalent purchased such Raw Materials in quantities consistent with Client's most recent Firm Commitment and the vendor's minimum purchase obligations, and at Client's election, Catalent shall promptly ship such unused Raw Materials to Client at Client's cost.

7. The following sentence is added to the end of Section 3.3 of the Agreement:

The parties acknowledge that delays with respect to the approval of artwork and labeling may result in the revision of the delivery date.

8. Section 3.4 of the Agreement is hereby deleted in its entirety and replaced with the following:

3.4 API Yield.

A. Catalent will give Client [***] inventory report of the API held by Catalent within [***] business days of the end of the most recent [***] in a Contract Year which contains the following information for such period: (a) quantity of API conforming to specifications that is received at the Facility ("Quantity Received"), (b) quantity of API dispensed in Processing Product at the Facility calculated by adding the Quantity Received to the inventory of API that complies with the specifications and is held by Catalent at the beginning of the applicable period, less the inventory of API that complies with the specifications and is held by Catalent at the end of the period ("Quantity Dispensed"), and (c) the total amount of API contained in the Product manufactured with the Quantity Dispensed delivered by Catalent and not rejected, recalled or returned due to Catalent Cause as defined below ("Quantity Converted").

B. Within [***] days after the end of each Contract Year, Catalent will prepare an annual reconciliation of API that sets out the "Actual Annual Yield" or "AAY" for the Product at the Facility during the Contract Year. AAY is the

percentage of the Quantity Dispensed that was converted to Product and is calculated as follows: Quantity Converted in Contract Year/Quantity Dispensed during Contract Year * 100. The parties agree that the "Target AAY" will be [***]. Without limiting Client's other rights or remedies, if AAY falls more than [***] below Target Yield in a Contract Year in which Client Processes and/or Packages at least [***] batches of Product for Client, then within [***] days after the end of the applicable Contract Year, Catalent will credit to Client's account the amount of the shortfall, calculated as follows: For non-packaged Product: [(Target Yield - [***]) - AAY] * API cost * Quantity Dispensed.

C. Catalent's liability for API calculated in accordance with this Section 3.4 will be subject to the limits on Catalent's liability set forth in Section 14.2.

9. Section 4.3(A) of the Agreement is hereby deleted in its entirety and replaced with the following:

A. From time to time as provided in this Section 4.3(A), Client shall submit to Catalent a binding, non-cancelable purchase order for (a) Bulk Product specifying the number of Batches to be Processed, the Batch size (to the extent the Specifications permit Batches of different sizes) and the requested delivery date for each Batch and for (b) Packaged Product specifying the number of Bottles to be Processed and the requested delivery date for each Batch (each, a "Purchase Order"). Concurrently with the submission of each Rolling Forecast, Client shall submit a Purchase Order for the Firm Commitment. Purchase Orders for quantities of Product in excess of the Firm Commitment shall be submitted by Client at least [***] days in advance of the delivery date requested in the Purchase Order.

10. The following sentence is added to the end of Section 5.4 of the Agreement:

For clarity, if Catalent replaces Defective Product that is Packaged Product pursuant to 5.4(A) Catalent must also replace the underlying Bulk Product at Catalent's cost.

11. Upon Client's request, Catalent will evaluate and confirm capacity to store Client supplied Bulk Product. Client supplied Bulk Product stored at Catalent for more than [***] days will be subject to Storage Fees as per Additional Fees in Attachment C.

12. The Packaged Product Specifications will be agreed upon prior to commercial manufacturing in accordance with Article 8.

13. Attachment C is hereby deleted in its entirety and replaced with Attachment C attached hereto.

14. Other Terms. Except as otherwise provided in this Second Amendment, the terms of the Agreement shall remain in full force and effect. Any capitalized terms used herein and not otherwise defined will have the same meaning as set forth in the Agreement. In the event of any conflict between this Amendment and the Agreement, the terms of this Amendment will control.

15. Counterparts. This Second Amendment may be executed in two or more counterparts, each of which shall be deemed an original document, and all of which, together with this writing, shall be deemed one instrument. An electronic signature is the legally binding equivalent of a hand-written signature and shall have the same force and effect as an original signature. Signatures delivered by electronic means, and signed counterpart PDFs delivered by email shall have the same force and effect as original signatures.

[signature page follows]

IN WITNESS WHEREOF, the parties have caused their respective duly authorized representatives to execute this Second Amendment effective as of the Second Amendment Effective Date.

Catalent Pharma Solutions, LLC

By: /s/ Michael J. Valazza

Name: Michael J. Valazza

Title: Catalent

ACADIA PHARMACEUTICALS INC.

By: /s/ Bob Mischler

Name: Bob Mischler

Title: SVP, Strategy and Technology Operations

ATTACHMENT C

[***]

Exhibit 10.53

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

MASTER COMMERCIAL MANUFACTURING SERVICES AGREEMENT

This Master Commercial Manufacturing Services Agreement (this "**Agreement**") is effective as of December 10, 2025 (the "**Effective Date**") and is made between Halo Pharmaceutical, Inc., a Delaware corporation ("**Halo**"), and Acadia Pharmaceuticals Inc., a Delaware corporation ("**Client**"). Each of Halo and Client may be referred to in this Agreement as a "**Party**" and together the "**Parties**." The contact information for each Party is included on the signature page of this Agreement.

RECITALS

A. Client develops, markets and sells pharmaceutical products.

B. Halo provides commercial manufacturing, packaging, analytical, and related services to the pharmaceutical industry on a contract basis.

C. Client desires to engage Halo to provide certain such services to Client, and Halo desires to accept such engagement, all on the terms and subject to the conditions set out below.

ARTICLE 1
DEFINITIONS

1.1. **Glossary**. When used in this Agreement, the following capitalized terms have the indicated meanings, with grammatical variations having corresponding meanings:

"**Affiliate**" means any Person that controls, is controlled by, or is under common control with a Party; *provided*, that, except for Noramco US Holdings, Inc. (which is Halo's parent company) and Persons controlled by it, no other Person shall be deemed an Affiliate of Halo hereunder. For the purposes of this definition only, "control" means (a) the ownership, directly or indirectly, of more than fifty percent (50%) of the voting securities or other ownership interest of a Person or (b) the possession, directly or indirectly, of the power to direct the management or policies of a Person, whether through the ownership of voting securities, by contract, or otherwise; with the grammatical variations "controlled by" and "under common control with" having corresponding meanings.

"**Agreement**" is defined in the introductory paragraph of this Agreement.

"**API**" means, with respect to a given Product, the active pharmaceutical ingredient(s) for such Product, whether chemical or biologic in nature, provided (or to be provided) by or on behalf of Client in accordance with this Agreement, as identified on Annex F to a Product Schedule.

"**API Cost**" means, with respect to a given API, Client's actual, documented out-of-pocket cost to purchase or produce such API and deliver it to Halo, a reasonable and good faith approximation of which is set forth on Annex F to a Product Schedule.

"**API Credit Value**" Means the value of the API as stated in Annex F of a Product Schedule

"**API Inventory, Usage and Annual Yield Report**" has the meaning defined in Section 3.3(d)(API Inventory, Usage and Annual Yield Reports).

"**Applicable Law**" means, to the extent applicable, (a) cGMPs as defined in this Agreement (unless the Parties agree in writing to the contrary on a case-by-case basis) and (b) all laws, statutes, ordinances, regulations, rules, judgments, decrees and orders, as amended, of any Authority (i) with respect to Halo and a given Service, applicable to the Services as of the Effective Date, and (ii) with respect to Client, in any jurisdiction in which Client operates or performs activities related to this Agreement and in any jurisdiction in which API or Product is produced, marketed, distributed, made available, used or sold by or for Client. In the context of a past event or circumstance, Applicable Law shall be construed as the Applicable Law that was in effect at the time of such event or circumstance.

"**Authority**" means any governmental authority, department, body or agency or any court, tribunal, bureau, commission or other similar body, whether international, supranational, federal, national, state, provincial, county or municipal with jurisdiction over either Party and/or the subject matter of this Agreement.

"**Batch**" means, with respect to a given Product, a defined quantity of API and Components converted (or to be converted) into a quantity of Product.

"**cGMPs**" means all applicable standards, as amended from time to time, relating to current manufacturing practices for intermediates, bulk products or finished pharmaceutical products (as appropriate), including, but not limited to, current good manufacturing practices promulgated by Regulatory Authorities, as amended, (a) with respect to Halo, in any jurisdiction applicable to the Services as of the Effective Date, and in any other jurisdiction that the Parties agree in writing to include in this clause (a) in accordance with Section 2.3 (Expansion of Territory) (collectively, the "**Manufacturing Jurisdictions**"), and (b) with respect to Client, in any jurisdiction in which Client operates or performs activities in respect of this Agreement and in any jurisdiction in which API or Product is produced, marketed, distributed, made available, used or sold, including, for the avoidance of doubt, the Territory. In the United States, cGMPs include, but are not limited to, 21 C.F.R. Parts 210 and 211 and all applicable rules, regulations, orders and guidance published or adopted by the FDA.

"**Client**" is defined in the introductory paragraph of this Agreement.

"**Client Indemnitees**" is defined in Section 10.2(a) (By Halo).

"**Client Inventions**" is defined in Section 12.2(a) (Client Inventions).

"**Commitment**" is defined in Section 4.1 (Rolling Forecasts).

"**Components**" means, with respect to a given Product, all raw materials, ingredients, Critical Components, Exclusive Components, and packaging (such as, for example only, syringes, tubes, bottles, cartons, labels, product inserts, and containers), other than API, incorporated into or used to produce (or to be incorporated into or to be used to produce) such Product.

"**Confidential Information**" is defined in Section 11.1(a) (Definition).

"**Contract Year**" means three hundred and sixty five (365) days starting on the date of the first approval of a Product in a Product Schedule by a Regulatory Authority in the Territory or if the Product is already

approved by a Regulatory Authority in the Territory at time of the execution of this Agreement then the Contract Year start date is the Effective Date.

"**Critical Components**" means, with respect to a given Product, any Components for such Product that are subject to long procurement lead times, difficult to procure, or unusually expensive, but that are not Exclusive Components.

"**Deficiency Notice**" is defined in Section 6.1(a) (Non-Conforming Product).

"**Discloser**" is defined in Section 11.1(a) (Definition)

"**Dispute**" is defined in Section 13.1 (Escalation).

"**Effective Date**" is defined in the introductory paragraph of this Agreement.

"**Equipment**" is defined in Section 3.5 (Equipment).

"**Evaluation**" is defined in Section 6.1(b) (Evaluation).

"**Exclusive Components**" means, with respect to a given Product, any Components that are unique to such Product (i.e., that Halo does not procure for any other customer or drug product).

"**Facility**" means the manufacturing site operated by Halo Pharmaceutical, Inc. located at [***].

"**Fault**" means a Party's negligence, recklessness, gross negligence, willful misconduct, fraud, violation of Applicable Law, or breach of this Agreement or the Quality Agreement.

"**FDA**" means the United States Food and Drug Administration or any successor thereto.

"**Firm Order**" is defined in Section 4.2(c) (Firm Orders).

"**Forecast**" is defined in Section 4.1 (Rolling Forecasts).

"**Halo**" is defined in the introductory paragraph of this Agreement.

"**Halo Indemnitees**" is defined in Section 10.2(b) (By Client).

"**Halo Inventions**" is defined in Section 12.2(b) (Halo Inventions).

"**Intellectual Property**" means all intellectual property and embodiments thereof, including patents, patent applications, trademarks, trademark applications, tradenames, copyrights, industrial designs, trade secrets, and know-how.

"**Invention**" means any innovation, improvement, development, discovery, method, know-how, process, technique, work of authorship, or similar invention, whether or not written or otherwise fixed in any form or medium and whether or not patentable or copyrightable, that is generated, conceived, or reduced to practice solely by either Party (or any of its employees, independent contractors, subcontractors, or agents), or jointly by the Parties, in connection with this Agreement; and all Intellectual Property rights therein.

"**Inventory**" means, with respect to a given Product, all stocks and inventories of Exclusive Components, Critical Components, and Product-Specific Items purchased, produced, held, or maintained by Halo in accordance with this Agreement solely for such Product, including any excess material purchased by reason of a Third-Party vendor's minimum purchase requirements and any long lead time material. The term Inventory does not include Product (whether work in process or finished) or API.

"**Latent Defect**" means any non-conformity that (a) causes a quantity of Product to be Non-Conforming Product and (b) could not have been detected at the time of quality release of such Product by reasonable visual inspection or the analytical methods used to release such Product.

"**Losses**" is defined in Section 10.2(a) (By Halo).

"**Manufacturing**" or "**Manufacture**" means, with respect to a given Product, the conversion of API and Components into Product intended to meet the Specifications performed (or to be performed) by Halo under this Agreement, from the dispensing of the first Component or API through the quality release (or rejection) of Product (or, if Halo is not responsible for final testing or quality release of Product, through Halo's issuance of a certificate of manufacture). The term Manufacturing includes, as applicable, weighing, compounding, mixing, pressing, coating, filling, finishing, quality control, quality assurance, testing, packaging, labeling, and interim storage.

"**Manufacturing Jurisdictions**" is defined in clause (a) of the definition of cGMPs.

"**Minimum Requirements"** means the minimum annual purchase of Product as set forth in a Product Schedule (The "Minimum Requirement") per Contract Year.

"**Non-Conforming Product**" means Product resulting from Services that fails to meet the warranty set forth in Section 9.3(d) (Product Warranty).

"**Notes**" is defined in Section 11.1(b) (Inclusions).

"**Party**" is defined in the introductory paragraph of this Agreement.

"**Person**" means any natural person, corporation, limited liability company, general or limited partnership, joint venture, proprietorship, trust or other business organization, as well as any Authority.

"**Price**" is defined in Section 5.1(a) (Consideration).

"**Product**" means a pharmaceutical product identified on a Product Schedule, as more specifically described in the Specifications as may be amended from time to time by mutual agreement of the Parties.

"**Product Schedule**" means, with respect to a given Product, the document agreed upon by the Parties and attached to and made part of this Agreement, as may be amended in writing from time to time. Each Product Schedule includes the following annexes, to the extent applicable, and such other annexes as the Parties may agree in writing from time to time (each, an "**Annex**" and, together, "**Annexes**"):

Annex A: Product Description
Annex B: Product Annual Volume, Price and Minimum Requirements
Annex C: Additional Services and Fees
Annex D: Form of API Inventory, Usage and Yield Report

Annex E: Critical Components and Exclusive Components
Annex F: API, & API Cost

"**Product-Specific Items**" is defined in Section 3.6 (Tooling & Supplies).

"**Proprietary IP**" is defined in Section 12.1 (Proprietary Intellectual Property).

"**Purchase Order**" is defined in Section 4.2(a) (Purchase Orders).

"**Quality Agreement**" is defined in Section 7.2 (Quality Agreement).

"Quantity Converted" means the total amount of API contained in the Product Manufactured with the Quantity Dispensed (including any additional Product produced in accordance with Article 6), delivered by Halo, and not rejected, recalled or returned in accordance with Article 6 because of Halo's failure to perform the Services in accordance with Specifications, cGMPs, and Applicable Laws.

"Quantity Dispensed" means the total quantity of API dispensed at the Facility during the applicable year. The Quantity Dispensed is calculated by adding the Quantity Received to the inventory of API that complies with the specifications and is held by Halo at the beginning of the applicable year, less the inventory of API that complies with the specifications and is held by Halo at the end of the year. The Quantity Dispensed will only include API received and dispensed in Manufacturing of Product and will not include any (i) API that must be retained by Halo as samples, (ii) API contained in Product that must be retained as samples, (iii) API used in testing (if applicable), and (iv) API received or dispensed in technical transfer activities or development activities during the applicable period, including without limitation, any regulatory, stability, validation or test Batches Manufactured during the applicable period, in each case of clauses (i) through (iv) in accordance with this Agreement.

"**Quantity Received**" means the total quantity of API that complies with the specifications and is received at the Facility during the applicable year.

"**Recall**" means any action (a) by Client to recover title to or possession of, or to issue a field alert or field correction with respect to, quantities of Product sold or shipped to Third Parties, including any voluntary withdrawal of Product from the market, or (b) by any Regulatory Authority to recall, withdraw from the market, order any corrective action, or otherwise detain or destroy any Product.

"**Recipient**" is defined in Section 11.1(a) (Definition).

"**Records**" is defined in Section 7.3 (Records and Samples).

"**Regulatory Authority**" means any Authority responsible for granting marketing, distribution, and related approvals for pharmaceutical, medicinal, or therapeutic device products intended for human use in the Territory. The term Regulatory Authority includes the FDA as applicable.

"**Representatives**" is defined in Section 11.1(a) (Definition).

"**Rejected Product**" is defined in Section 6.1(c) (Remedies).

"**Services**" is defined in Section 2.1 (Services).

"**Specifications**" means, with respect to a Product, the written specifications for such Product in its final configuration for purposes of this Agreement (e.g., bulk tablets in bags by weight, a quantity of tablets

in bottles with labels and package inserts, etc.), comprised of a list of tests, references to analytical procedures, and appropriate acceptance criteria, which are numerical limits, ranges, or other objective criteria for the tests described, as provided by Client to Halo..

"**Term**" is defined in Section 8.1 (Term).

"**Territory**" shall have the meaning ascribed to such term in the applicable Product Schedule.

"**Third Party**" means any Person that is not a Party or an Affiliate of a Party.

"**Third Party Claim**" is defined in Section 10.2(a) (By Halo).

"**Year**" means, (a) with respect to the first year of this Agreement, the period from the Effective Date up to and including December 31, 2026, (b) with respect to the last year of this Agreement, the period from January 1 of such last calendar year up to and including the date of termination or expiration of this Agreement, and (c) for all periods in between, a calendar year.

1.2. **Conventions**. When used in this Agreement (unless otherwise specified): (a) all monetary amounts are expressed in, and all references to "$" or "dollars" mean, the lawful currency of the United States; (b) the word "including" (with its grammatical variations) means "including without limitation" or "including but not limited to"; (c) the word "Client" includes its Affiliates whenever the context requires or to the extent applicable; (d) the word "days" means calendar days; (e) the word "copy" (with its grammatical variations) includes, to the extent available, electronic copies, files, portals, or databases containing the information to which such word applies; (f) the word "or" is used in the inclusive sense (i.e., and/or) unless prefaced by the word "either" (i.e., "either/or"); and (g) all references to the singular include the plural and vice versa.

ARTICLE 2
ARRANGEMENT

2.1. **Services**. On the terms and subject to the conditions of this Agreement, Halo shall Manufacture Product at the Facility and perform any additional Product-related services on which the Parties may agree in writing from time to time, such as qualification, validation, and stability services as more particularly set forth in the applicable Product Schedule (collectively, "**Services**"). Any such written agreement for additional services shall reference this Agreement, be subject to the terms and conditions of this Agreement and specify, as applicable, the scope, timing, parameters, protocols, fees, and other matters pertinent to such additional services. To the extent the Parties have agreed upon any additional services as of the Effective Date, they are set forth on Annex C of a Product Schedule.

2.2. **Products Schedules**. To allow for the inclusion of multiple Products into this Agreement, the Parties agree to utilize this Agreement as the main terms and conditions between the Parties for the Manufacture of any Product(s) by Halo for Client that will be defined and incorporated into this Agreement as a Product Schedule. Upon entering into a new Product Schedule, the Parties shall concurrently amend the Quality Agreement as appropriate, including to add Specifications for each additional Product.

2.3. **Expansion of Territory**. From time to time during the Term, Client may wish to sell Product supplied hereunder in a country that requires compliance with good manufacturing practices other than those of the then-current Manufacturing Jurisdictions and Territory. In such case, Client shall notify Halo, and the Parties shall discuss in good faith Halo's then-current global regulatory status. If Halo has

not then been approved to Manufacture drug products for sale in such country, Halo will, at Client's request and cost, undertake a cGMP gap analysis and should Halo agree, such agreement not to be unreasonably withheld, to add the additional country to the Territory in writing, Client will pay for any appropriate gap closure activities.

2.4. **Purchases**. Subject to the express terms of this Agreement and unless as otherwise set forth in the applicable Product Schedule, Client shall purchase a minimum of [***] Batches of Product in the first Year of this Agreement and a minimum of $[***] of Product in all other Years during the Term.

2.5. **Subcontracting.** Halo shall not subcontract any of the Services unless approved in advance by Client in writing (email is sufficient), such approval not to be unreasonably withheld. In the event Client approves of any such subcontracting by Halo, Halo shall remain responsible for the performance of any such permitted subcontractor hereunder and for their compliance with the terms and conditions of this Agreement. Halo shall be responsible for any and all payments to such permitted subcontractors. For clarity, Halo utilizes third party analytical testing laboratories to support the portions of analytical testing on Programs that cannot be performed by Halo. Halo will make its approved third-party analytical testing labs known to Client during the development/transfer phase of the program and Halo agrees not to change the testing labs without prior notification and approval of Client.

2.6. **Facility.** Halo shall only Manufacture the Product at the Facility set forth in the applicable Product Schedule. Halo shall be responsible for obtaining, at Halo's sole expense, any facility licenses or permits, and any other regulatory or governmental approvals necessary for the performance of Services under this Agreement.

ARTICLE 3
MANUFACTURING

3.1. **EH&S**. Promptly after execution of a Product Schedule, Client shall provide Halo with all reasonably available or requested environmental, health, and safety information relating to API or Product, including safety data sheets. Client shall promptly provide Halo any updates to such documentation as they become available.

3.2. **Specifications**. Prior to FDA approval of a Product, Client shall provide Halo with a preliminary copy of the Specifications for that Product and Halo may rely upon those preliminary Specifications for the Manufacture of Product prior to Regulatory Authority approval. Prior to Client placing its first Purchase Order for delivery of Product after Regulatory Authority approval, Client shall provide Halo with originally executed copies of final Specifications and any other Product-related information reasonably requested by Halo in connection with the Services. If such final Specifications are different from the preliminary Specifications provided by Client, Section 5.1(d) (Technical Changes) shall apply. Thereafter, Client may revise the Specifications from time to time, subject to Section 5.1(d) (Technical Changes) and such revised Specifications shall be appended to the Quality Agreement.

3.3. **API**.

(a) API Procurement. Client shall, at its sole cost and expense, deliver the API to [***] in such quantities and at such times as the Parties may agree to enable Halo to timely provide the Services on a non-rush basis, but in any event at least [***] days prior to the delivery date specified in the Firm Order for the Batch in which such API will be used, unless otherwise agreed by the Parties in writing. Client shall be responsible at its expense for securing any necessary export or import, or similar clearances or governmental permits required in respect of the provision of API to Halo. Title to and risk

of loss of the API shall at all times remain with Client, and Client will insure the API at Client's cost; provided, however, that, in the event that a Product is a Non-Conforming Product caused by Halo's Fault, Halo shall reimburse Client for the cost of the API used in the replacement Products in accordance with the Shortfall calculation.

(b) API Intake. Halo shall (i) upon receipt of API, compare shipping documents against labeling to verify identity and quantity received, (ii) test API to the extent expressly required by the Quality Agreement, (iii) promptly, and in any event within [***] business days after receipt of API at the Facility (or such other period as may be specified in the Quality Agreement), notify Client if it detects a defect in API and follow Client's reasonable written instructions in respect of return or disposal of defective API, at Client's cost, (iv) store API in a manner designed to avoid adulteration or loss of efficacy and in accordance with the specifications therefor (or Client's other written instructions) and Applicable Law, (v) use API only to provide the Services, (vi) turn over inventory of API in accordance with cGMP to optimize its shelf life, (vii) maintain the API free and clear of any encumbrances imposed as a result of any act or omission of Halo.

(c) API Delay. If Client fails to supply conforming API when required under Section 3.3(a) (API Procurement), Halo reserves the right to, in its discretion, either (i) treat such failure as a cancellation of the applicable Firm Order by Client under Section 4.2(c) (Firm Orders) or (ii) postpone the Manufacturing of all or any part of any Firm Order upon written notice to Client. Halo will promptly notify Client, in any case within [***] business days, in writing of any such election. If Halo elects postponement, Halo shall use its [***] (A) to fill the manufacturing slot that was scheduled for the Product with other customers' orders and (B) to reschedule the postponed Product Manufacturing for the next slot available after Halo's receipt of conforming API. If any such postponement results in idle manufacturing capacity notwithstanding Halo's efforts pursuant to the foregoing clause (A), Client shall pay Halo a reasonable fee to compensate Halo for its opportunity cost.

(d) API Inventory, Usage and Annual Yield Reports. Halo shall provide Client with an annual API Inventory, Usage and Annual Yield report for each API held at a Facility (an "**API Inventory, Usage and Annual Yield Report**") within [***] business days after the end of each calendar year. Each inventory report shall be incorporated into a Product Schedule as Annex D thereto and will be the in the form as per Attachment 1 to this Agreement. After Halo has Manufactured a minimum of ten successful commercial production Batches of Product and has Manufactured Batches for at least [***] months at the Facility (collectively, the "**Target Yield Determination Batches**"), the Parties will agree on the target yield for the Product at the Facility (each, a "**Target Yield**"). The Target Yield will be revised annually to reflect the actual manufacturing experience as agreed to by the Parties.

(e) Shortfall or Overage Calculation. In a Year in which at least [***] Batches of Product were delivered by Halo to Client the Annual Yield (as calculated in accordance with the applicable Annex D) is [***] percent ([***]%) below or above the Target Yield in a Year, then the shortfall or overage for the applicable Year (the "**Shortfall or Overage**") will be calculated as follows:

Shortfall = [(Target Yielded Amount - [***]*% of Target Yielded Amount) – Quantity Converted less Non-Conforming Product] * API Cost per kg*

Overage = [(Target Yielded Amount + [***]*% of Target Yielded Amount)*

*–Quantity Converted less Non-Conforming Product] * API Cost per kg*

(i) Credit for Shortfall. If there is a Shortfall for a Product in a Year, then Halo will credit Client's account for the amount of the Shortfall not later than [***] days after the end of the Year. The maximum credit in any Year in connection with a Shortfall shall be [***] dollars ($[***]).

(ii) Credit for Overage. If there is an Overage for a Product in a Year, then Client will issue a check to Halo for the amount of the overage not later than [***] days after the end of the Year. The maximum payment in any Year in connection with an Overage shall be [***] dollars ($[***]).

(iii) Miscellaneous. Each credit or payment owed under this Section 3.3 will be summarized on the reconciliation report form set forth in Annex D of the applicable Product Schedule. Upon expiration or termination of a Product Schedule, any remaining credit or payment owing under this Section 3.3 will be paid to Client or Halo respectively within [***] days of the expiration or termination of the Product Schedule. The annual Shortfall or Overage, if any, will be disclosed by Halo on the reconciliation report form.

(iv) No Material Breach. It will not be a material breach of this Agreement by Halo under Section 8.2(a) (Breach) if the Annual Yield is less than the Target Yield unless in any Year in which Halo has delivered [***] or more Batches the Annual Yield is more than [***] percent ([***]%) below the Target Yield.

3.4. **Components**.

(a) Procurement. Halo shall purchase all Components as required by the Specifications and as further described in this Section 3.4 (Components) from vendors identified in the Quality Agreement or otherwise agreed to in writing by the Parties. Halo shall test all Components after receipt at the Facility to the extent required by the Quality Agreement.

(b) Reliance on Forecast. Client understands and acknowledges that Halo will rely on the Forecast, Commitment and Firm Orders to procure the Components necessary for Halo to fulfill its obligations to supply Product under this Agreement. Accordingly, Client authorizes Halo to purchase Components sufficient to timely satisfy Client's Product requirements set forth in the first [***] months of Client's most recent Forecast or for any longer period of the Forecast as required to secure Components with a standard lead time greater than [***] months.

(c) Critical Components and Exclusive Components. Set forth on Annex E to the applicable Product Schedule is a list of Critical Components and Exclusive Components that Halo expects to purchase under this Agreement. Halo shall provide Client with a purchasing summary of all Critical Components and Exclusive Components, consistent with the Product volumes set forth in the then-current Forecast, Commitment and Firm Orders, as follows: (i) an initial version following the signing of this Agreement, (ii) a revised version following receipt of final Specifications, and (iii) thereafter, an updated version on an annual basis. The list set forth on Annex E to the applicable Product Schedule and each purchasing summary shall indicate those Critical Components and Exclusive Components that have a limited shelf life and/or minimum order quantities. Client shall reimburse Halo its documented costs for procuring and testing all Critical Components and Exclusive Components purchased by Halo

in accordance with this Section 3.4 (Components) that are not used to perform Services by the earlier of (A) [***] months after the Forecasted month in respect of which such purchases were made and (B) expiration of the Critical Component's or Exclusive Component's shelf life. In accordance with the Quality Agreement, Halo shall be responsible for auditing and qualifying all Critical Component and Exclusive Component vendors, for clarity this does not include the API supplier for which Client will audit and qualify accordingly.

(d) Delays. Halo shall not be liable for any delay in delivery of Product if Halo is unable to obtain any Component in a timely manner provided Halo placed orders for such Component in accordance with this Section 3.4 (Components) and the vendor's ordering policies, including any minimum order quantities and lead times.

3.5. **Equipment**. Halo shall provide at its sole cost all machinery, devices, computers, software, and other equipment not specific to Product (collectively, "**Equipment**") needed to perform the Services at volumes defined in Annex B to the applicable Product Schedule, subject to the following:

(a) Prior Arrangements. If, prior to the Effective Date, Halo was aware that it required any Equipment that it did not own in order to perform the Services, and the Parties agreed for Client to bear all or any portion of Halo's costs to procure, install, qualify, or validate such Equipment, such agreement (including the intended disposition of such Equipment upon expiration or termination if this Agreement) shall be set forth on Annex C to the applicable Product Schedule.

(b) Arrangements for Changes. If, after the Effective Date, Halo requires Equipment that it does not own due to proposed changes in or expansion of the Services, material increases in Client's Forecasts, as compared to the immediately preceding Forecast, or other such circumstances, Halo shall promptly notify Client. Only if Halo requires Equipment that it does not own due to proposed material changes in or expansion of the Services or material increases in Client's Forecasts, as compared to the immediately preceding Forecast, then the Parties shall negotiate in good faith an appropriate solution, which may include an allocation between themselves of the costs to procure, install, qualify, and validate additional Equipment; *provided*, that if such solution involves new Equipment dedicated solely to Client, such dedicated Equipment may be either (i) purchased by Halo and charged through to Client at Halo's actual cost plus a [***] percent ([***]%) administrative fee or (ii) purchased directly by Client and supplied to Halo [***] at Client's sole cost. Any resulting agreement (including any use by Halo of such dedicated Equipment for other customers and the intended disposition of any co-funded Equipment upon expiration or termination if this Agreement) shall be set forth on Annex C to the applicable Product Schedule, amended in accordance with Section 14.7 (Amendments).

3.6. **Tooling & Supplies**. To the extent not already in Halo's possession, Halo shall purchase all tooling, change parts, consumables, reference standards, and any other Product-specific items that are reasonably necessary for Halo to perform the Services but that do not comprise API, Components, or Equipment (collectively, "**Product-Specific Items**"). All Third Party vendor fees for such purchases shall be pre-approved in writing by Client and charged through to Client at Halo's actual cost plus a [***] percent ([***]%) administrative fee.

3.7. **Packaging**.

(a) Artwork & Content. Client shall be solely responsible for the development of all artwork and labeling in connection with Product packaging, including all associated content and Intellectual Property matters. Client may, in its sole discretion and at its cost, make changes to Product packaging,

including labels, inserts and cartons, subject to Section 5.1(d) (Technical Changes). Halo's name shall not appear on any Product packaging without Halo's prior written consent.

(b) Packaging Services. Halo shall package Product as and to the extent required by the Specifications. For clarity, packaging may be in bulk or in secondary packaging. Halo shall be responsible for imprinting or affixing the batch number, U.S. Drug Supply Chain Security Act serialization code (to the extent required by Applicable Law), and expiration date of each Batch onto the Product packaging and shipping cartons as described in the Specifications and required by the Quality Agreement and Applicable Laws.

3.8. **Quality Control**.

(a) Batch Number. Halo will assign each Batch a unique batch number using Halo's batch numbering system. This batch number will appear on all documents relating to the Batch. Halo will calculate the expiration date of each Batch of Product based on the date on which Halo added the API to the blending process during Manufacture of the applicable Batch of Product and based on the Client-provided expiry period of such API.

(b) Halo Quality Release. Halo shall perform Product quality control and quality assurance testing as and to the extent required by the Quality Agreement. Batch review and release to Client shall be the responsibility of Halo's quality assurance group. Halo shall perform such Batch review and release responsibilities in accordance with Halo's standard operating procedures. Client shall review and respond to any Batch investigational report provided by Halo in the timeframe provided in the Quality Agreement. Each time Halo delivers a Batch to Client, Halo shall provide Client with a certificate of compliance and/or analysis, as applicable, and any other certificates or Batch documentation that the Quality Agreement requires Halo to provide at the time of Product delivery. At Client's reasonable request, Halo will provide copies of additional Batch documentation, such as Batch manufacturing records, equipment data printouts, raw material data, and laboratory notebooks.

(c) Client Quality Release. Client shall have sole responsibility for the release of Product to the market.

(d) Post Marketing Stability Testing. At Client's request, in consideration of the fees set forth on Annex C to the applicable Product Schedule, Halo shall conduct post marketing stability testing on Product in accordance with such commercial and Product stability protocols as the Parties may agree in writing pursuant to Section 2.1 (Services).

3.9. **Product Discontinuation**. Client shall use [***] to provide at least [***] months' advance notice to Halo if it intends to no longer order Services for a Product due to its election to discontinue or otherwise withdraw any Product from all or part of any market.

3.10. **Supply Shortages and Safety Supplies**.

(a) Supply Shortage. A "Supply Shortage" shall be deemed to have taken place if quantities of conforming Product supplied by Halo to Client on or before or within [***] days after the scheduled delivery date are less than [***]% of the quantities specified in Firm Orders issued by Client, over a period of [***] consecutive months, unless such shortage is the result of any one or more of the following reasons: (i) a lack of availability of API due to Client's failure to supply such API on a timely basis, (ii) defects in the API as of the date it is delivered to Halo by Client or its designee, which is not reasonably discoverable by Halo by visual inspection and testing as required under Section 3.4 (Components), (iii)

a significant increase in Client's Forecast for Product that results in a shortage of any Components, or (iv) any Force Majeure Event. A Supply Shortage shall be considered a material breach of this Agreement, but such breach shall be deemed cured upon tender of delivery by Halo of conforming Product within the applicable cure period.

(b) Failure to Supply. At any time during the Term following the date of the first Firm Order under this Agreement, in the event a Supply Shortage, which shall include the provision of Non-Conforming Product, Client may, in its sole discretion and by providing written notice to Halo, indicate its election to immediately reduce the applicable Minimum Requirement and applicable purchase requirement in Section 2.4 (Purchases) by an amount equal to the value of the Product not supplied, as such value is set forth in the applicable Product Schedule.

(c) Failure to Meet Specifications. Upon Halo's discovery that there is a potential for any Batch or lot of Products (in-process, released and/or marketed) to fail to conform to the Specifications at the time of delivery to Client, Halo will promptly notify Client of the discovery thereof and of the nature thereof in detail, including supplying Client with all investigatory reports, data and communications, out-of-specification reports and data and the results of all outside laboratory testing and conclusions, if any. Halo shall investigate all such failures promptly as set forth in the Quality Agreement, and at its expense (unless such failure is due to supply of defective API to Halo hereunder, in which case the expense will be borne by Client), cooperate with Client or its designee in determining the cause for the failure and a corrective action to prevent future failures.

(d) Safety Supplies. Halo shall maintain an inventory of API and Components (or have ordered Components or notified Client that more API is required to Manufacture the Commitment volumes, in each case, so far in advance that Client would reasonably expect Halo to timely deliver Product in accordance with the then-current Forecast) that would reasonably be expected to suffice for Halo to meet Client's then-current Forecast. Halo shall turn over all such safety supplies as new API and Components are received or new lots of Product are delivered, respectively, to optimize the shelf life of such safety supplies. Halo shall promptly notify Client in writing at any time if it reasonably anticipates that additional amounts of API will be needed for Halo to meet Client's then-current Forecast. If Halo reasonably believes that it is or will be unable to obtain a sufficient supply of Components from Third Party vendors for Halo to meet Client's then-current Forecast, Halo shall promptly notify Client in writing and the Parties will collaborate and jointly determine a plan to engage the suppliers to secure an adequate supply of such Components. Should Halo purchase Components to meet Client's Forecast and Client then drops the Product volumes in the Commitment period such that Halo will no longer be able to consume the Components during Manufacturing within a [***] month period, Halo may charge Client for the Components purchased and are now in excess and should the Components be consumed in future Manufacturing, Halo will issue a credit back to Client for the Components on a unit basis at time of Product invoicing.

ARTICLE 4
FORECASTS, ORDERS & SHIPMENT

4.1. **Rolling Forecasts**. Concurrently with the signing of this Agreement, Client shall provide Halo with a written [***] month forecast setting forth the volume of each Product that it expects Halo to supply during each month of such period (the "**Forecast**"). Thereafter, Client shall provide Halo with an updated Forecast on or before the [***] day of each calendar month. The first [***] months of each Forecast shall be binding on Client (the "**Commitment**"), and the balance shall be a non-binding, good faith estimate.

4.2. **Orders**.

(a) Purchase Orders. Concurrently with Client's submission to Halo of the first Forecast pursuant to Section 4.1 (Rolling Forecasts), Client shall submit to Halo a binding, non-cancellable purchase order identifying an order number, the Product to be Manufactured, the number of Batches, the Batch size (to the extent the Specifications permit Batches of different sizes), Client's requested delivery date for each Batch, and any other elements reasonably necessary to ensure the timely production and delivery of Product (each, a "**Purchase Order**") covering the entire Commitment of such Forecast. Thereafter, concurrently with the submission to Halo of each updated Forecast, Client shall submit a Purchase Order for all portions of the Commitment not previously ordered and the [***] month of such Purchase Order shall not be for Product volumes in excess of an additional [***] Batches from the previous month's Forecast's [***] month and the total number of Batches ordered for such month shall not exceed the defined maximum monthly volume in Annex B of the Product Scheule. For clarity, Halo's ability to supply this additional volume is dependent upon its ability to secure any additional Components and API necessary to fulfill the requested order.

(b) Minimum Order Quantity. Subject to any greater or lesser minimum order quantities provided for in Annex B of the applicable Product Schedule, each Purchase Order submitted by Client shall be for at least 1 full Batch and be in full Batch increments.

(c) Firm Orders. Halo will confirm in writing each Purchase Order, including the Product, quantity, and expected delivery date, within [***] business days after receipt, provided that if Client receives no written communication from Halo within [***] business days of receipt of the Purchase Order, the Purchase Order will be deemed accepted by Halo. If Halo is unable to meet the delivery date requested by Client in its Purchase Order, Halo shall so notify Client in Halo's confirmation of such Purchase Order and provide to Client an alternative delivery date, which shall not be more than [***] business days earlier or later than the initial delivery date requested by Client in its Purchase Order. Only upon Halo's confirmation, or deemed acceptance as set forth above, of Client-issued Purchase Orders will such orders become firm (each, a "**Firm Order**"). Halo may change the expected delivery date of any Firm Order within a [***]-day window upon written notice to Client. Halo may not change the quantity of Product in any Firm Order except with Client's prior written approval; provided, that Client shall accept any minor change in quantity delivered due to normal yield variation. Client may not cancel or modify any Firm Order without Halo's prior written consent; provided, that Client may cancel any Firm Order without penalty or other liability if (i) Halo is unable to meet the delivery date requested by Client in its Purchase Order within [***] days earlier or later than the initial delivery date requested by Client in its Purchase Order or (ii) a Supply Shortage then exists; unless any failure by Halo to meet such delivery date or such Supply Shortage is due to a failure to supply API on a timely basis to Halo hereunder. Halo will use its [***] to accommodate any such Client request for cancellation or modification; however, Halo reserves the right to condition its consent to any such Client request on Client's payment of the full Price of the cancelled Batches, less the cost of any Components not used because of such cancellation.

(d) Rejection; Excess Volume. Halo may only reject any Purchase Order without penalty or liability to Client if (i) such Purchase Order is for Product quantities in excess of the Commitment, or (ii) such Purchase Order is not given in accordance with this Agreement. Notwithstanding the foregoing, Halo shall use [***] to supply Client with quantities of Product that are up to [***] percent ([***]%) of Commitment quantities, subject to Halo's other supply commitments and manufacturing, packaging, and equipment capacity.

4.3. **Shipment.** Halo shall deliver Product to Client or its designee [***] and at Client's request, Halo will load the Product onto Client's carrier's vehicle strictly as a courtesy and not as part of delivery. Risk of loss shall transfer to Client in accordance with such Incoterm or, if Product is moved into storage at the Facility, upon transfer of Product into storage. To the extent not already held by Client, title shall transfer to Client concurrently with risk of loss. Halo shall pack and label shipping containers in accordance with Applicable Law and transport guidelines, the Specifications, and Client's written instructions (to the extent not inconsistent with any of the foregoing). Client shall arrange for insurance and shall select the freight carrier to be used to ship Products.

4.4. **Storage**. If Client fails to take possession of Product or any materials or Product produced as part of the registration of the Product or ongoing support of the Product upon tender of delivery under Section 4.3 (Shipment), Halo will move Product into storage at the Facility. Such storage shall comply with cGMP, the Specifications, and Client's written instructions. Storage shall be free of charge for the first [***] months following Product release by Halo's quality group. Client shall thereafter pay Halo the monthly storage fee set forth in Annex C of the applicable Product Schedule for storing such Product. Upon [***] weeks written notice to Client in accordance with Section 14.4 (Notices) and acknowledgement of receipt by Client, Halo may ship to Client, at Client's cost, (a) any released Product that has been held by Halo in storage longer than [***] months and (b) any API, Critical Components or Exclusive Components that have been held by Halo in inventory longer than [***] months and that are not reasonably expected to be needed for Halo to Manufacture Product based on Client's then-current Forecast.

ARTICLE 5
PRICING & PAYMENT

5.1. **Price for Manufacturing Services**.

(a) Consideration. Subject to the terms of this Agreement, Client shall pay Halo the total per-unit price set forth on Annex B of the applicable Product Schedule, as the same may be adjusted in accordance with this Agreement (the "Price"), for Manufacturing Product.

(b) Annual Price Adjustments. Effective on January 1 of each Year, the Price shall be adjusted as follows: (i) the portion of the Price in the "Conversion Fee" column of Annex B of the applicable Product Schedule shall be adjusted to reflect inflation, which adjustment shall be based on the increase in the U.S. Producer Price Index (PPI) for Pharmaceutical Preparations PCU325412325412 published by the U.S. Department of Labor, Bureau of Labor Statistics, in September of the then-current Year compared to the same month of the preceding Year, and (ii) the portion of the Price in the "Component Cost" column of Annex B of the applicable Product Schedule shall be adjusted to reflect actual, out-of-pocket, documented changes in Component costs plus a [***]% administrative charge so as to pass on to Client the actual amount of any increase or decrease in such costs. Halo shall provide in writing to Client by August 1 of each Year the updated Price for the subsequent Year, with reasonable supporting documentation. Such revised Price shall be effective with respect to any Product delivered by Halo after December 31st of the then-current Year.

(c) Current Year Price Adjustments. During any Year, the Price shall be adjusted in accordance with this Section 5.1(c) to reflect extraordinary increases or decreases in Component costs (whether individually or in the aggregate) due to market conditions. An extraordinary increase or decrease shall be deemed to have occurred if the cost of foil has increased or decreased by [***]% or more or if the aggregate cost for all Components of a given Product increases or decreases by [***]

percent ([***]%) or more of the total Component costs for such Product upon which the most recent fee quote was based. To the extent that a Price has been previously adjusted pursuant to Section 5.1(b) (Annual Price Adjustments) or this Section 5.1(c) to reflect an extraordinary increase or decrease in the cost of one or more Components, the adjustments provided for in this Section 5.1(c) shall operate based on the costs attributed to such Component(s) at the time the last such adjustment was made. Halo shall provide the revised Price to Client in writing, with reasonable supporting documentation. Such revised Price shall be effective with respect to any Product delivered by Halo on or after the [***] day of the month following Client's receipt of Halo's adjustment notice.

(d) Technical Changes. Amendments to a Product's master batch record, Specifications or the applicable Quality Agreement requested by either Party will be implemented only after a technical and cost review by the Parties and are subject to Client and Halo reaching agreement on appropriate revisions to the Price and any other impacted fees, allocation of costs, and a timeframe for implementation by Halo. If the Parties agree to proceed with such amendment and Client accepts a proposed fee revision, the Parties shall memorialize the amendment in writing (and where the amendment is to Specifications, Client shall provide Halo with originally executed copies of such revised Specifications), Halo shall implement the proposed amendment on the agreed timeframe, and the revised fee shall apply only to Products that are Manufactured under the amended master batch record, Specifications or Quality Agreement, as applicable. Client shall purchase from Halo all Product (whether finished or work-in-process) Manufactured by Halo against Firm Orders and all Inventory rendered obsolete because of such amendment.

5.2. **Supplemental Charges**.

(a) Taxes. All taxes, duties, assessments, deductions, withholdings, and other charges imposed by any Authority specifically with respect to API, Product, Services, or other amounts due hereunder (excluding tax based on Halo's net income or real property) are the responsibility of Client. Halo shall reasonably cooperate with Client to utilize any legally available tax reductions or exemptions.

(b) Annual Product Review. Halo shall have the right to charge Client the annual product review fee set forth on Annex C of the applicable Product Schedule for the services provided pursuant to Section 7.4 (Data and Reports).

(c) Product-Based Fees. If a Product is a "generic" drug, Halo shall have the right to charge Client the following: (i) as a contribution towards amounts payable by Halo to the FDA under the Generic Drug User Fee Amendments of 2012, as amended and reauthorized from time to time, the GDUFA fee set forth on Schedule B; and (ii) a pro rata share of any similar fees imposed by any Regulatory Authority in any other country in the Territory. If a Product is not a generic drug, this provision shall not apply with respect to that Product. If, after the Effective Date, any Regulatory Authority in a country in the Territory imposes any new fees on the pharmaceutical industry (or any subset thereof that includes Halo) that are a result of Halo's Manufacture of a Product, Halo shall have the right to charge Client a pro rata share of such fee.

(d) Retesting. Halo reserves the right to charge Client for retesting and required investigational studies performed that are not directly due to Halo's Fault; provided, however, that any testing performed pursuant to this Agreement to determine each Party's fault shall not be charged until it is finally determined that any Non-Conforming Product or Product that otherwise does not meet the applicable Specifications was not due to Halo's Fault. Any tests or investigations requested by Client

that are not required pursuant to the Quality Agreement will be charged to Client at Halo's then-current documented standard rates.

5.3. **Invoicing**.

(a) Recipient. Halo shall send invoices by email to: [***].

(b) Product Invoices. If Halo is responsible for Product release testing under the Quality Agreement, Halo shall invoice Client for Product on the date on which Halo notifies Client that Product is released by Halo's quality assurance department and is ready for shipment. If Halo is not responsible for Product release testing under the Quality Agreement, Halo shall invoice Client for Product upon completion of Manufacturing and issuance of certificate of manufacture. Each Product invoice shall, to the extent applicable, identify Client's Purchase Order number, Batch numbers, Product names and quantities, Price, freight charges and the total amount to be remitted by Client. Halo shall also submit to Client with each shipment of Product an invoice covering such shipment. Invoices for Product that incorporates any Component for which Client has pre-paid (e.g., under Section 5.3(c) (Component Reimbursement), Section 5.4 (Payment Terms), or 5.6 (Launch Stocks)) shall reflect a credit for the applicable pre-payment amount.

(c) Component Reimbursement. Halo shall invoice Client for any reimbursement to which Halo is entitled under Section 3.4(c) (Critical Components and Exclusive Components) when the applicable Component has not been used within the required period or has expired. Halo shall deliver to Client documentation reasonably sufficient to support the amount of such reimbursement; *provided*, that Halo shall not be obligated to provide specific pricing information regarding any Component that is subject to confidentiality obligations between Halo and its vendor that prohibit the sharing of any such information. In respect of any unused, but unexpired, Components reimbursed by Client hereunder, to the extent such Components are incorporated into or used in connection with Product after such reimbursement, Halo will credit Client for the amount reimbursed to Halo.

(d) Other Amounts. Halo shall invoice Client for all other amounts due under this Agreement (such as in connection with stability testing or reimbursement of pass-through costs provided for herein) as and when earned or accrued. Any fees assessed on an annual basis will be invoiced as of the [***] day of each Year. Each such invoice shall reference this Agreement and identify in reasonable detail the nature of the charges therein.

5.4. **Payment Terms**. Client shall pay all invoiced amounts that are not subject to a good faith dispute by Client in full within [***] days following Client's receipt of the invoice. Client shall make payment in (and all prices, fees and charges set forth in this Agreement are quoted in) U.S. dollars to the account indicated in the applicable invoice. If any undisputed payment is not received by Halo by its due date, Halo shall have the right, in addition to any other remedies available at law or in equity, to suspend performance until all undisputed overdue amounts are paid in full (during which period, Halo's Manufacturing and delivery obligations shall be tolled), to charge Client interest on the outstanding sum from the due date (both before and after any judgment) at (i) [***] percent ([***])% per month during the first [***] days past due, and (ii) [***] percent ([***]%) per month thereafter, (or, in either case (i) or (ii), if less, the maximum amount permitted by Applicable Law) until paid in full, and/or require Client to pre-pay for Components to be procured by Halo.

5.5. **Validation and Engineering Batches**. Client will be responsible to pay for all engineering or validation Batches and related Services required to get the Product approved by any Regulatory

Authority. Client is also responsible to pay for any engineering or additional validation activities and related Services to meet any required Specification changes, qualify second sources of API or Components, scale up Batches if so requested by Client or to meet any Regulatory agency requirements. Halo will be responsible to pay for any engineering or validation Batches or related Services, with Client supplying the required API, related to any changes in Halo equipment used to Manufacture the Product or Halo-requested scale up Batches as agreed to by Client in writing.

5.6. **Launch Stocks**. Notwithstanding anything to the contrary in this Agreement, Client shall pay in advance for quantities of Exclusive Components, Critical Components and Product-Specific Items required for commercialization of the applicable Product prior to Halo ordering these supplies. This amount will be invoiced separately and due [***] days after Client's receipt of the invoice. Invoices issued to Client for Product manufactured using pre-paid Exclusive Components or Critical Components will reflect a credit for the applicable portion of the pre-payment.

ARTICLE 6
PRODUCT CLAIMS & RECALLS

6.1. **Product Claims**.

(a) Non-Conforming Product. Client has the right to reject any portion of any shipment of Product that is alleged to be Non-Conforming Product without invalidating any remainder of such shipment. Upon receipt of each Product shipment under this Agreement, Client shall visually inspect each Batch and perform any testing that the Quality Agreement requires Client to perform. Client shall give Halo written notice of any claim that a Batch is Non-Conforming Product and a sample of the allegedly Non-Conforming Product (together, a "**Deficiency Notice**") within [***] days after Client's receipt of such Batch or, in the case of a Latent Defect, within [***] days after Client's discovery of the Latent Defect, but in no event after the expiration date of the Batch in question. If Client fails to timely provide Halo with a Deficiency Notice for a Batch in accordance with this Section 6.1(a), Client shall be deemed to have accepted such Batch. If Halo agrees with Client's assertions in a Deficiency Notice, then the Product identified in such Deficiency Notice shall be deemed properly rejected for purposes of this Section 6.1. If Halo disagrees with a Deficiency Notice, then Section 6.1(b) shall apply.

(b) Evaluation. If Halo disagrees with a Deficiency Notice, Halo shall give Client written notice of such disagreement within [***] days after receiving the Deficiency Notice. If, within [***] days after Client's receipt of Halo's disagreement notice, Client and Halo fail to agree as to whether each Batch identified in the Deficiency Notice is Non-Conforming Product, the Parties shall mutually select an independent laboratory or qualified person, as appropriate, to evaluate whether such Products are Non-Conforming Product and the cause of any non-conformity (the "**Evaluation**"). The Evaluation shall be binding on the Parties. If the Evaluation confirms that a Batch is Non-Conforming Product (or if Halo does not timely disagree with a Deficiency Notice), then the applicable Batch shall be deemed properly rejected for purposes of this Section 6.1 and Halo shall bear the cost of the Evaluation. If the Evaluation determines that a Batch is not Non-Conforming Product, then Client shall be deemed to have accepted such Batch and Client shall bear the cost of the Evaluation.

(c) Remedies. In respect of any Batch properly rejected under this Section 6.1 as Non-Conforming Product ("**Rejected Product**"), Halo will, in its reasonable discretion, (i) to the extent permitted by cGMPs, rework or reprocess the Rejected Product at Halo's sole cost, (ii) replace the Rejected Product at Halo's sole cost, so long as Client provides the necessary API, or (iii) credit Client's account for the invoiced Price for the Rejected Product. In the case of clause (i) above, Halo shall pay

for the return shipping of the Rejected Product to the Facility. In the case of clause (ii) or (iii) above, Halo shall reimburse Client for either the cost of destroying Rejected Product or return shipping of the Rejected Product to the Facility, so long as Client destroys or returns the Rejected Product as instructed by Halo; provided, further that Halo shall be responsible for the cost of any replacement API necessary for re-performance by Halo in accordance with the Annual API Yield calculation.

(d) Validated Testing. Any tests conducted by Client under Section 6.1(a) (Non-Conforming Product) or by a Third Party as part of any Evaluation shall employ only the then-current validated methods and procedures required to be used by Client or Halo, as applicable, under the Specifications or Quality Agreement.

6.2 **Product Recalls**. Each Party shall promptly notify the other Party by telephone (confirmed by written notice) of any information of which it becomes aware that might affect the safety, efficacy, or marketability of any Product and/or that could reasonably be expected to result in a Recall. The conduct of and regulatory filings for any Recall shall be controlled, implemented, and made by Client, and Halo will co-operate in such Recall as reasonably requested by Client, having regard to all Applicable Law. Client shall provide Halo with an advance copy of any proposed submission to a Regulatory Authority in respect of any Recall and shall consider in good faith any comments from Halo. Client shall bear the cost of any Recall and reimburse Halo for the expenses incurred by Halo in connection with any Recall, unless such Recall is a Class 1 Recall required by the FDA or the equivalent Regulatory Authority caused solely by Halo's Fault and conducted in the Manufacturing Jurisdiction and/or Territory , in which case Halo will reimburse Client for Client's reasonable, actual, and documented out-of-pocket costs of conducting such Recall in such Manufacturing Jurisdiction and/or Territory and bear the expenses incurred by Halo in connection with such Recall in such Manufacturing Jurisdiction and/or Territory, not to exceed the lesser of: (i) [***] times the payments paid by Client to Halo for Services related to the Product being recalled over the previous Year or (ii) the maximum amount of liability set forth in Section 10.1(c)(Maximum Liability). For clarity, to the extent that a Recall involves Product that is alleged to be Non-Conforming Product, the Parties' respective rights and remedies with respect to such Product (including destruction costs) shall be governed by Section 6.1 (Product Claims). As it relates to any third party claims associated with a Recall that is caused solely by Halo's Fault and conducted in the Manufacturing Jurisdiction and/or Territory, Halo's maximum liability shall not exceed the lesser of (i) [***] times the payments paid by Client to Halo for the Services related to the Product being recalled over the previous Year or (ii) the maximum amount of liability set forth in Section 10.1(c)(Maximum Liability).

6.3 **Disposition of Product**. Client shall not use or sell any Product that does not, or that Client has reason to believe does not, meet the Specifications or comply with Applicable Law. Client shall not, without Halo's prior written consent, (a) destroy or otherwise dispose of any Products in relation to which it intends to assert a claim against Halo as being Non-Conforming Products or Recalled Products or (b) return any Product to Halo.

6.4 **Customer Inquiries**. Client shall have the sole responsibility for responding to questions and complaints from Client's customers, for handling customer returns of Product and for all other pharmacovigilance activities. Halo will promptly refer to Client in writing any questions or complaints that it receives from Client's customers in accordance with this Section 6.4. At Client's request and cost, Halo shall reasonably co-operate with Client to allow Client to determine the cause of, respond to, and resolve any customer questions and complaints.

6.5 **Limitations**. For the avoidance of doubt and without limitation, errors in Services, non-conformities in Product, and other Losses caused solely by any of the following shall not be deemed Halo's Fault: (a) incorrect, unlawful or deficient Specifications (including artwork and labeling) provided or approved by Client; (b) defects in API that Halo could not reasonably discover by visual inspection or testing required under Section 3.3(b) (API Intake); (c) actions of Client, its Affiliates, or Third Parties occurring after possession of Product is transferred to Client's common carrier under Section 4.3 (Shipment), including Product distribution and commercialization activities (specifically including mishandling and off-label marketing); (d) any breach of Client's obligations, representations, warranties or covenants under this Agreement; or (e) problems with safety, efficacy or marketability of Product that occur even when the Product meets the Specifications.

6.6 **Sole Remedy. Except for Halo's indemnity obligations under Section 10.2(a) (By Halo), and subject to the limitations expressly set forth in this Agreement (including Section 10.1 (Limitation of Liability)), the remedies described in this Article 6 (Product Claims & Recalls) shall be Client's sole remedy and Halo's sole obligation in connection with any Non-Conforming Product.**

ARTICLE 7
COOPERATION

7.1. **Liaisons; Quarterly Review**. Promptly after the Effective Date, each Party shall appoint one of its employees to be a relationship manager responsible for liaising between the Parties with respect to the Products. The relationship managers shall meet quarterly to review the status of the business relationship and manage any issues that have arisen. The Parties shall cooperate in good faith to ensure a stable supply of Product to Client within the terms of this Agreement by timely providing relevant information to one another through the relationship managers.

7.2. **Quality Agreement**. As soon as reasonably practicable after entering into a Product Schedule, and in any event prior to Client's submission of its first Purchase Order, either (a) the Parties shall negotiate in good faith and enter into an agreement setting out the quality assurance standards and protocols applicable to the Services and the Parties' responsibilities in respect thereof or (b) if the Parties have already entered into such an agreement, the Parties shall review and amend such agreement as necessary to ensure that it covers the Products and Services (in either case, the "**Quality Agreement**"). The Parties acknowledge and agree that the Quality Agreement is required by Applicable Law and is intended only to assign responsibility for performance of quality-based activities relating to the Services. As such, (i) the Quality Agreement shall not determine a Party's financial responsibility for the performance or non-performance of the responsibilities set forth therein, (ii) any breach of the Quality Agreement by a Party shall be deemed a breach of this Agreement and subject to the terms and conditions of this Agreement, including Article 10 (Indemnities & Insurance), and (iii) neither Party shall have a cause of action for breach of the Quality Agreement except as a cause of action for breach of this Agreement. In the event of a conflict between any of the provisions of this Agreement and the Quality Agreement with respect to quality-based activities, the provisions of the Quality Agreement shall govern. In the event of a conflict between any of the provisions of this Agreement and the Quality Agreement with respect to any commercial matters, including allocation of risk, liability and financial responsibility, the provisions of this Agreement shall govern.

7.3. **Records and Samples**. Halo shall timely prepare and maintain complete and accurate records of the Manufacture, testing, storage, and shipping of Product, including master batch records, completed Batch records, quality control documentation, and results of acceptance tests performed (collectively, "**Records**"), and retain samples of Product, in accordance with its standard operating procedures, the

Quality Agreement, and Applicable Law, as well as to assist with resolving any Product Complaints and other similar investigations. The Records shall be and hereby are owned by Client. For clarity, Halo shall retain physical custody and control of all original Records required to be maintained at the Facility in accordance with cGMPs, and Client's ownership refers to the Records' informational content and use rights. Unless and to the extent otherwise expressly required by the Quality Agreement or Applicable Law, Halo shall keep Records and retain samples for each Batch for a period of [***] following the expiration date of such Product. Halo shall not destroy Records without providing Client reasonable advanced written notice of its intention to do so (including by delivering written notice in accordance with Section 14.4 (Notices)) to offer Client the opportunity to take delivery and possession of such Records at Client's cost.

7.4. **Data and Reports**. On an annual basis, to the extent not previously provided to Client during the Year, Halo will provide Client with a copy of Product data in its control as specified in the Quality Agreement (such as release test results, complaint test results, and investigations in manufacturing, testing and storage) for purposes of enabling Client to complete any filing required by the FDA or DEA for the applicable year. Notwithstanding the foregoing, if the Quality Agreement requires, or Client requests, that Halo perform and provide Client with an "annual product review" or "annual product quality review", Halo will be entitled to charge Client the associated fee set forth on Annex C of the applicable Product Schedule. Further, any certificates, Batch documentation, data or reports requested by Client that are not required to be provided pursuant to the Quality Agreement or this Agreement, including multiple copies of information previously provided, shall be subject to an additional fee to be agreed upon by the Parties. For the avoidance of doubt, in accordance with the Quality Agreement, Client shall have the right to conduct an onsite or remote analytical data review at least every [***] years.

7.5. **Client Inspections**. Unless and to the extent otherwise expressly provided in the Quality Agreement, the following procedures shall apply: Once every [***] years (or, (i) if requested more frequently by Client without cause, for the associated fee set forth on Annex C of the applicable Product Schedule (ii) if for cause, more frequently as reasonably agreed by the Parties), upon at least [***] days' prior written notice, Halo shall grant Client access, during normal business hours, to (i) areas of the Facility in which API, Product or any intermediaries thereof is Manufactured, handled, stored or shipped (ii) inspect the materials used in the Manufacture of Products, (iii) the holding facilities for such materials, including the API and the Products, (iv) the Equipment used in the Services, and (v) all records relating to such Services and the Facility in order to verify that Halo is performing the Services in accordance with the Specifications and cGMPs. During any such inspection, Halo shall also permit Client to inspect Records, samples, and reports relating to this Agreement. The Parties' relationship managers shall arrange such inspections. Inspections shall be designed to minimize disruption of operations at the Facility and shall be limited to 2 Client representatives for up to [***] consecutive days. A Halo representative shall be present at all times during each inspection. Client's representatives shall comply with the Facility's reasonable and documented rules. Client shall indemnify and hold harmless Halo for any act or omission of Client's representatives while on Halo's premises.

7.6. **Regulatory Inspections**. Unless and to the extent otherwise expressly provided in the Quality Agreement, the following procedures shall apply: Halo shall notify Client within [***] of learning of any inspections by any Regulatory Authority specifically involving any Products, and Client shall have the right to be onsite at the applicable Facility during any such inspection but not in the audit room or in meetings with the regulators. Client acknowledges that it may not direct the manner in which Halo fulfills its obligations to permit inspection by and to communicate with Regulatory Authorities. Halo shall notify Client of receipt of any Form 483s, warning letters or other significant regulatory action that could reasonably be expected to impact the regulatory status of the Products or Halo's ability to perform the

Services in accordance with the terms of this Agreement. Halo shall provide Client with copies of the sections of all Form 483s or comparable regulatory notices that are specific to any Product, redacted as necessary to preserve the confidentiality of Halo's other information. Likewise, Client shall provide Halo with any material correspondence with any Regulatory Authority, including any FDA refusal to file, rejection or warning letters, that could reasonably be expected to impact the timing and volume of Client's Product purchases under this Agreement. If any inspection by a Regulatory Authority is specific to a Product (including any pre-approval inspection or any inspection in connection with adding a country as a Manufacturing Jurisdiction pursuant to Section 2.3 (Expansion of Territory)), (a) the Parties shall cooperate in good faith to prepare for such inspection and (b) Client shall be responsible for all costs related to such inspection, including (i) reimbursement of Halo's reasonable, actual, and documented out-of-pocket costs and (ii) compensation for Halo personnel time at the rate set forth on Annex C of the applicable Product Schedule.

7.7. **Regulatory Filings**.

(a) Client Approvals. Subject to the terms of this Agreement, including Section 7.4 (Data and Reports) and Section 7.7(b) (Halo Approvals), and unless and to the extent otherwise expressly provided in the Quality Agreement, Client shall have the sole responsibility for filing all Product-specific documents with all Regulatory Authorities and taking any other actions that may be required for the receipt and/or maintenance of Regulatory Authority approval for the commercial manufacture and sale of the Products. Halo shall assist Client, to the extent consistent with Halo's obligations under this Agreement, to obtain Regulatory Authority approval for the commercial manufacture of all Products as quickly as reasonably possible.

(b) Halo Approvals. Subject to the terms of this Agreement, including any applicable fees payable by Client under Exhibit B, and unless and to the extent otherwise expressly provided in the Quality Agreement, Halo shall have the sole responsibility for filing all documents with Regulatory Authorities and taking any other actions that may be required for the receipt and/or maintenance of Regulatory Authority licensure of the Facility.

(c) Access to CMC. Unless and to the extent otherwise expressly provided in the Quality Agreement, at the time of submission and from time to time thereafter at Halo's reasonable request, Client shall provide to Halo a copy of any portion of any filing with a Regulatory Authority that incorporates or relies on data generated by Halo in connection with a Product. Client shall not include, assert or represent in any Regulatory Authority filing that Halo has performed any activities that Halo has not in fact performed as of the date of such submission, or that Halo is responsible to perform in the future any activities that Halo is not in fact required to perform under this Agreement, without Halo's prior written consent.

ARTICLE 8
TERM & TERMINATION

8.1. **Term**. This Agreement shall commence as of the Effective Date and shall continue until the expiry of each Product Schedule incorporated into to this Agreement. Each Product Schedule shall expire after five (5) Contract Years, unless terminated earlier in accordance with Section 8.2 (Termination). Each Product Schedule shall automatically extend for successive two (2) Year periods unless and until either Party gives the other Party at least eighteen (18) months' written notice of its desire to terminate a Product Schedule as of the end of the then-current term. The period of effectiveness of this Agreement

and any Product Schedules, as extended in accordance with this Section 8.1 and/or terminated in accordance with Section 8.2 (Termination), is referred to as the "**Term**".

8.2. **Termination**.

(a) Breach. Either Party may terminate this Agreement upon written notice to the other Party if the other Party has failed to remedy a material breach of this Agreement within [***] days following receipt of a written notice that describes the breach in reasonable detail and expressly states that it is a notice under this Section 8.2(a)(Breach); provided further, that Client may terminate this Agreement immediately upon notice to the Halo in the event of a breach of any representation or covenant in Sections 9.3(c) (Debarment) or (f)(Anti-Bribery / Anti-Corruption Statutes).

(b) Bankruptcy. Either Party may terminate this Agreement immediately without further action in the event that (i) the other Party is declared insolvent or bankrupt by a court of competent jurisdiction, and such declaration or order remains in effect for a period of [***] days, (ii) a voluntary petition of bankruptcy is filed in any court of competent jurisdiction by such other Party, or (iii) this Agreement is assigned by such other Party for the benefit of creditors.

(c) Regulatory Considerations. In the event that (i) any Authority takes any action that prevents Client from importing, exporting, purchasing or selling a given Product in a portion of the Territory or (ii) subject to Section 3.9 (Product Discontinuation), Client elects to discontinue selling a given Product or otherwise withdraws a Product from a portion of the Territory, Client may terminate this Agreement as it relates to such Product in the applicable portion of the Territory upon [***] days' prior written notice to Halo.

(d) Force Majeure. Either party may terminate this Agreement upon written notice as permitted by Section 14.3 (Force Majeure).

8.3. **Obligations on Termination**. Upon expiration or termination of this Agreement, with respect to terminated Product(s):

(a) Work In Process. At Client's election, Halo shall either (i) complete any Product that is a work in process, which Product shall be subject to Section 8.3(b) (Product), or (ii) cease such work and transfer such work in process into storage containers, and Client shall be obligated to pay Halo a pro rata amount of all work to such date; it being understood that if Client fails to timely make such an election or if termination is by Halo under Section 8.2(a) (Breach) or 8.2(b) (Bankruptcy), clause (ii) above shall automatically apply.

(b) Product. Client shall take delivery of and pay for, at the Price in effect at the time, all completed, undelivered Product that Halo has produced pursuant to a Firm Order.

(c) Inventory. Client shall purchase, at Halo's actual, documented out-of-pocket cost (to the extent not already paid for by Client in accordance with Section 3.6 (Tooling & Supplies)), all Inventory then in stock or that is later delivered by a Third Party vendor pursuant to non-cancellable orders, and shall reimburse Halo for any actual, documented cancellation fees assessed by Third Party vendors for Inventory orders that are cancellable.

(d) Client-Owned Materials. Halo shall return to Client all unused API and other materials provided to Halo by or on behalf of Client and deliver to Client all Inventory paid for by Client pursuant

to clause (c) above and copies of all Records except to the extent that Halo is not required to delete or return electronic copies of records stored securely as part of electronic documentation back-up procedures.

(e) Records & Samples. Halo shall maintain reserve samples and Records in accordance with Applicable Law and this Agreement.

(f) Stability. At Client's election, Halo shall either (i) continue to perform any ongoing stability testing or (ii) ship the stability samples to Client; it being understood that if Client fails to timely make such an election or if termination is by Halo under Section 8.2(a) (Breach) or 8.2(b) (Bankruptcy), clause (ii) above shall automatically apply.

(g) Return of Confidential Information. Each Party shall, at the request of the other Party, return all data, files, records and other materials in such Party's possession or control containing or comprising the other Party's Confidential Information, except one copy which may be retained for legal purposes only.

(h) Wind-Down Costs. Any costs incurred by Halo to comply with its obligations under Section 8.3 (Obligations on Termination), including shipping and related expenses, shall be borne by Client, except in the event of termination of this Agreement by Client for Halo's uncured material breach under Section 8.2(a) (Breach) in which case Halo shall bear all such expenses. In lieu of taking possession of any of the materials described in Section 8.3 (Obligations on Termination), Client may direct Halo to destroy such items, which Halo shall cause to be done at Client's cost.

8.4. **Survival**. Expiration or termination of this Agreement shall be without prejudice to any rights or obligations that accrued to either Party prior to such expiration or termination. Notwithstanding any expiration or termination of this Agreement for any reason, the Parties' rights and obligations under the following provisions shall survive and continue in effect in accordance with their respective terms: Articles/Sections 4.3 (Shipment), 4.4 (Storage), 5.2 (Supplemental Charges), 5.3 (Invoicing), 5.4 (Payment Terms), 6 (Product Claims & Recalls), 7.2 (Quality Agreement), 7.3 (Records & Retains), 8.3 (Obligations on Termination), 8.4 (Survival), 9.4 (Limited Warranty), 10 (Indemnities & Insurance), 11 (Confidentiality), 12 (Intellectual Property), 13 (Dispute Resolution) and 14 (Miscellaneous).

ARTICLE 9
REPRESENTATIONS & WARRANTIES

9.1 **Authority**. Each Party represents and warrants to the other that (a) it has the full right and authority to enter into this Agreement, (b) it is in good standing in its jurisdiction of organization and all jurisdictions in which it operates, (c) the execution and delivery of this Agreement and the performance of such its obligations hereunder do not conflict with, or constitute a default or require any consent under, any contractual obligation of such Party, and (d) it will comply with all Applicable Law in performing its obligations under this Agreement.

9.2 **Client Warranties**. Client covenants, represents, and warrants to Halo as follows:

(a) Preliminary Specifications. To Client's knowledge as of the Effective Date, the preliminary copy of the Specifications provided by Client to Halo further to Section 3.2 (Specifications) is true and accurate in all material respects.

(b) Rights to Specifications. Client owns or has a valid right and license to use all Specifications for each Product and Client may lawfully disclose all Specifications to Halo for Halo's use in connection with providing Services.

(c) Rights to Intellectual Property. All Intellectual Property provided by Client to Halo for use in connection with providing Services (i) may lawfully be used by Halo in connection with providing Services and (ii) so long as Halo uses such Intellectual Property solely as contemplated by this Agreement, such use does not and will not infringe, misappropriate, violate, or misuse any rights held by Third Parties.

(d) Third Party Intellectual Property. There are no rights held by Third Parties related to Client's Intellectual Property that would be infringed, misappropriated, violated, or misused by Client's performance of this Agreement and, as of the Effective Date, Client has no knowledge of any claims of infringement or misappropriation that have been made by Third Parties against Client in connection with the Product.

(e) Compliance with Law. All artwork, the content of all labeling and packaging, and all other Specifications provided or approved by Client comply with Applicable Law.

(f) Status. The Product is not a "controlled substance" within the meaning of Applicable Law, AND/OR The Product is not a "generic" product (e.g., filed for marketing approval in the United States under an Abbreviated New Drug Application), unless otherwise specifically identified as such in the applicable Product Schedule.

(g) API Warranty. All API provided to Halo hereunder have been manufactured in accordance with Applicable Law, including cGMPs, and shall at the time of delivery to Halo meet all relevant Specifications and not be adulterated, misbranded, or mislabeled within the meaning of Applicable Law.

(h) API Cost. As of the Effective Date, the API Cost set forth in the applicable Product Schedule fairly and accurately reflects Client's actual out-of-pocket cost to procure or produce the API and deliver it to Halo.

(i) Use of Product. All Product delivered to Client by Halo hereunder shall be held, stored, used, distributed, sold, and otherwise disposed of by or on behalf of Client in accordance with all Applicable Law.

9.3. **Halo Warranties**. Halo covenants, represents, and warrants to Client as follows:

(a) Third Party Intellectual Property. To the best of Halo's knowledge, there are no rights held by Third Parties related to Halo's Intellectual Property that would be infringed, violated, or misused by Halo's performance of this Agreement.

(b) Claims. As of the Effective Date, it has no knowledge of any claims, actions or other actual or threatened legal proceedings by any Regulatory Authority or other Third Party, the subject of which is the infringement, violation or misuse of any rights held by Third Parties related to any Halo's Intellectual Property.

(c) Debarment. It does not and will not use in the performance of its obligations under this Agreement the services of any Person debarred or suspended under 21 U.S.C. §335(a) or (b); and it does not have and will not hire as an officer or employee any Person who has been convicted of a felony under the laws of the United States for conduct relating to the regulation of any drug product under the U.S. Federal Food, Drug, and Cosmetic Act, as amended. Debarment may result in immediate termination of this Agreement.

(d) Product Warranty. (i) It shall have performed the Manufacturing of all Products provided to Client hereunder in accordance with this Agreement, Applicable Law (including cGMPs) and the Quality Agreement, (ii) all Products provided to Client hereunder shall (1), at the time of delivery under Section 4.3 (Shipment), meet all preliminary or final Specifications, as applicable, and conform with the certificate of analysis and certificate of compliance provided therewith, if applicable, (2) not be adulterated, misbranded or mislabeled within the meaning of Applicable Law, (3) have been manufactured at the Facility, which is in compliance with Applicable Laws at the time of such Manufacture, (4) be Manufactured, packaged, and labeled in accordance with cGMP and ICH guidelines and in accordance with the requirements of the applicable Regulatory Authorities; (5) be free from defects in material and workmanship; (6) if the Product has a shelf life of [***] months or greater then deliver Product per Section 4.3 (Shipments) with at least [***]% remaining shelf life (7) conform to the applicable batch number and expiration date; *provided*, that a Product will not fail to comply with the foregoing representation and warranty to the extent such failure results from (and Halo shall not be liable for any defect in Product attributable to) matters not caused by Halo's Fault, including those matters described in Section 6.5 (Limitations).

(e) No Liens. Upon delivery of Products to Client, Halo shall convey, and Client shall have, good and marketable title to such Products, free and clear of any encumbrances.

(f) Exclusion. Halo represents that it has not been excluded from any federal health care program including, but not limited to, Medicare, Medicaid and the Civilian Health and Medical Program of the Uniformed Services. If Halo is excluded during the Term, Halo shall immediately notify Client in writing and cease all work hereunder. Exclusion may result in immediate termination of this Agreement.

(g) Anti-Bribery / Anti-Corruption Statutes. Halo is aware of and understands that there are anti-bribery and anti-corruption statutes (including but not limited to the US Foreign Corrupt Practices Act, the UK Bribery Act and Sapin II) to which Client is subject that prohibit the payment or offering, giving, promising to give, or authorizing the giving of, directly or indirectly, anything of value to a Government Official (as defined below), or any relative, business associate or employee thereof, for the purpose of obtaining or retaining any business under this Agreement or otherwise related to Client or inducing or influencing any governmental act or decision affecting Client. Halo agrees to refrain from any activity in connection with this Agreement that would constitute a violation by Halo or Client of such anti-bribery and anti-corruption statutes, including sharing, directly or indirectly, any of the fees paid to Halo under this Agreement with a Government Official. Similarly, Halo shall not, directly or indirectly, request, accept, or agree to accept any item of value that could be seen as an attempt to compromise its independence of judgment or improperly influence a business decision. Upon Client's request, or should Client ever become the subject of an audit or investigation by a US, European or other governmental

authority, including under any anti-boycott regulations, anti-bribery legislation, or related export legislation, Halo agrees to cooperate fully with Client in connection with such investigation and to provide such information and records to Client with respect to Halo's activities under this Agreement as may be reasonably requested by Client. "Government Official" means any officer (elected or appointed) or employee of a government or public organization or institution, or a department, agency or instrumentality of any of the foregoing, any official of a political party or a candidate for political office, or anyone otherwise categorized as a Government Official under Applicable Laws.

9.4. **Limited Warranty**. NEITHER PARTY MAKES ANY REPRESENTATION, WARRANTY OR GUARANTEE OF ANY KIND, EITHER EXPRESS OR IMPLIED, BY FACT OR LAW, OTHER THAN THOSE EXPRESSLY SET FORTH IN THIS ARTICLE 9. HALO EXPRESSLY DISCLAIMS ANY IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE AND ANY WARRANTY OF MERCHANTABILITY WITH RESPECT TO THE PRODUCTS AND SERVICES.

ARTICLE 10
INDEMNITIES & INSURANCE

10.1. **Limitation of Liability**.

(a) No Consequential Damages. Under no circumstances whatsoever shall either Party be liable to the other Party in contract, tort, negligence, breach of statutory duty or otherwise for (i) any direct or indirect loss of profits, revenues, production, anticipated savings, data, business or goodwill or (ii) any other liability, damage, cost or expense of any kind incurred by the other Party of an indirect, incidental, consequential, punitive or special nature, regardless of any notice of the possibility of such damages.

(b) API Liability. Except as expressly set forth in this Agreement, under no circumstances whatsoever shall Halo be responsible for any loss or damage to API.

(c) Maximum Liability. Halo's maximum liability under this Agreement for any reason whatsoever (in the aggregate) shall not exceed the smaller of (i) [***] and (ii) [***] dollars ($[***]).

(d) Exclusions. Notwithstanding any provision to the contrary in this Agreement, including the foregoing clauses (a), (b) and (c), a Party's liability shall not be limited in connection with (i) damages arising from such Party's gross negligence or wilful misconduct, (ii) subject to the final sentence of Section 6.2, any amounts due to Third Parties as a result of such Party's indemnification obligations under Section 10.2 (Indemnification), (iii) damages arising from such Party's breach of Article 11 (Confidentiality) or (iv) damages arising from such Party's breach of Article 12 (Intellectual Property) .

10.2. **Indemnification**.

(a) By Halo. Halo shall defend, indemnify and hold harmless Client, its Affiliates, and its Representatives ("**Client Indemnitees**") from and against any and all losses, damages, costs, expenses (including reasonable attorneys' fees and reasonable investigative costs), judgments and liabilities ("**Losses**") in connection with any suit, demand, claim or action by any Third Party ("**Third Party Claim**") arising or resulting from (i) a breach by Halo of this Agreement, including any Non-Conforming Product, or (ii) the Fault of any Halo Indemnitee; *in each case*, except to the extent that such Losses fall under Client's indemnification obligations in Section 10.2(b)(By Client)**.**

(b) By Client. Client shall defend, indemnify and hold harmless Halo, its Affiliates, and its Representatives ("**Halo Indemnitees**") from and against any and all Losses in connection with any Third Party Claim arising or resulting from (i) a breach by Client of this Agreement or (ii) the Fault of any Client Indemnitee (iii) any actual or alleged infringement, violation or misuse of any rights held by Third Parties in respect of any aspect of any Product (other than solely by reason of Halo's practice of Halo's Intellectual Property), or (iv) any distribution, sale or use of or exposure to any API or Product ; *in each case*, except to the extent that such Losses fall under Halo's indemnification obligations in Section 10.2(a)(By Halo). In addition, if the Product is a "generic" drug product, Client shall defend, indemnify and hold harmless the Halo Indemnitees from and against any and all Losses resulting from or relating to any filings with any Regulatory Authority by or on behalf of Client or any of its Affiliates or licensees, including filings under 21 U.S.C. 355 and/or Section 505 of the U.S. Food and Drug Act (and/or non-U.S. equivalents) and related claims or proceedings (including Losses associated with Halo's obligation to respond to Third Party subpoenas).

(c) Procedure. In the event a Party seeks indemnity under this Section 10.2, it shall: (i) promptly notify the indemnifying Party of the Third Party Claim subject to indemnification; (ii) use [***] to mitigate the effects of such Third Party Claim; (iii) reasonably cooperate with the indemnifying Party in the defense of such Third Party Claim; (iv) not settle or compromise such Third Party Claim or make any admission relating thereto; and (v) permit the indemnifying Party to control the defense and settlement of such Third Party Claim using counsel reasonably satisfactory to the indemnified Party, all at the indemnifying Party's cost and expense. The indemnified Party may be represented by its own counsel in connection with such Third Party Claim, and such representation shall be at the indemnified Party's own expense unless the indemnifying Party fails to assume the defense of such Third Party Claim as required hereunder. The indemnifying Party shall have the right to settle any such Third Party Claim without the consent of any indemnitee so long as such settlement does not admit to any wrongdoing by any indemnitee, does not impose any liability or obligation (whether financial or otherwise) on any indemnitee and fully releases the indemnitees from liability in connection with such Third Party Claim. The indemnified Party's consent to any other settlement shall be required.

10.3. **Insurance**. During the Term and for at least [***] years thereafter, each Party shall obtain and maintain prudent insurance coverage appropriate to cover its activities related to and obligations under this Agreement. Such insurance shall be procured from reputable and financially secure insurance carriers. Each Party shall provide to the other Party a certificate evidencing such insurance upon the other Party's request.

10.4. **Reasonable Allocation of Risk**. The Parties agree that (a) the provisions of this Agreement (including this Article 10) are reasonable and create a reasonable allocation of risk having regard to the relative profits the Parties respectively expect to derive from the Products, (b) Halo, in its fees for the provision of the Services, has not accepted a greater degree of the risks arising from the manufacture, distribution, sale and use of the Products based on the fact that Client has developed the Products and requires Halo to manufacture and label the Products strictly in accordance with the Specifications, and (c) Client and not Halo is in a position to inform and advise potential users of the Products as to the circumstances and manner of use of the Products.

ARTICLE 11
CONFIDENTIALITY

11.1. **Confidential Information**.

(a) Definition. In this Agreement, "**Confidential Information**" means any and all information disclosed by or on behalf of one Party ("**Discloser**") to the other Party ("**Recipient**") or any of its Affiliates or its or their respective directors, officers, employees, professional consultants, attorneys, advisors or agents (such Affiliates and Persons collectively, "**Representatives**"), (i) whether before, on or after the Effective Date, (ii) whether tangible or intangible, (iii) whether written, electronic, oral, visual (e.g., obtained by observation at a site visit) or in any other form or medium and (iv) whether or not marked with a legend such as "Confidential" or "Proprietary". For the avoidance of doubt, the term Confidential Information shall be construed as "Discloser's Confidential Information."

(b) Inclusions. Confidential Information includes (i) trade secrets, research and development activities; marketing plans, business strategies, and business opportunities; pricing, costs, and financial information; data, specifications, formulae, models, and processes; customers and vendors; regulatory strategies and information; and non-public intellectual property (e.g., knowhow and trade secrets), (ii) information of Affiliates and Third Parties, (iii) any copies, summaries and other analyses of other Confidential Information prepared by or for Recipient or its Representatives (such copies, summaries and analyses collectively "**Notes**"), and (iv) the existence and terms of this Agreement.

(c) Exclusions. Confidential Information excludes any information that, as proven by competent evidence, (i) is or becomes available to the general public other than by a breach of confidentiality owed to Discloser, (ii) was known to Recipient or any of its Representatives without any limitation on use or disclosure prior to its receipt from or on behalf of Discloser, (iii) is received by Recipient or any of its Representatives from a Third Party without any obligation of confidentiality owed to Discloser, or (iv) was independently developed by or for Recipient or any of its Representatives without reference to or reliance on any Confidential Information. For the avoidance of doubt, Confidential Information shall not be deemed to be in the public domain or in the prior possession of a Person where it is merely embraced by or contained in more general information that is in the public domain or in such Person's possession.

11.2. **Restrictions on Use & Disclosure**. In consideration of receiving Confidential Information, Recipient shall use Confidential Information only for performing its obligations and exercising its rights under this Agreement and shall not disclose Confidential Information to any Person other than as expressly permitted by this Article 11 or as authorized in writing by Discloser. Recipient may disclose Confidential Information to those of its Representatives who (i) have a need to know such information in connection with Recipient's performance of its obligations and the exercise of its rights under this Agreement, (ii) have been advised of Recipient's obligations under this Agreement, and (iii) are bound to Recipient by obligations of confidentiality and non-use at least as stringent as those contained in this Article 11. Recipient shall be liable to Discloser for any breach of this Article 11caused by Recipient's Representatives.

11.3. **Standard of Care**. Recipient shall protect Confidential Information with the same degree of care that it uses to protect its own confidential information, but no less than a reasonable degree of care. Recipient shall comply with all Applicable Law relating to Confidential Information, including in respect of data privacy and the export of information outside of national borders. Recipient will not remove or obscure any copyright or trademark notice, proprietary legend, indication of confidentiality or other

restrictive notation on any Confidential Information. Recipient will promptly notify Discloser of any actual or suspected disclosure, use or loss of Confidential Information in contravention of this Article 11, including a description of the circumstances, Persons involved, steps taken to mitigate resulting damage, and steps taken to prevent any further such disclosure, use or loss.

11.4. **Compelled Disclosure**. Recipient may disclose Confidential Information to the extent required by Applicable Law or by the listing standards, rules or agreements of any public exchange on which any securities of Recipient or its Affiliates are listed, so long as Recipient (a) uses [***] to give Discloser as much prior notice of such required disclosure as circumstances permit, (b) allows Discloser to contest such disclosure or to seek a protective order or similar remedy, and reasonably cooperates with Discloser in any such efforts, at Discloser's request and expense, and (c) limits the disclosure to only the information required to be disclosed.

11.5. **Ownership**. As between the Parties, Confidential Information is the property of Discloser, and Discloser shall retain all right, title and interest in and to its Confidential Information. The disclosure of Confidential Information to Recipient or any of its Representatives does not, in itself, grant or imply to Recipient or any such Representative any right or license to use or practice any Intellectual Property of Discloser. Any such right or license shall be solely as set forth in Article 12 (Intellectual Property).

11.6. **Return of Information**. Upon termination of this Agreement or Discloser's earlier written request, Recipient shall immediately cease using all Confidential Information and promptly either, as directed by Discloser, return it to Discloser or destroy it (and certify as to such destruction), including all Notes; *provided*, that Recipient may destroy, and need not deliver to Discloser, such Notes. Notwithstanding the foregoing, (a) Recipient may retain a single copy of Confidential Information in the secure files of its legal counsel or a senior executive for the sole purpose of proving what was disclosed, (b) Recipient is not required to return or destroy any Confidential Information if doing so would violate (or result in the violation of) any Applicable Law, (c) Recipient shall not be required to expunge any minutes or written consents of its board of directors (or equivalent governance body), and (d) to the extent that Recipient's computer back-up or archiving procedures create copies of Confidential Information, Recipient may retain such copies for the period it normally archives backed-up computer records, so long as such copies are not readily accessible and are not used or consulted for any purpose other than disaster recovery. Any Confidential Information retained pursuant to the foregoing sentence shall remain subject to this Agreement until destroyed or no longer deemed Confidential Information based on Section 11.1(c) (Exclusions).

11.7. **Injunctive Relief**. The Parties acknowledge and agree that, due to the unique nature of the Confidential Information, the breach of this Article 11 by Recipient may cause irreparable damage to Discloser for which monetary damages would be inadequate. Accordingly, Discloser shall be entitled to seek injunctive relief or other remedies in connection with a threatened or actual breach of any of Recipient's obligations under this Article 11, and the Parties waive the requirement of any bond being posted as security in any application for such relief.

11.8. **Publicity**. Subject to Section 11.4 (Compelled Disclosure), neither Party shall use the other Party's name in any public context or make any press release, announcement, or other form of public disclosure relating to this Agreement or the transactions contemplated hereby, including identifying the other Party as a business partner or in connection with any scholarly or industry publications or presentations, without the other Party's prior written consent, including as to the form, nature, content and time of release thereof.

11.9. **Survival**. This Article 11 shall survive the termination of this Agreement for [***] years; *provided*, that Confidential Information that is otherwise protected by law or regulation (e.g., trade secret and data privacy) shall remain protected as, and for as long as, such law or regulation permits or requires.

ARTICLE 12
INTELLECTUAL PROPERTY

12.1. **Proprietary Intellectual Property**. For purposes of this Agreement, as between the Parties: (a) all Intellectual Property owned by a Party or any of its Affiliates as of the Effective Date shall be deemed owned by such Party; (b) all Intellectual Property licensed to a Party or any of its Affiliates by a Third Party at any time shall be deemed owned by such Party; and (c) all Intellectual Property generated, conceived or reduced to practice by or for a Party or any of its Affiliates outside the scope of activities under this Agreement shall be deemed owned by such Party (collectively, such Party's "**Proprietary IP**").

12.2. **Inventions**.

(a) Client Inventions. As between the Parties, all Inventions to the extent (i) specific to the development, Manufacture, use or sale of Client's Product or (ii) relating to Client's Proprietary IP, shall be the exclusive property of Client ("**Client Inventions**"). To the extent applicable, Halo hereby assigns to Client all right, title, and interest in the Client Inventions.

(b) Halo Inventions. As between the Parties, all Inventions that (i) do not comprise Client Inventions and (ii) are dependent on Halo's Proprietary IP shall be the exclusive property of Halo ("**Halo Inventions**").

(c) Disclosure. Halo shall submit to Client a written description of all Inventions of which it becomes aware during the Term. Client may disclose Halo Inventions in any patent application claiming Client's Inventions, as Client may reasonably require to support the claimed subject matter of such patent application, subject to Halo's prior written approval, which shall not be unreasonably withheld.

(d) Cooperation; Costs. The Parties shall cooperate to achieve the allocation of rights to Inventions anticipated herein. Each Party shall be solely responsible for the costs of filing, prosecution and maintenance of patents and patent applications on, and otherwise protecting, its Inventions.

12.3. **Licenses**.

(a) To Halo. Client hereby grants to Halo and its Affiliates a non-exclusive, paid-up, royalty-free, non-transferable, sublicensable (solely to Halo's subcontractors) right and license during the Term to use Client's Intellectual Property (including Client Inventions) solely in connection with the Services.

(b) To Client. Halo hereby grants to Client a non-exclusive, non-transferable, sublicensable (solely to Client's subcontractors) right and license to use Halo Inventions to develop, Manufacture, sale, use, and otherwise exploit the Client's Product in any lawful way.

(c) No Other Rights. Neither Party has, nor shall it acquire, any interest in any Intellectual Property of the other Party, and neither Party shall use any Intellectual Property of the other Party, except to the extent expressly permitted by this Section 12.3.

12.4. **Ownership of Data**. Except as set forth in Section 12.2(b) (Halo Inventions), all data and information resulting from the conduct of the Services, including Records, shall be the sole property of Client and shall be subject to Client's exclusive use, commercial or otherwise.

ARTICLE 13
DISPUTE RESOLUTION

13.1. **Escalation**. The Parties shall try to resolve any dispute arising out of or in connection with this Agreement other than a dispute determined in accordance with Section 6.1(b) (Evaluation) (a "**Dispute**") amicably between themselves before resorting to any formal dispute resolution proceeding. To this end, either Party may send a notice of Dispute to the other. Within [***] business days following the date of the Dispute notice, each Party shall appoint a single, senior executive with the full power and authority to resolve the Dispute. The executives shall meet and discuss as necessary to try to resolve the Dispute as quickly as practicable. If a Dispute relates exclusively to technical aspects of the Services, the executives shall be competent to address the technical nature of the issues in question and may elect to engage an independent laboratory or expert to assist them in their discussions; *however*, the input of such laboratory or expert shall not be binding on either Party. If a Party fails to timely appoint an executive or if, despite their reasonable efforts, the executives have not resolved a Dispute within [***] from the date of the Dispute notice, either Party may resort to binding arbitration pursuant to Section 13.3 (Arbitration) or any other method of binding dispute resolution on which the Parties may agree.

13.2. **Governing Law**. This Agreement shall be construed and enforced in accordance with the laws of the State of Delaware and the laws of the United States applicable therein, without regard to any conflicts of law principles. The UN Convention on Contracts for the International Sale of Goods shall not apply to this Agreement.

13.3. **Arbitration**. Any Dispute that the Parties are unable to amicably settle themselves, including pursuant to Section 13.1 (Escalation), shall be resolved in accordance with the [***]. The tribunal shall consist of a single arbitrator appointed by mutual consent of both Parties or, if no such consent is obtained within [***] days of the initiation of arbitration by one Party, in accordance with said Rules. The seat of arbitration shall be [***], and the language shall be English. Any award issued by the arbitrator may be enforced in any court of competent jurisdiction. The award shall be final and binding on the Parties, and each Party hereby waives to the fullest extent permitted by law any right it may otherwise have under the laws of any jurisdiction to any form of appeal. For the avoidance of doubt, any Dispute, including all negotiations, proceedings, evidence, documents and settlement terms, shall be subject to Article 11 (Confidentiality), except that any award entered in a court need not be filed under seal.

13.4. **Prevailing Party**. The arbitrator in any Dispute resolution proceeding may require, as part of a final award, the Party whose position does not prevail to reimburse the prevailing Party's costs and expenses incurred in such proceeding, including reasonable fees for attorneys, expert witnesses, and court costs, and to pay all costs and expenses of arbitration, in addition to any other relief awarded. If the arbitrator allocates a level of fault to both Parties, the arbitrator may require each Party to pay a share of the foregoing costs and expenses in proportion to their respective fault. The arbitrator will not have the power to award any damages excluded by, or in excess of, any damage limitations set forth in this Agreement.

ARTICLE 14
MISCELLANEOUS

14.1. **Further Assurances**. The Parties agree to execute, acknowledge, and deliver such further instruments and to take all such other incidental acts as may be reasonably necessary or appropriate to carry out the purpose and intent of this Agreement.

14.2. **Right to Dispose and Settle**. If Halo requests in writing Client's direction with respect to disposal of any Inventory, API, Product, work-in-process, Equipment, Records, samples or other items belonging to Client and is unable to obtain a response from Client within a reasonable time period after making reasonable efforts to do so, Halo shall have the right to dispose of such items at Client's expense (which may be by set off against any credit on Client's account).

14.3. **Force Majeure**. Neither Party shall be liable for the failure to perform its obligations under this Agreement if such failure is occasioned by a cause or contingency beyond such Party's reasonable control, whether or not foreseeable, including, but not limited to, strikes or other labor disturbances, lockouts, riots, quarantines, communicable disease outbreaks, wars, acts of terrorism, fires, floods, storms, interruption of or delay in transportation, lack of or inability to obtain fuel, power, materials or components, or compliance with any order or regulation of any Authority acting within color of right (each, a "Force Majeure Event"). A Party claiming a right to excused performance under this Section 14.3 shall promptly notify the other Party in writing of the extent of its inability to perform and the nature of the Force Majeure Event. Such excuse shall continue as long as the Force Majeure Event continues. Upon cessation of such Force Majeure Event, the affected Party shall promptly resume performance under this Agreement as soon as it is commercially reasonable for the Party to do so. Neither Party shall be entitled to rely on a Force Majeure Event to relieve it from an obligation to pay money (including any interest for delayed payment) that would otherwise be due and payable under this Agreement.

14.4. **Notices**. Any notice or other communication required or permitted by this Agreement shall be in writing and deemed given to the other Party (a) upon receipt if delivered personally, (b) upon receipt or refusal if sent by reputable overnight courier service or registered/certified mail with tracking capability, postage prepaid, or (c) on the next business day if sent by email with electronic verification of delivery, in each case to the mailing address or email address set forth below (or to such other contact information provided to the other Party in accordance with the terms of this Section 14.4):

To Client: Acadia Pharmaceuticals Inc.

Attention:

To Halo: Halo Pharmaceutical, Inc.

Attention:

With copy to: Noramco

Attention:

14.5. **Assignment; No Third Party Beneficiaries**. This Agreement shall be binding upon and inure to the benefit of the Parties, their successors and permitted assigns. Neither Party may assign this Agreement, in whole or in part, without the prior written consent of the other Party, except that either Party may, without the other Party's consent (but subject to prior written notice), assign this Agreement in its entirety to an Affiliate or to a successor to all or substantially all of the business or assets of the assigning Party or the assigning Party's business unit responsible for performance under this Agreement. This Agreement shall not confer any rights or remedies upon any Person other than the Parties named herein and their respective successors and permitted assigns. Any assignment not in accordance with this Section 14.5 shall be null and void.

14.6. **Entire Agreement**. This Agreement, together with the Quality Agreement and the Product Schedules, constitutes the entire and integrated agreement between the Parties relating to the subject matter hereof and supersedes all previous written or oral negotiations, commitments, agreements, transactions, and understandings with respect to the subject matter hereof.

14.7. **Amendments**. Any modification, amendment or supplement to this Agreement must be in writing and signed by both Parties to be effective, except to the extent otherwise expressly provided in this Agreement.

14.8. **Waivers**. Either Party's failure to require the other Party to comply with any provision of this Agreement shall not be deemed a waiver of such provision or any other provision of this Agreement, or of any other breach of such provision.

14.9. **Conflicts**. No terms, provisions or conditions of any purchase order, order acknowledgement, quote, proposal, invoice, or other business form or written authorization used by Client or Halo will have any effect on the rights, duties or obligations of the Parties under, or otherwise modify, this Agreement, regardless of any failure of Client or Halo to object to such terms, provisions, or conditions, except to the extent such document specifically refers to this Agreement, sets forth an express intent to override it, and is signed by both Parties.

14.10. **Construction**.

(a) Independent Contractors. The Parties are independent contractors to one another, and this Agreement shall not be construed to create between them any other relationship such as, by way of example only, that of employer-employee, principal-agent, joint-venturers, partners or any similar relationship, the existence of which is expressly denied by the Parties. Neither Party shall have the power or authority to bind the other Party or to assume or create any obligation, express or implied, on the other Party's behalf or in the other Party's name, and it will not represent to any Person that it has such power or authority.

(b) Drafting Party. The language in this Agreement is to be construed in all cases according to its fair meaning. Each Party and its counsel have reviewed and revised this Agreement and any rule of construction to the effect that any ambiguities are to be resolved against the drafting Party is not to be employed in the interpretation of this Agreement.

(c) Severability. If any provision of this Agreement is determined by a court of competent jurisdiction to be invalid, illegal, or unenforceable in any respect, such determination shall not impair or affect the validity, legality, or enforceability of the remaining provisions hereof, and each provision is hereby declared to be separate, severable, and distinct.

(d) Divisions. The division of this Agreement into Articles, Sections, subsections, clauses and Schedules and the insertion of headings are for convenience of reference only and shall not affect the interpretation of this Agreement. Unless otherwise indicated, any reference in this Agreement to an Article, Section, subsection, clause, or Schedule refers to the specified Article, Section, subsection, clause, or Schedule to this Agreement. In this Agreement, the terms "this Agreement", "hereof", "herein", "hereunder" and similar expressions refer to this Agreement as a whole (including any Schedules hereto) and not to any one Article, Section, subsection, clause, Schedule, or other provision hereof.

14.11. **Counterparts**. This Agreement may be executed in counterparts, by original, electronic, or facsimile signature, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. This Agreement may be delivered electronically.

Signature page follows

IN WITNESS WHEREOF, the duly authorized representatives of the Parties have executed this Agreement as of the Effective Date.

HALO PHARMACEUTICAL, INC.

By /s/ John Bender

Name: John Bender

Title: Vice President, Business Development

ACADIA PHARMACEUTICALS INC.

By /s/Marlon Carlos

Name: Marlon Carlos

Title: Sr. VP TDOQ

Attachment 1

API INVENTORY, USAGE AND ANNUAL YIELD REPORT

[***]

Exhibit 21.1

List of Subsidiaries

NAME OF SUBSIDIARY	JURISDICTION OF INCORPORATION
Acadia Pharma Limited	England and Wales
Acadia Pharmaceuticals A/S	Denmark
Acadia Pharmaceuticals GmbH	Switzerland
Acadia Pharmaceuticals Holdings Inc.	Delaware
Acadia Pharmaceuticals (Canada) Inc.	Ontario, Canada
Acadia Pharmaceuticals (France) SAS	France
Acadia Pharmaceuticals (Germany) GmbH	Germany
Acadia Pharmaceuticals (Italy) S.R.L.	Italy
Acadia Pharmaceuticals (Netherlands) B.V.	Netherlands
Acadia Pharmaceuticals (Spain), S.L.	Spain
Amorsa Therapeutics Inc.	Massachusetts
CerSci Therapeutics Incorporated	Delaware
Levo Therapeutics, Inc.	Delaware
Pandeia Therapeutics Limited	England and Wales

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statements (Form S-3 Nos. 333-171722, 333-185639, 333-248401, and 333-287145) of Acadia Pharmaceuticals Inc.,

(2) Registration Statement (Form S-8 No. 333-115956) pertaining to the 1997 Stock Option Plan, 2004 Equity Incentive Plan, and 2004 Employee Stock Purchase Plan of Acadia Pharmaceuticals Inc.,

(3) Registration Statements (Form S-8 Nos. 333-128290, 333-137557, 333-146398, 333-153346, and 333-161057) pertaining to the 2004 Equity Incentive Plan and 2004 Employee Stock Purchase Plan of Acadia Pharmaceuticals Inc.,

(4) Registration Statements (Form S-8 Nos. 333-176212, 333-183151, 333-197872, and 333-241711) pertaining to the 2004 Employee Stock Purchase Plan of Acadia Pharmaceuticals Inc.,

(5) Registration Statements (Form S-8 Nos. 333-207971, 333-219785, 333-226834, 333-266680, and 333-269611) pertaining to the 2010 Equity Incentive Plan and 2023 Inducement Plan of Acadia Pharmaceuticals Inc.,

(6) Registration Statements (Form S-8 Nos. 333-168667, 333-190400, 333-213109, and 333-232981) pertaining to the 2004 Employee Stock Purchase Plan, 2010 Equity Incentive Plan and 2023 Inducement Plan of Acadia Pharmaceuticals Inc.,

(7) Registration Statement (Form S-8 No. 333-279784) pertaining to the 2024 Equity Incentive Plan of Acadia Pharmaceuticals Inc., and

(8) Registration Statement (Form S-8 No. 333-282295) pertaining to the 2024 Inducement Plan of Acadia Pharmaceuticals Inc.

of our reports dated February 25, 2026, with respect to the consolidated financial statements and schedule of Acadia Pharmaceuticals Inc. and the effectiveness of internal control over financial reporting of Acadia Pharmaceuticals Inc. included in this Annual Report (Form 10-K) of Acadia Pharmaceuticals Inc. for the year ended December 31, 2025.

/s/ Ernst & Young LLP

San Diego, California
February 25, 2026

EXHIBIT 31.1

CERTIFICATION
Pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934,
as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Catherine Owen Adams, certify that:

1. I have reviewed this annual report on Form 10-K for the year ended December 31, 2025 of Acadia Pharmaceuticals 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 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 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/ Catherine Owen Adams

Catherine Owen Adams
Chief Executive Officer
(Registrant's Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION
Pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934,
as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Mark C. Schneyer, certify that:

1. I have reviewed this annual report on Form 10-K for the year ended December 31, 2025 of Acadia Pharmaceuticals 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 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 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/ MARK C. SCHNEYER
Mark C. Schneyer
Executive Vice President, Chief Financial Officer
(Registrant's Principal Financial 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 Acadia Pharmaceuticals Inc. (the "Company") on Form 10-K for the period ended December 31, 2025, as filed with the Securities and Exchange Commission on or about the date hereof (the "Report"), I, Catherine Owen Adams, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"); and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition of the Company at the end of the period covered by the Report and results of operations of the Company for the period covered by the Report.

Date: February 25, 2026

/s/ CATHERINE OWEN ADAMS
Catherine Owen Adams
Chief Executive Officer
(Registrant's Principal Executive Officer)

This certification shall not be deemed "filed" for purposes of Section 18 of the Exchange Act or otherwise subject to the liability of Section 18 of the Exchange Act. Such certification shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent that the Company specifically incorporates it by reference.

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 Acadia Pharmaceuticals Inc. (the "Company") on Form 10-K for the period ended December 31, 2025, as filed with the Securities and Exchange Commission on or about the date hereof (the "Report"), I, Mark C. Schneyer, Executive Vice President and Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"); and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition of the Company at the end of the period covered by the Report and results of operations of the Company for the period covered by the Report.

Date: February 25, 2026

/s/ MARK C. SCHNEYER
Mark C. Schneyer
Executive Vice President, Chief Financial Officer
(Registrant's Principal Financial Officer)

This certification shall not be deemed "filed" for purposes of Section 18 of the Exchange Act or otherwise subject to the liability of Section 18 of the Exchange Act. Such certification shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent that the Company specifically incorporates it by reference.